National Clinical Guideline Centre

DRAFT FOR CONSULTATION

Fractures (non-complex): assessment and management

Fractures: diagnosis, management and follow-up of fractures

Clinical guideline <...>

Appendices G-I

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Appendices

Appendix G: Clinical evidence tables

G.1 Initial pain management and immobilisation

G.1.1 Initial pharmacological pain management

Table 1: Borland 2007[20]

Study	Borland 2007[20]
Study type	Randomised controlled trial
Number of studies (number of participants)	1 (n=67)
Countries and setting	Conducted in Australia; Setting: Tertiary paediatric ED with an annual census of 42000 attendances
Line of therapy	1st line
Duration of study	Intervention and follow up: 4 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years): Children aged 7–15
Inclusion criteria	Children aged 7–15 presenting with clinically deformed closed long-bone fractures, identified at triage.
Exclusion criteria	If they received narcotic analgesic within 4 hours of arrival in the ED; had sustained a head injury resulting in impaired judgement; were known to be allergic to opiate analgesics had a blocked or traumatised nose, preventing nasal administration; or were unable to perform pain scoring for any reason.
Age, gender and ethnicity	Age - Mean (range): 10.9 (6–15). Gender (M:F): Not reported. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=33) Intervention 1: Intranasal - Opioids. Fentanyl (150ug/ml) was manufactured in the hospital pharmacy (AstraZeneca Pty Ltd, Balata, WA, Australia). The initial drug dose was 1.4 ug/kg (equivalent to 1 ug/kg IV, with 71% bioavailability). Duration 30 minutes. Concurrent medication/care: Patients received IV placebo (saline Further details: 1. Prior medication: Not applicable/Not stated/Unclear (n=34) Intervention 2: Intravenous - Opioids (Morphine). Initial morphine dose of 0.1mg/kg administered through an IV cannula. Duration 30 minutes. Concurrent medication/care: Patients' received placebo intra-nasal (saline)

	Further details: 1. Prior medication: Not applicable/Not stated/Unclear
Funding	Academic or government funding (ACEM Morson Taylor Research Grant)
<u>Pain at 1 hour</u> Pain at 30 minutes; Risk of bias: Low; Indirectness of outcome: Serious indirectness- GIV. Mean Difference = -4; Standard Error (6.12). <u>Adverse effects - Nausea</u> Vomiting at 30 minutes; Group 1: 1/32, Group 2: 0/33; Risk of bias: Low; Indirectness of outcome: No indirectness <u>Need for rescue analgesia</u> Need for rescue analgesia at 30 minutes; Group 1: 1/33, Group 2: 1/34; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life

Table 2: Charney 2008[27]

Study	**Charney 2008[27]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=128)
Countries and setting	Conducted in USA; Setting: Tertiary University Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 16 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years): Children aged 4–17
Inclusion criteria	Children with suspected isolated forearm fractures.
Exclusion criteria	Administration of prior narcotic, a history of adverse effects to study medications or non-English speaking parents or guardians.
Age, gender and ethnicity	Age - Mean (SD): 10.5 (8.5–12.3). Gender (M:F): 1:1. Ethnicity:
Indirectness of population	No indirectness
Interventions	(n=56) Intervention 1: Oral - Opioids - Codeine. 2mg of codeine per kilogram bodyweight. Duration 180 minutes. Concurrent medication/care: Up to 120 mg (n=51) Intervention 2: Oral - Opioids - Codeine. Oxycodone 0.2mg per kilogram of body weight. Duration 180 minutes.

	Concurrent medication/care: Up to 15 mg
Funding	Funding not stated
Pain at 4–6 hours Pain at 180 minutes; Risk of bias: Low; Indirectness of outcome: Serious indirectness- GIV. Mean Difference = -0.4; Standard Error (0.152). Adverse effects - Nausea Vomiting at 180 minutes; Group 1: 1/56, Group 2: 1/49; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Need for rescue analgesia

Table 3: Clark 2007[28]

Study	**Clark 2007[28]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=176)
Countries and setting	Conducted in Canada; Setting: Tertiary care emergency department paediatric hospital (55,000 patients per annum)
Line of therapy	1st line
Duration of study	Intervention and follow up: 7 months
Stratum	Children (0–15 years)
Inclusion criteria	Children aged 6–17 with pain from musculoskeletal injury (to extremities, neck and back) occurring in the previous 2 days.
Exclusion criteria	Contraindication to study drug, open fracture, required resuscitation, had an IV line placed, had taken a study drug within the past 6 hours.
Age, gender and ethnicity	Age - Mean (SD): 12 (3). Gender (M:F): 3:1. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=51) Intervention 1: Oral - Paracetamol. 15 mg/kg of acetaminophen. Duration 120 minutes. Concurrent medication/care: Maximum dose 650 mg (n=58) Intervention 2: Oral - NSAIDs. 10 mg/kg ibuprofen. Duration 120 minutes. Concurrent medication/care: maximum dose 600mg

	(n=50) Intervention 3: Oral - Opioids - Codeine. 1 mg/kg codeine. Duration 120 minutes. Concurrent medication/care: up to 60 mg
Funding	Academic or government funding (Children's Hospital of Eastern Ontario)
Pain at 1 hour (Change Score) Pain at 30 minutes; Group 1: mean (SD) -14 (18.21); n=51, Group 2: mean (SD) -29 (25.26); n=58, Group 3 mean (SD) -7 (3.61); n=58; Visual analogue scale 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness.	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Adverse effects; Need for rescue analgesia

Table 4: Craig 2012[33]

Study	**Craig 2012[33]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=55)
Countries and setting	Conducted in United Kingdom; Setting: Emergency department of NHS Hospital with 60,000 patients per annum.
Line of therapy	1st line
Duration of study	Intervention time: 10 month
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults 18 years or over
Inclusion criteria	Isolated limb trauma, Moderate to severe pain, with initial verbal pain score of 7 or more, Age >15 and <66 years, Estimated weight >50 kg.
Exclusion criteria	Chest pain, Glasgow Coma Scale <15, Allergy to morphine or paracetamol, Known liver disease, or patient clinically jaundiced, Major trauma, Known pregnancy, Breast feeding, Patients requiring an immediate limb-saving procedure, Patients in extreme distress, Communication difficulties (foreign language, prior confusion)preventing informed consent or cooperation with pain scoring.
Recruitment/selection of patients	Patients were required to provide informed consent.
Age, gender and ethnicity	Age - Mean (range): 36.5 (16–62). Gender (M: F): 1:1. Ethnicity: Not reported
Indirectness of population	Serious indirectness: Major trauma patients excluded but definition meets other inclusion criteria.

Interventions	(n=28) Intervention 1: Intravenous Opiates - Morphine. 10 mg of morphine sulphate. Duration 15 minutes. Concurrent medication/care: After the initial infusion the patient's pain relief was judged to be inadequate, intravenous morphine titrated to effect was used as 'rescue analgesia'. If the patient complained of nausea, intravenous metoclopramide was offered as an antiemetic to those older than 21 years. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 hours. (n=27) Intervention 2: Intravenous paracetamol - Acetaminophen. 1g of intravenous paracetamol. Duration 15 minutes. Concurrent medication/care: After the initial infusion the patient's pain relief was judged to be inadequate, intravenous morphine titrated to effect was used as 'rescue analgesia'. If the patient complained of nausea, intravenous metoclopramide was offered as an antiemetic to those older than 21 years. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. If the patient was discharged following the study they were advised to take no more than 3 g of paracetamol in the next 24 h. If admitted, an inpatient drug chart was written so that no more than 3 g of paracetamol could be administered over the next 24 h. Further details: 1.
Funding	Academic or government funding (College of Emergency Medicine)

Pain (Final Score)

Pain at 30 minutes; Group 1: mean (SD) 55.0 (29.7); n=27, Group 2: mean (SD) 63.5 (22.3); n=28; Visual analogue scale 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness.

Pain at 60 minutes; Group 1: mean (SD) 44.0 (22.6); n=27, Group 2: mean (SD) 52.9 (27.4); n=28; Visual analogue scale 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness

Need for further analgesia Incidence of Adverse Effects at 60 minutes; Group 1: 8/27, Group 2: 8/28; Risk of bias: High; Indirectness of outcome: No indirectness.	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Adverse effects;

Table 5: Friday 2009[44]

Study	**Friday 2009[44]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=68)
Countries and setting	Conducted in USA; Setting: Tertiary care children's hospital with 60,000 patients per annum.
Line of therapy	1st line
Duration of study	Intervention + follow up: 15 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years)
Inclusion criteria	Isolated extremity injury and a pain score of at least 5 out of 10 on initial triage
Exclusion criteria	Allergy or prior adverse reaction to acetaminophen, administration of any analgesic within 6 hours of ED visit, significant limb deformity or vascular insufficiency, inability to use the pain instrument, renal disease, pregnancy, any laceration near the injury, chronic hepatic disease. Concurrent use of central nervous system depressants.
Age, gender and ethnicity	Age - Mean (SD): 10.4 (3.4). Gender (M:F): 1:1. Ethnicity: White 40%; African American 15%; Hispanic 45%
Indirectness of population	Serious indirectness
Interventions	(n=34) Intervention 2: Oral - NSAIDs. Ibuprofen (10 mg/kg). Duration 60 minutes. Concurrent medication/care: 10 mg/kg. maximum 400 mg (n=34) Intervention 1: Oral - Opioids - Codeine. Acetaminophen-codeine (1 mg/kg). Duration 60 minutes. Concurrent medication/care: Maximum 60 mg
Funding	Funding not stated
Pain at 1 hour (Change) Pain at 20 minutes; Group 1: mean -1.4 (SD 1.4); n=34, Group 2: mean -0.8 (SD 1.94); n=32; Visual Analogue Scale 0-10 Top=High is poor outcome; Risk of bias: Very High; Indirectness of outcome: No indirectness Pain at 60 minutes; Group 1: mean -2.1 (SD 2.2); n=32, Group 2: mean -2.3 (SD 1.94) n=32; Visual Analogue Scale 0-10 Top=High is poor outcome; Risk of bias: Very	

High; Indirectness of outcome: No indirectness <u>Adverse effects</u> Nausea at 4 hours; Group 1: 0/34, Group 2: 1/32; Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Need for rescue analgesia

Table 6: Furyk 2009[45]

Study	**Furyk 2009[45]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=77)
Countries and setting	Conducted in USA; Setting: Mixed adult and paediatric tertiary hospital ED
Duration of study	Intervention and follow up: 1 Year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with pain from a clinically suspected limb fracture and pain considered sufficient to manage with narcotic analgesia.
Exclusion criteria	American Society of Anaesthesiologists grade >1, chronic medical condition, active asthma, concurrent upper respiratory tract infection or allergy to fentanyl or morphine.
Age, gender and ethnicity	Age - Mean (SD): 7.1 (2.4). Gender (M:F): Not reported. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=38) Intervention 1: Intranasal - Opioids. Nebulised fentanyl 4ug/kg (maximum 200 ug). Duration 30 minutes. Concurrent medication/care: The volume made up to 5ml with normal saline in a standard nebuliser circuit (MICRO MIST Nebuliser, Hudso Respiratory Care, Temecula, CA, USA) and administered with Oxygen. (n=39) Intervention 2: Intravenous - Opioids (Morphine). 0.1 mg/kg Morphine. Duration 30 minutes. Concurrent medication/care: Topical anaesthetic cream was applied to IV cannula site
Funding	No funding (None declared)
<u>Pain at 1 hour</u> Pain at 30 Minutes; Group 1: mean 3.51 (SD 2.4); n=35, Group 2: mean 4.03 (SD 2.3); n=37; Wong and Baker faces pain scale 0-10 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness	

Adverse effects Nausea at 30 Minutes; Group 1: 0/35, Group 2: 1/37; Risk of bias: Very high; Indirectness of outcome: No indirectness Need for rescue analgesia Insufficient Analgesia at 30 Minutes; Group 1: 1/35, Group 2: 0/37; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life

Table 7: Jalili 2012[69]

Study	**Jalili 2012[69]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=110)
Countries and setting	Conducted in Iran; Setting: Academic tertiary care adult ED (annual census 50,000 patients).
Line of therapy	1st line
Duration of study	Follow up (post intervention): 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (16 years and over): Adults older than 16
Subgroup analysis within study	Not applicable
Inclusion criteria	Acute extremity fracture with scores of higher than 3 out of 10 on a numeric pain scale.
Exclusion criteria	Patients unable to communicate due to language barrier or other causes; altered consciousness because of alcohol, sedatives, or other causes, concurrent significant trauma or life threatening condition known opioid allergy; history of chronic respiratory, renal, hepatic, heart failure, administration of analgesics before ED admission; addiction to narcotics reported by either the patients or family; pregnancy; or systolic BP lower than 90 mm Hg.
Age, gender and ethnicity	Age - Mean (SD): 35 (13). Gender (M:F): 4:1. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=55) Intervention 1: Oral - Opioids - Morphine. 0.4 mg sublingual buprenorphine. Duration 60 minutes. Concurrent medication/care: 5 ml sterile water (n=55) Intervention 2: Intravenous - Opioids (Morphine). 5 mg IV morphine sulphate. Duration 60 minutes. Concurrent medication/care: Plus 1 sublingual placebo.

Funding	Academic or government funding (Tehran University of Medical Sciences)
<u>Pain at 1 hour (Final Score)</u> Pain Score at 30 min; Group 1: mean 5.0 (SD 1.8); n=49, Group 2: mean 5.0 (SD 1.7); n=50; Numeric Pain Scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness) Pain Score at 1 hour; Group 1: mean 2.2 (SD 0.7); n=44, Group 2: mean 2.2 (SD 0.7); n=45; Numeric Pain Scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness <u>Adverse effects - Actual outcome - Nausea</u> Nausea at 30 minutes; Group 1: 7/49, Group 2: 6/50; Risk of bias: Very high; Indirectness of outcome: No indirectness Nausea at 60 minutes; Group 1: 0/44, Group 2: 1/45; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Need for rescue analgesia

Table 8: Kariman 2011[77]

Study	**Kariman 2011[77]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=100)
Countries and setting	Conducted in Iran; Setting: Major trauma centre with 60000 patients annually. (1/3 trauma)
Line of therapy	1st line
Duration of study	Intervention and follow up: 9 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (16 years and over)
Inclusion criteria	Patients 15–85 presenting with isolated extremity trauma. Isolated injuries were confirmed by X-ray. The trauma had to have occurred within the past 6 hours and patients pain had to be scored as moderate to severe (4–10) according to the visual analogue scale. Patients had to be verbally and visually co-operative.
Exclusion criteria	Associated head and trunk injuries, non-orthopaedic limb injuries, Glasgow Coma Score <15, abdominal distension, lung disease, pneumothorax and or haemothorax. Taking any pre-hospital analgesia
Age, gender and ethnicity	Age - Mean (SD): 36.4 (20.0). Gender (M:F): 4:1. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Inhaled - Nitrous Oxide (Entonox). 50:50 mix of nitrous oxide and oxygen. Duration 15 minutes.

	Concurrent medication/care: Self-administered by the patient Further details: 1. Prior medication: Not applicable/Not stated/Unclear (n=50) Intervention 2: Intravenous - Opioids. 2 ug/kg fentanyl by slow IV injection. Duration Not specified. Concurrent medication/care: No dose limit. Receiving continuous oxygen at 6 l/min Further details: 1. Prior medication: Not applicable/Not stated/Unclear
Funding	No funding (Nothing declared)
<u>Pain at 1 hour (Change Score)</u> Pain at 1 hours; Group 1: mean 7.9 (SD 1.7); n=50, Group 2: mean 7.8 (SD 1.8); n=50; Visual Analogue Scale 0–10 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Adverse effects; Need for rescue analgesia

Table 9: Koller 2007[81]

Study	**Koller 2007[81]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=66)
Countries and setting	Conducted in USA; Setting: Tertiary care paediatric emergency department.
Line of therapy	1st line
Duration of study	Intervention and follow up: 10 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Inclusion criteria	Children aged 6–18 who presented to the ED with a suspected orthopaedic injury. The patient had to report with a baseline pain score >4FPS.
Exclusion criteria	Facial Pain Score <4, allergy to ibuprofen or opioids, analgesic given within the last 12 hours, injury with obvious bony deformity , open fracture, multiple trauma, altered mental status, inability to self-report a pain score, American Society of Anaesthesiologists classification of greater than II, bleeding dyscasias, hypotension, peptic ulcer disease, active GI bleeding, renal or hepatic insufficiency, respiratory depression or pregnancy.
Age, gender and ethnicity	Age - Mean (SD): 11.3 (3.0). Gender (M:F): 1:1. Ethnicity: White 56.1%, African American 39.4%, Other 4.6%
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Oral - Opioids - Codeine. Oxycodone [0.1 mg/kg]. Duration 120 minutes. Concurrent medication/care: max 10mg + placebo.

	(n=22) Intervention 2: Oral - NSAIDs. Ibuprofen 10 mg/kg. Duration 120 minutes. Concurrent medication/care: Max (800mg) + placebo. (n=22) Intervention 3: Oral - Opioids - Codeine. Combination Oxycodone (0.1 mg/kg) + Ibuprofen (10 mg/kg). Duration 120 minutes. Concurrent medication/care: No placebo.
Funding	Academic or government funding (University of Louisville Paediatrics Foundation)
<u>Adverse Effects</u> Nausea; Group 1: 0/22, Group 2: 0/22, Group 3:1/21 Risk of bias: Very high; Indirectness of outcome: No indirectness <u>Need for rescue analgesia</u> Need for rescue analgesia; Group 1: 1/22, Group 2: 0/22, Group 3:0/21 Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 1 hour; Pain at 4–6 hours; Quality of life; Adverse effects

Table 10: Mahar 2007[88]

Study	**Mahar 2007[88]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=95)
Countries and setting	Conducted in USA; Setting: A level II paediatric ED with a free standing children's hospital and an estimated volume of 55,000 patients pet annum
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Inclusion criteria	With a Visual analogue pain rating greater than 50/100 (0–100 scale), an American Society of Anaesthesia status of I or II.
Exclusion criteria	History of loss of consciousness, altered level of consciousness, multiple traumatic injuries, or if patients had received prior analgesic medication.
Age, gender and ethnicity	Age - Mean (SD): 11.5 (2.75). Gender (M:F): 2:1. Ethnicity: Not reported
Indirectness of population	No indirectness

Interventions	(n=50) Intervention 1: Oral - Opioids - Morphine. Oral trans mucosal fentanyl citrate. Duration 75 minutes. Concurrent medication/care: Received a OTFC lozenge on a holder containing 200 or 400 ug fentanyl depending on weight (appox 10 to 15 ug/kg). (n=45) Intervention 2: Intravenous - Opioids (Morphine). IV morphine (0.1 mg/kg). Duration 75 minutes.
Funding	No funding (No external funding noted)
<u>Pain (Final Score)</u> Pain at 30 minutes; Risk of bias: High; Indirectness of outcome: No indirectness GIV. Mean Difference = -10.9; Standard Error (4.94). Pain at 60 minutes; Risk of bias: High; Indirectness of outcome: No indirectness. Mean Difference = -14.4; Standard Error (5.0). <u>Adverse effects</u> Nausea - Group 1: 4/47, Group 2: 2/40; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life; Need for rescue analgesia

Table 11: Marco 2005[92]

Study	**Marco 2005[92]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=73)
Countries and setting	Conducted in USA; Setting: Emergency Department Community Teaching Hospital.
Line of therapy	1st line
Duration of study	Intervention and follow up: 10 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (16 years and over)
Inclusion criteria	Adults and adolescents patients with an acute fracture (less than three days) and severe pain, with pain scores >5 on a 0–10 scale, considered by the treating physician likely to benefit from either oxycodone-acetaminophen or hydrocodone-acetaminophen therapy.
Exclusion criteria	Less than 12 years, refusal to consent, positive pregnancy test, serious renal, hepatic, or pulmonary disease, chronic alcohol abuse, history of opioid or other substance abuse, chronic low back pain, hypersensitivity to hydrocodone, oxycodone, or acetaminophen, planning to drive home or operate machinery, and any other relevant contraindication
Age, gender and ethnicity	Age - Mean (SD): 36 (11.5). Gender (M:F): 2:1. Ethnicity: 1.5:1 White to African American/Hispanic

Indirectness of population	No indirectness
Interventions	(n=39) Intervention 1: Oral - Opioids - Codeine. A singel (po) dose of oxycodone, 5mg. Duration 3 days. Concurrent medication/care: 325 mg acetaminophen Each group also received sufficient medication for a subsequent 3 days use. (n=34) Intervention 2: Oral - Opioids - Codeine. A single dose of hydrocodone, 5mg. Duration 3 days. Concurrent medication/care: 325 mg acetaminophen Each group also received sufficient medication for a subsequent 3 days use.
Funding	Funding not stated
<u>Pain at 1 hour (Change)</u> Pain at 30 minutes; Group 1: mean -3.7 (SD 2.3); n=32, Group 2: mean -2.5 (SD 2.2); n=30; Numeric Pain Scale 0-10 Top=High is poor outcome; Risk of bias: Very High; Indirectness of outcome: No indirectness7 Change in Pain Score at 60 minutes; Group 1: mean -4.4 (SD 2.9); n=26, Group 2: mean -3 (SD 2); n=21; Numeric Pain Scale 0–10 Top=High is poor outcome; Risk of bias: Very High; Indirectness of outcome: No indirectness <u>Adverse effects - Nausea</u> Group 1: 1/16, Group 2: 2/18; Risk of bias: Very high; Indirectness of outcome: No indirectness <u>Need for rescue analgesia</u> Group 1: 4/35, Group 2: 7/32; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life

Table 12: Neri 2013[101]

Study	**Neri 2013[101]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=125)
Countries and setting	Conducted in Italy; Setting: Tertiary urban paediatric emergency department (Trieste, Italy)
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years): Age 4–17

Subgroup analysis within study	Not applicable
Inclusion criteria	Age 4–17; presence of suspected fracture or dislocation; presence of pain .6, evaluated at ED admission with 10 point Visual Analogue Scale or faces pain rating scale
Exclusion criteria	Children with finger trauma, analgesic drug usage in the prior 24 hours, history or hypersensitivity to NSAIDs, chronic illnesses and comorbidities.
Age, gender and ethnicity	Age - Median (range): 13 (8–15. Gender (M:F): 2:1. Ethnicity: Not reported
Further population details	1. Age (Adult): 2. Age (Child): Child 1–15 Years 3. Fracture Site: 4. Pain Level:
Indirectness of population	No indirectness
Interventions	(n=64) Intervention 1: Oral - NSAIDs. Ketorolac or the equivalent placebo, 0.5 mg/kg, to a maximum of 20 mg (=0.025 ml/kg of the solution, maximum 1 ml). Duration 2 hours. Concurrent medication/care: Each child enrolled received both the active drug and a matched placebo of the treatment. Oral solutions, 20 mg/ml for ketorolac. (n=67) Intervention 2: Oral - Opioids - Tramadol. Tramadol or equivalent placebo, 2mg/kg, to a maximum of 100 mg (0.020 ml/kg of solution, max 1 ml). Duration 2 hours. Concurrent medication/care: 100mg/ml construal was used for sublingual administration.
Funding	Funding not stated
<u>Adverse effects</u> Vomiting at 2 hours; Group 1: 0/60, Group 2: 2/65; Risk of bias: Low; Indirectness of outcome: No indirectness <u>Need for rescue analgesia</u> Need for rescue analgesia at 2 hours; Group 1: 2/60, Group 2: 8/65; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4–6 hours; Quality of life

Table 13: Poonai[114]

Study	**Poonai 2014[114]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=183)
Countries and setting	Conducted in Canada; Setting: Paediatric ED of a children's hospital.
Line of therapy	1st line
Duration of study	Intervention time:

Study	Poonai 2014[114]
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0-15 years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Children aged 5-17 with a non-operative, radiographically evident extremity fracture sustained within 24 hours of arrival at the ED.
Exclusion criteria	Patients with known hypersensitivity to ibuprofen or morphine, chronic use of NSAIDS or opioids or associated injuries requiring analgesia such as renal disease. Poor fluency in English, sleep apnoea and pregnancy.
Age, gender and ethnicity	Age - Mean (SD): 10.75 (3.2). Gender (M:F): 1:1. Ethnicity: Not reported
Further population details	1. Age (Adult): 2. Age (Child): 3. Fracture Site: 4. Pain Level:
Indirectness of population	No indirectness
Interventions	(n=68) Intervention 1: Oral - NSAIDs. Ibuprofen (Advil; Pfizer Canada, 10mg/kg, max. 600mg). Duration 24 hours. Concurrent medication/care: To be taken every 6 hours as needed for pain (max 4 doses) Further details: 1. Prior medication: (n=66) Intervention 2: Oral - Opioids - Morphine. ratio-Morphine (Ratiopharm0.5mg/kg, max 10 kg). Duration 24 hours. Concurrent medication/care: To be taken every 6 hours as needed for pain (max 4 doses) Further details: 1. Prior medication: Not applicable / Not stated / Unclear
Funding	Academic or government funding (Schulich Research Opportunities from Western University)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: NSAIDS versus OPIODS - MORPHINE

<u>Pain at 4-6 hours</u>
Pain Level at 4 hours; Group 1: mean 1.3 (SD 1); n=68, Group 2: mean 1.5 (SD 1.2); n=66; Risk of bias: High; Indirectness of outcome: No indirectness

<u>Adverse effects</u>
Vomiting at 24 hours; Group 1: 2/68, Group 2: 8/66; Risk of bias: Low; Indirectness of outcome: No indirectness

<u>Need for rescue analgesia</u>
Need for acetaminophen at 24 hours; Group 1: 17/68, Group 2: 10/66; Risk of bias: Low; Indirectness of outcome: No indirectness

Study	Poonai 2014[114]
Protocol outcomes not reported by the study	Pain at 1 hour; Quality of life

Table 14: Rainer 2010[116]

Study	Rainer 2000 [116]
Study type	Randomised controlled trial
Number of studies (number of participants)	1 (n=94)
Countries and setting	Prince of Wales Hospital, Shatin, New Territories of Hong Kong
Line of therapy	1st line
Duration of study	Not reported
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (16 years and over)
Inclusion criteria	Presentation to the emergency room for fracture management with a painful limb injury
Exclusion criteria	History of substance abuse, dementia, indigestion, peptic ulceration or gastrointestinal haemorrhage, recent anti-coagulation, pregnancy, cardiac/renal/hepatic complications, recent NSAIDs usage, visual, physical or cognitive impairment.
Age, gender and ethnicity	Age - Mean (SD): 53.55 years (21.8). Gender (M:F): 1:2. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=75) Intervention 1: Intravenous - NSAIDs. Ketorolac 10 mg/ml solution administered as a intravenously over 60 seconds and followed by 5.0 mg infusions every 5 minutes up to 20 minutes. (n=73) Intervention 2: Intravenous - Morphine. 15/mg/dose Intravenous morphine as a 5mg loading dose over 60 seconds followed by 5.0mg infusions every 5 minutes up to 20 minutes.
Funding	Chinese University of Hong Kong and the Health Services Research Committee of Hong Kong
<u>Adverse effects</u> Nausea; Group 1: 0/75, Group 2: 27/73; Risk of bias: Low; Indirectness of outcome: Some indirectness	
Protocol outcomes not reported by the study	Pain at 1 hour; Pain at 4–6 hours; Quality of life

Table 15: Sheperd 2009[132]

Study	Shepherd 2009[132]
Study type	Randomised controlled trial
Number of studies (number of participants)	1 (n=94)
Countries and setting	Conducted in New Zealand; Setting: Children's Emergency Department, Starship Hospital, Auckland approximately 32,000 patients per annum
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children (0–15 years)
Inclusion criteria	Presentation to the emergency room for fracture management within 24 hours of injury, an acute, non-pathological fracture of distal humerus, radius, or ulna, or any tibula or fibula and the patient able to be discharged from the CED
Exclusion criteria	Inability to reliably use and complete the questionnaire, other injuries or conditions likely to cause pain, known hypersensitivity to paracetamol or ibuprofen and a history of renal impairment.
Age, gender and ethnicity	Age - Mean (range): 96 months. Gender (M:F): 1:1. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: Oral - NSAIDs. Ibuprofen 10mg/kg/dose every 8 hours. Duration 2 days. Concurrent medication/care: Doses administered at specified time up to 2 days later (n=43) Intervention 2: Oral - Paracetamol. 15/mg/kg dose Paracetamol every 4 hours. Duration 2 days. Concurrent medication/care: Doses administered at specified time up to 2 days later
Funding	No funding (Nil)

<u>Adverse effects</u>
Nausea/Vomiting at 2 days; Group 1: 2/29, Group 2: 0/43; Risk of bias: Very high; Indirectness of outcome: No indirectness
Delayed Union at 2 days; Group 1: 0/29, Group 2: 0/43; Risk of bias: Very high; Indirectness of outcome: No indirectness

<u>Need for rescue analgesia</u> Rescue Analgesia at 2 hours; Group 1: 4/29, Group 2: 3/43; Risk of bias: Very high; Indirectness of outcome: No indirectness Rescue Analgesia at 48 hours; Group 1: 2/29, Group 2: 2/43; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 1 hour; Pain at 4–6 hours; Quality of life

G.1.2 Paediatric nerve blocks femoral fractures

Table 16: Wathen 2007 [149]

Study	Wathen 2007[149]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=55)
Countries and setting	Conducted in USA; Setting: Tertiary care children's hospital and Level 1 trauma centre.
Line of therapy	1st line
Duration of study	Intervention + follow up: 40 Months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients presenting with an acute femur fracture
Exclusion criteria	Children outside of the specified range (1-15), altered mental status, had a nerve or vascular injury in the affected limb, had abnormal bone structure, received fracture reduction, had a hypersensitivity to the study agents used, presented with a significant multisystem distracting injuries (such as additional long bone fractures), or had social concerns including non-accidental trauma.
Recruitment/selection of patients	Patient selection was a convenience sampling based on availability of research assistants and physicians available to administer the fascia iliaca compartment nerve block.
Age, gender and ethnicity	Age - Median (range): 5.5 (1.3-15.1). Gender (M:F): 3:1. Ethnicity: Not reported
Further population details	1. Age: Child (From 1 year to 15 years) 2. Pain level: Not applicable / Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=26) Intervention 1: Nerve Block - Fascia iliaca compartment block. Performed with the local anaesthetic ropivacvine (Naropin). A 0.5 % solution of ropivacine (Half live of 4.2 hr [1 hour] epidural) was drawn up at a dose of 0.75mL/kg for children less than 20kg and 0.5 mL/kg for children greater than 20kg, with a maximum dose of 30mL.. Duration Not specified. Concurrent medication/care: Surface landmarks were established by palpating the lateral aspect of the pubic bone and the adjacent anterior superior iliac spine. A point was then marked, using a surgical skin marker, along the inguinal ligament two things the distance laterally between 2 landmarks. A 22-gauge by 1-inch B-Plex short beveled needle (Plexufix brachinal plexus anesthesia set; B.Braun Medical Inc., Bethlehem, PA) was inserted at a 90 degree angle. Further details: 1. Prior Medication: Not applicable / Not stated / Unclear

Study	Wathen 2007[149]
	(n=29) Intervention 2: Standard analgesia - Intravenous. Morphine was dosed at 0.1 ml/kg.. Duration Not specified. Concurrent medication/care: Not specified Further details: 1. Prior Medication: Not applicable / Not stated / Unclear
Funding	Academic or government funding (The Children's Hospital Research Institute)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: FASCIA ILIACA COMPARTMENT BLOCK versus INTERVENOUS Protocol outcome 1: Pain at 1 hours - Actual outcome: CHEOPS score at 5 minutes; Group 1: mean 1.65 (SD 0.79); n=26, Group 2: mean 0.95 (SD 0.78); n=29; CHEOPS score 4-13 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: CHEOPS score at 30 minutes; Group 1: mean 3.34 (SD 1.53); n=26, Group 2: mean 1.95 (SD 1.54); n=29; CHOEPS Score 4-13 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Nerve and vascular damage - Actual outcome: Central nerve damage at 12 Hours; Group 1: 0/26, Group 2: 2/29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Respiratory depression (<6 hours) - Actual outcome: Respiratory Depression at 12 Hours; Group 1: 1/26, Group 2: 6/29; Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 4: Nausea and vomiting - Actual outcome: Vomiting at 12 Hours; Group 1: 0/26, Group 2: 4/29; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Pain at 4-6 hours; Quality of life; Missed/Delayed diagnosis of department syndrome; Femoral Injury; Delayed bone healing; Haematoma; Local Infection; Admission solely for recovery from pharmacological agent including cardiac depression, arrhythmia; Need for rescue analgesia

G.2 Acute stage assessment and diagnostic imaging

G.2.1 Selecting patients for imaging – prediction rules for ankle fractures

Table 17: Fan 2006[38]

Study	Fan 2006[38]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=124)
Countries and setting	Conducted in Canada; Setting: Urgent care department in Canada
Line of therapy	1st line
Duration of study	Not clear:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Clinical assessment
Stratum	Adults (16 years and over)
Subgroup analysis within study	Not applicable
Inclusion criteria	History of twisting trauma to ankle or foot in past 7 days; 18 years or older
Exclusion criteria	Neurovascular compromise; visible limb deformity; open fracture; non-isolated ankle/foot injury
Recruitment/selection of patients	All patients attending the urgent care department who were eligible and who gave consent
Age, gender and ethnicity	Age - Range of means: 65–70. Gender (M:F): 71:53. Ethnicity: Not reported
Further population details	
Extra comments	Adult patients presenting to a single academic urgent care department
Indirectness of population	No indirectness
Interventions	(n=65) Intervention 1: Clinical prediction rule for ankle fracture - Ottawa clinical prediction rule. Carried out by the triage nurse using a standardised form detailing the Ottawa clinical prediction rule. Concurrent medication/care: X-rays would be given in response to positive Ottawa findings, and negative findings would be examined by an emergency

	physician prior to a decision on X-ray. This additional level of assessment beyond the Ottawa makes this intervention indirect with respect to the review question (n=65) Intervention 2: Clinical examination for ankle fracture - Clinical examination. Emergency physician clinically examined patients to decide on X-ray. Duration unclear. Concurrent medication/care: X-ray for those who were deemed to be at risk
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: OTTAWA CLINICAL PREDICTION RULE versus CLINICAL EXAMINATION Protocol outcome 1: Length of stay Ottawa: mean 73 minutes (SD 39.7); n=62, Clinical examination: mean 79.7 minutes (SD 39.7); n=62; *Risk of bias: low; Indirectness of outcome: serious indirectness* Protocol outcome 2: Patient satisfaction Sun satisfaction scale; Ottawa: median 4 (IQR 3.75 to 5); n=55, Clinical examination: median 4 (IQR 3 to 5); n=53;5 point ordinal scale; *Risk of bias: Very high; Indirectness of outcome: serious indirectness* Protocol outcome 3: Proportion having X-rays Patients having X-rays at index visit within 2 hours; Ottawa: 58/62, Clinical examination: 54/61; *Risk of bias: low; Indirectness of outcome: serious indirectness*	
Protocol outcomes not reported by the study	Quality of life; Missed fractures; Misdiagnosis of fractures; Patient pain; Hospitalisation

G.2.2 Imaging of scaphoid

G.2.2.1 Management of a suspected scaphoid fracture – Diagnostic RCTs

Table 18: Brooks 2005[23]

Study	Brooks 2005[23]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=28)
Countries and setting	Conducted in Australia; Setting: Emergency departments in five major city and suburban hospitals (2000–2002)
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: all patients with suspected scaphoid fracture and indeterminate initial X-ray findings
Stratum	Skeletally mature: Adults (18+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age >18 years, suspected scaphoid fracture requiring immobilisation with normal and/or inconclusive initial wrist radiographs
Exclusion criteria	Contraindications to MRI (pacemaker, cerebral aneurysm clip, cochlear implant, presence of metal/shrapnel in strategic locations such as the eye, claustrophobia), unable to provide informed consent
Recruitment/selection of patients	Consecutive patients admitted to the participating ED and meeting the inclusion criteria were invited to participate
Age, gender and ethnicity	Age - Median (IQR): MRI = 35 years (27–41); Control = 29 years (24–75). Gender (M:F): 13:15. Ethnicity: Unreported
Indirectness of population	No indirectness
Interventions	(n=10) Intervention 1: MRI within 2–5 days following presentation at ED. Concurrent medication/care: Treatment as usual (n=17) Intervention 2: Immobilisation and re-assessment 2 weeks following presentation at ED. Majority of patients received X-ray at follow-up, but some patients may have received other imaging techniques (e.g. bone scintigraphy, MRI). Concurrent medication/care: Treatment as usual

Funding	Funded by the Consultative Committee on Diagnostic Imaging
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MRI versus IMMOBILISATION + LATER RE-ASSESSMENT Protocol outcome 1: Number of outpatient visits - Actual outcome for Adults (18+): Healthcare use; Risk of bias: Low; Indirectness of outcome: Serious indirectness Protocol outcome 2: Time in plaster cast - Actual outcome for Adults (18+): Unnecessary immobilisation at 3-months; Risk of bias: Low; Indirectness of outcome: Serious indirectness Protocol outcome 3: Pain - Actual outcome for Adults (18+): Pain (patient rated wrist evaluation) at 1 month; Risk of bias: High; Indirectness of outcome: No indirectness - Actual outcome for Adults (18+): Pain (patient rated wrist evaluation) at 2 month; Risk of bias: High; Indirectness of outcome: No indirectness - Actual outcome for Adults (18+): Pain (patient rated wrist evaluation) at 3 month; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health-related quality of life; AE - Non-union/Malunion; AE - Post-traumatic arthritis; AE - Missed injury; AE - Avascular necrosis; AE - Additional radiation exposure; Return to normal activities; Psychological wellbeing; Range of motion; Grip strength.

Table 19: Patel 2013[112]

Study	**Patel 2013[112]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=91)
Countries and setting	Conducted in United Kingdom; Setting: Medium sized general hospital over three years (2003–2006)
Duration of study	Intervention and follow up: Intervention + 42-week follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosis of suspected scaphoid fracture made by senior ED doctor
Stratum	Skeletally mature: adults aged 16–80 years
Subgroup analysis within study	Not applicable

Inclusion criteria	Suspected scaphoid fracture but indeterminate initial X-ray findings, age 16–80 years.
Exclusion criteria	Previous wrist injury, contraindications or intolerance to MRI, wrist surgery within the previous year, patients who were vulnerable or unable to consent.
Recruitment/selection of patients	All consecutive patients admitted to the participating hospital and meeting the inclusion criteria were invited to enter the study.
Age, gender and ethnicity	Age: MRI mean age = 36.2 years; Control mean = 33.3 years. Gender (M:F): 37 male:47 female. Ethnicity: not reported
Indirectness of population	No indirectness
Interventions	(n=46) Intervention 1: MRI within 2 working days following discharge from ED. The results of the MRI were available to patients on the same day. Patients without injury were advised to remove the cast and mobilise, and were not offered a follow-up appointment. Patients with injury were advised to retain the cast and attend a clinic appointment 14 days later. Concurrent medication/care: All patients placed in a removable scaphoid cast ('backslab') prior to secondary imaging. (n=45) Intervention 2: Immobilisation and re-assessment 2-weeks following presentation at ED. Majority of patients received X-ray at follow-up, but some patients may have received other imaging techniques (e.g. bone scintigraphy, MRI). Concurrent medication/care: All patients placed in a removable scaphoid cast ('backslab') prior to secondary imaging. Further details: 1. Timing of imaging: Further imaging 7-14 days after discharge (10-14 days after initial assessment).
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MRI versus IMMOBILISATION + LATER RE-ASSESSMENT

Protocol outcome 1: Number of outpatient visits
- Actual outcome for Adults (18+): Mean fracture clinic appointments at unclear; Group 1: mean 1.1 appointments (SD 0.5); n=45, Group 2: mean 2.3 appointments (SD 0.8); n=39; Risk of bias: High; Indirectness of outcome:

Protocol outcome 2: AE - Additional radiation exposure
- Actual outcome for Adults (18+): Mean number of X-rays after initial assessment at unclear; Group 1: mean 1.2 plain radiographs (SD 0.8); n=45, Group 2: mean 1.7 plain radiographs (SD 1.1); n=39; Risk of bias: High; Indirectness of outcome:

Protocol outcome 3: Pain

- Actual outcome for Adults (18+): Self-reported pain (author developed scale) at 14 days; Risk of bias: High; Indirectness of outcome: - Actual outcome for Adults (18+): Self-reported pain (author developed scale) at 42 days; Risk of bias: High; Indirectness of outcome:	
Protocol outcomes not reported by the study	Health-related quality of life; Time immobilised; AE - Non-union/Malunion; AE - Post-traumatic arthritis; AE - Missed injury; AE - Avascular necrosis; Return to normal activities; Psychological wellbeing; Range of motion; Grip strength.

G.2.2.2 Management of a suspected scaphoid fracture – Diagnostic accuracy

Table 20: Ilica 2011[65]

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
Ilica et al. Diagnostic accuracy of mulitdetector computed tomography for patients with suspected scaphoid fractures and negative radiographic examinations. Jpn J Radiol 2011; 29: 98-103	Prospective observational	54 patients with 55 wrists with suspected scaphoid fractures	Patients had clinically suspected scaphoid fractures after a negative initial post trauma wrist X-rays. All patients were tender in the anatomical snuff-box and scaphoid tubercle. Trauma occurred <72 hrs (otherwise they were excluded).	**MDCT** (multi-detector computed tomography) 64 detector mulitslice system (Brillance 64, Philips, Best, The Netherlands). Body position: prone with hand above their head and wrist placed flat on the CT table. 0.6mm detectors Slice reconstruction in 0.9mm widths (tube voltage 120kVp, effective tube current-	**MRI** (Magnetic Resonance Imaging) Signa 1.5T MR system with a dedicated wrist coil Body position: prone, with affected arm above the body Sequences: 1.coronal and axial T1-weighted fast spin echo	1 week after the trauma	**Fracture definition:** evidence of a cortical fracture line, a trabecular fracture line or a combination of these abnormalities **MRI results:** There were 22 fractures in 20 wrists. 16 of these were scaphoid fractures. 35 wrists were normal, 39 had no scaphoid fractures. **MDCT** detected 19 fractures in 17 wrists. 14 of these were scaphoid fractures. 38 had no fractures and 41 had no scaphoid fractures.		Not reported	Radiologists were blinded to the clinical measures and scan results ended in consensus. MDCT scans were done prior to the MRI scans. Unclear how and where the patients were selected (consecutive

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
			Patients were 18 years and older (all men, mean age 22yrs, range 20–40 years). Initial XR: 3 projections (postero anterior with the wrist in max ulnar deviation, lateral, and semi supinated oblique (scaphoid view). Radiographs reviewed by an orthopaedic surgeon and confirmed by a radiologist. Patients with an X-ray (without a	time 300 mAs, detector collimation 20 x 0.625mm, beam pitch 0.654, rotation time 0.75s, field of view 10-12cm, reconstruction thickness 0.9mm, reconstruction increment 0.45mm, postprocessing kernel Standard B, surview tube potential 120kV, surview tube current time 30mAs, surview field of view 500mm. CTs reviewed by 2 radiologists with at least 4yr MDCT experience. They revised the CT images before MRI was undertaken. Images reviewed: interactive cine mode, axial images, 2D and £D post processing techniques, multiplanar reformations,	(TR/TE 360-600/10-20; 3 -5mm slice thickness, 0.5mm gap 2. coronal and axial fat saturated proton density weighted fast spin echo with fat saturation (TR/TE 2100-2800/30-44; 3 -5mm slice thickness, 0.5-1.0mm gap. 3. coronal T2* weighted (TR/TE 350-500/10; 20 degree flip angle, 3mm slice thickness. Field of view: 120mm		**Scaphoid fractures for MDCT (calculated from figures given in the paper)**			/random, unclear setting- ?Military) Risk of selection bias as 36% of the patients had a fracture (higher than cited in other literature) Radiographic technique reported not to have been standardized (busy clinical circumstances), so no additional views taken. Reproducibility was not tested.
							Sensitivity	0.875		
							Specificity	1.0		
							PPV	1.0		
							NPV	0.91		

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
			sharp radiolucent line in the trabecular pattern, distinct break of the cortex or a sharp step off in the cortex) then went on for the further assessments 1 week after the trauma. All patients wore a scaphoid cast until the diagnosis was confirmed.	maximum intensity projection, volume rendering techniques. Reformations done in real time on the same day as it was taken. Display parameters (width, level, opacity, brightness) were adjusted by the radiologists. Reformation duration ~15 mins per radiologist.						

Table 21: Jorgsholm 2013[74]

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
Jorgsholm 2013[74,74]	Prospective observa	296 skeletally mature	Patients with posttraumatic radial wrist	**X-ray** Radiographs of the	**MRI** A 0.23-T low-	X-rays performed	**MRI results:** There were 224 fractures in 196 wrists. 125 of these		Supported by grants	

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
	tional	patients (300 wrists)	tenderness. Selection was based on interview and physical examination, which included testing for tenderness along the anatomical snuffbox and at the scaphoid tubercle and for radial-sided wrist pain by pressing the thumb longitudinally. Exclusion criteria were age under 18 years and a delay of more than 14 days from injury to MRI. Patients were	wrist in dorsovolar and lateral projections with an additional 4 views of the scaphoid. A fracture was defined as a break in the continuity of the bone **CT** A 16-slice CT scanner. A scout view was obtained before the scan. Axial sections of 0.6mm thick slices were obtained with 1- or 2-mm thick reconstructions in the coronal and capital planes defined by the long axis of the scaphoid as well as the creation of a 3-dimensional image of the wrist. Criteria for fracture on CT images were the presence of a sharp lucent line within the trabecular bone, a break in the continuity of the cortex, a sharp step in the cortex, or a	field MRI unit was used with a dedicated small joint coil and the following study protocol: coronal short tau inversion recovery (STIR), 3-mm slice thickness, coronal T1 field echo 3-dimensional, 2-mm slice thickness, axial T1 fast spin-echo, 3.5mm slice thickness, and sagittal T1 field echo 3-dimensional, 2mm slice thickness	immediately at admission, MRI performed up to 14 days after injury (unclear), CT performed after X-ray and MRI (unclear timeframe).	were scaphoid fractures (107 isolated scaphoid fractures, 18 scaphoid fractures with associated other fractures). **X-ray** detected 121 fractures out of 224 fractures identified by MRI. Of these X-ray identified 88 scaphoid fractures from the 125 scaphoid fractures identified by MRI. X-rays identified 3 false positive fractures in the 175 patients identified as not having a fracture by MRI **CT** was conducted in 122 of the 125 wrists identified as positive for scaphoid fracture by MRI. Of these, CT identified 116 scaphoid fractures. **X-ray** Sensitivity (95% CI) 0.70 (61-78) Specificity 0.98 (95-		from Region Skane and the Skane Hospital Foundation	

Reference	Study type	Number of patients	Patient characteristics	Index test	Reference test	Time between tests	Outcome (Index/Ref)	Effect sizes	Source of funding	Comments
			referred from the emergency department for wrist and scaphoid radiographs. Regardless of the result, MRI was performed up to 14 days post-injury. CT was conducted only in those patients with positive x-ray or MRI findings.	disclocation of bone fragments.			(95% CI)	100)		
							CT			
							Sensitivity (95% CI)	0.95 (91-97)		

G.2.3 Hot reporting

Table 22: Hardy 2013[56]; Hardy 2013a[55]

Study (subsidiary papers)	Hardy 2013[55], Hardy 2013[56]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=1502)
Countries and setting	Conducted in United Kingdom; Setting: A&E departments in five hospitals from three NHS Trusts across the North of England: Mid Yorkshire Hospitals NHS Trust (Dewsbury and Pontefract); Pennine Acute Hospitals NHS Trust (Oldham

	and Fairfield); Royal Liverpool & Broadgreen University Hospitals NHS Trust (Royal Liverpool University Hospital).
Line of therapy	1st line
Duration of study	Intervention and follow up: Intervention and readmission within 2-weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: No breakdown of patient injuries
Stratum	Overall: Patients admitted to A&E with a musculoskeletal injury
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients admitted to A&E with a muscoloskeletal injury sustained in the previous 48 hours. Ability to provide informed consent. All demographics.
Exclusion criteria	Patients attending with additional visceral injuries (e.g. chest, abdomen)
Recruitment/selection of patients	Consecutive patients admitted with muscoloskeletal injuries during the study recruitment period were screened and invited to participate in the study
Age, gender and ethnicity	Age - Range: 0–92 years. Gender (M:F): 828:674. Ethnicity: Unreported
Further population details	Child (0–17 years) n=402 (26.8%); adult (18–64) n=966 (64.3%); elderly (65+) n=134 (8.9%)
Indirectness of population	Serious indirectness: Unclear what injuries, in addition to fractures, were included
Interventions	(n=752) Intervention 1: Definitive report during hospital attendance - Definitive report by radiographer. Radiographic examination was undertaken and the patient was asked to wait in the radiology department for the image to be reviewed by a radiographer and the report generated. The report arrived in the emergency department at the same time as the patient (either electronically or in hard copy). Duration During hospital attendance. Concurrent medication/care: None reported Further details: 1. Skill level/Seniority of clinician: (n=750) Intervention 2: No radiology report during hospital attendance - Delayed radiology report. Radiography examination undertaken as normal practice and the patient asked to return to the ED to await initial interpretation of the images by the referring clinician. This included any normal practice of radiographers flagging abnormal images (e.g. 'red dot' reporting). The radiographic report was returned to the emergency department at a later date, following standard practice locally.. Duration Unclear. Concurrent medication/care: None reported Further details: 1. Skill level/Seniority of clinician:
Funding	Academic or government funding (National Institute of Health Research (Research for Patient Benefit Programme PB-

	PG-0407-13033))
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HOT REPORTING versus COLD REPORTING Protocol outcome 1: Quality of life - Actual outcome: EQ-5D at Final score 8-weeks post ED attendance; Risk of bias: High; Indirectness of outcome: Serious indirectness - Actual outcome: EQ-5D at Change between initial presentation and 8-weeks post ED attendance; Group 1: mean 0.34 (SD 0.3327); n=383, Group 2: mean 0.345 (SD 0.3314); n=380; Risk of bias: Low; Indirectness of outcome: Serious indirectness Protocol outcome 2: AE - Missed fractures - Actual outcome: Missed fractures on day of injury; Group 1: 1/752, Group 2: 12/750; Risk of bias: Low; Indirectness of outcome: Protocol outcome 3: AE - Patient recalled at Define - Actual outcome: Patient recalled on receipt of radiographic report; Group 1: 0/752, Group 2: 7/750; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - Pain at Define; Patient outcomes - return to normal activities at Define; Patient outcomes - psychological wellbeing at Define; AE - Change in management plan at Define

G.3 Management and treatment plan in the emergency department

G.3.1 Reduction anaesthesia – distal radius fractures

G.3.1.1 Clinical effectiveness review

Table 23: Abbaszadegan 1990[2]

Study	Abbaszadegan 1990[2]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=99)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line

Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People with displaced Colles' fractures
Exclusion criteria	Severely displaced fractures with a shortening of 5 mm or more and people with hypertension
Recruitment/selection of patients	Consecutive patients
Age, gender and ethnicity	Age - Mean (range): 64 (21–86). Gender (M:F): 11/88. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Anaesthetic technique - IV regional anaesthesia. 3 mg/kg prilocain. Further details: 1. Timing: Not applicable/Not stated/Unclear 2. Use of image intensifier: no image intensifier (n=49) Intervention 2: Anaesthetic technique - Haematoma block. 15–20ml prilocain. Duration. Further details: 1. Timing: Not applicable/Not stated/Unclear 2. Use of image intensifier: no image intensifier
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA versus HAEMATOMA BLOCK

Protocol outcome 1: Pain
- Actual outcome: Pain during reduction; Group 1: mean 1 (SD 2.3); n=50, Group 2: mean 2.5 (SD 2.3); n=49; Visual Analogue Scale 0–10 Top=High is poor. Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Need for re-operation
- Actual outcome: Re-reduction and external fixation at 10 days; Group 1: 0/50, Group 2: 4/49; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Nerve damage
- Actual outcome: Median nerve decompression at 3 months; Group 1: 2/50, Group 2: 2/49; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 24: Bajracharya 2002[13]

Study	Bajracharya 2002[13]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=100)
Countries and setting	Conducted in Nepal; Setting: Tertiary care hospital
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Radiologically confirmed
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults with distal forearm fractures
Exclusion criteria	People receiving analgesics within 8 hours of the time of reduction
Recruitment/selection of patients	Consecutive patients
Age, gender and ethnicity	Age - Mean (SD): 44. Gender (M:F): 46/54. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Anaesthetic technique - Regional nerve block. Brachial plexus block (dose according to body weight 4.5–7mg/kg) in the supraclavicular region of the patient. Duration. Concurrent medication/care: After ten to fifteen minutes the reduction and immobilization of the fracture was done by Junior Resident blinded to the anaesthesia technique Further details: 1. Timing: after day of injury 2. Use of image intensifier: no image intensifier (n=50) Intervention 2: Anaesthetic technique - Haematoma block. 1.5% Xylocaine (amount according to body weight-4.5 mg/kg) at the fracture hematoma site from the dorsal aspect. The drug was given by Junior Resident (J1) posted at the fracture clinic. Prior to the injection of the drugs, the part was painted first with Spirit (95% alcohol), then with 7.5% Povidone iodine. No massage was done at the fracture site after injection of the drug. Duration. Concurrent medication/care: After ten to fifteen minutes the reduction and immobilization of the fracture was done by Junior Resident blinded to the anaesthesia technique Further details: 1. Timing: after day of injury 2. Use of image intensifier: no image intensifier
Funding	--

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: REGIONAL NERVE BLOCK versus HAEMATOMA BLOCK Protocol outcome 1: Pain - Actual outcome: Pain during procedure; Group 1: mean 1.7 (SD 0.64); n=50, Group 2: mean 2.08 (SD 0.85); n=50; Visual Analogue Scale 0-10 Top=High is poor outcome; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation - Actual outcome: Re-manipulation (10 days after reduction) ; Group 1: 1/50, Group 2: 1/50; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 3: Laryngospasm/Respiratory depression - Actual outcome: Bronchial spasm ; Group 1: 1/50, Group 2: 0/50; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 4: Infection - Actual outcome: Infection ; Group 1: 0/50, Group 2: 1/50; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Cardiac arrhythmias; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 25: Goh 2002[47]

Study	**Goh 2002[47]**
Study type	Quasi-RCT
Number of studies (number of participants)	(n=67)
Countries and setting	Conducted in Singapore; Setting: Accident & emergency department
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adult patients (18 years and above) with closed fractures of the distal radius that were clinically judged to require M&R
Exclusion criteria	People unable to give informed consent, received prior analgesia within the past 4 hours, known allergy to involved drugs, open fractures, severe cardiovascular or respiratory disease, pregnancy, severe hypertension, peripheral vascular disease, crush injuries, pneumothorax, bowel obstruction, middle ear disease or diving-related illness.

Recruitment/selection of patients	Consecutive patients between August and September 2000
Age, gender and ethnicity	Age - Mean (range): 62 (21–87). Gender (M:F): 15/52. Ethnicity: Predominantly Chinese (~80%) and Malay (~20%)
Further population details	1. Age: Not applicable/Not stated/Unclear
Extra comments	The presence of factors that potentially made M&R difficult (e.g. impacted or comminuted fractures, obese patients) did not influence the selection process.
Indirectness of population	No indirectness: 4 of 67 fractures were volar angulated
Interventions	(n=32) Intervention 1: Anaesthetic technique - IV regional anaesthesia. Affected arm elevated to promote venous drainage. The pneumatic tourniquet was inflated to approximately 100 mmHg above systolic blood pressure up to a maximum of 250 mmHg. This was followed by the intravenous injection of 2 mg/kg of 1% lignocaine and diluted to 20 mls with normal saline into the affected arm. After reduction and immobilisation of the limb, the tourniquet was deflated, having ensured that it had been in place for at least 15 minutes. Duration. Concurrent medication/care: The M&R was carried out only after a wait of 5 minutes for the onset of analgesia. Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier (n=35) Intervention 2: Anaesthetic technique - Entonox. Entonox was inhaled for a minimum of 3 minutes before and during the M&R and immobilisation, after which it was discontinued. Patients in whom analgesia was inadequate were allowed to continue inhalation of the Entonox beyond 3 minutes until adequate analgesia was achieved. Duration. Concurrent medication/care: The patient is instructed on the proper use of the demand valve mask. A proper seal to the face and proper breathing technique is ensured. Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA versus ENTONOX Protocol outcome 1: Pain - Actual outcome: Pain perception ; Group 1: mean 2.2 (SD 2.3); n=32, Group 2: mean 5.8 (SD 2.8); n=35; Visual Analogue Scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation - Actual outcome: Failed first manipulation ; Group 1: 2/32, Group 2: 8/35; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Patient admitted; Group 1: 1/32, Group 2: 3/35; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 26: Haasio 1990[52]

Study	Haasio 1990[52]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=35)
Countries and setting	Conducted in Finland; Setting: Accident & emergency
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People with Colles' fracture not older than 6 hours that required closed reduction
Exclusion criteria	None detailed
Age, gender and ethnicity	Age - Mean (SD): 62. Gender (M:F): 2/33. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Anaesthetic technique - Haematoma block. 15 ml of 10 mg/ml prilocaine into haematoma from dorsum of the wrist. Duration. Concurrent medication/care: Sensation tested using pin prick method before closed reduction undertaken by surgeon Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier (n=16) Intervention 2: Anaesthetic technique - Regional nerve block. Cubital nerve block. 15 ml of 10 mg/ml prilocaine was injected into areas innervated by the radial, ulnar and median nerves in the elbow region. Duration. Concurrent medication/care: Sensation tested using pin prick method before closed reduction undertaken by surgeon Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HAEMATOMA BLOCK versus REGIONAL NERVE BLOCK Protocol outcome 1: Pain - Actual outcome: Moderate/severe pain during reduction ; Group 1: 6/19, Group 2: 9/16; Risk of bias: Very high; Indirectness of outcome: No indirectness	

Protocol outcomes not reported by the study	Mortality; Quality of life; Need for re-operation; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 27: Kendall 1997[79]

Study	**Kendall 1997[79]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=150)
Countries and setting	Conducted in United Kingdom; Setting: Accident & emergency
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People (16 years and over) with Colles' fracture requiring closed reduction by manipulation (>15 degrees dorsal angulation and >2 mm radial shortening)
Exclusion criteria	None detailed
Recruitment/selection of patients	Consecutive patients across two centres
Age, gender and ethnicity	Age - Mean (SD): 63. Gender (M:F): 17/125. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=70) Intervention 1: Anaesthetic technique - Haematoma block. 8.8 ml of lignocaine was mixed with 1.2 ml of diluent to constitute a 10 ml volume haematoma block. Either sodium bicarbonate or sodium chloride was the diluent. Duration. Concurrent medication/care: Closed reduction: distraction of the fracture followed by palmar flexion and ulnar deviation, and the forearm was placed in an incomplete Colles' plaster backslab Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier (n=72) Intervention 2: Anaesthetic technique - IV regional anaesthesia. Bier block. Prilocaine 0.5 % was used in all cases, the volume being calculated on the basis of the patient's weight. An anaesthetist was not required for the

	performance of Bier's block, although there were two doctors present in the department during the procedure. Duration. Concurrent medication/care: Closed reduction: distraction of the fracture followed by palmar flexion and ulnar deviation, and the forearm was placed in an incomplete Colles' plaster backslab Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HAEMATOMA BLOCK versus IV REGIONAL ANAESTHESIA Protocol outcome 1: Pain - Actual outcome: Pain score during reduction (median); Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation - Actual outcome: Re-manipulation; Group 1: 17/70, Group 2: 4/72; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 28: Man 2010[89]

Study	Man 2010[89]
Study type	Quasi-RCT
Number of studies (number of participants)	(n=67)
Countries and setting	Conducted in Hong Kong (China); Setting: Accident & emergency
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults (18 years or above) with a distal radius fracture less than 24 hours old
Exclusion criteria	People with severe cardiac or respiratory disease, peripheral vascular disease, crush injury, pregnancy, pneumothorax, intestinal obstruction, middle ear disease, diving-related illness, poor overlying skin condition, allergy

	to lignocaine and use of any analgesia 12 hours before the consultation
Recruitment/selection of patients	Consecutive patients. April 2008 to December 2008
Age, gender and ethnicity	Age - Mean (range): 66 (26–94). Gender (M:F): 14/53. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=34) Intervention 1: Anaesthetic technique - Haematoma block. 5 ml 2% lignocaine infiltrated into the fracture haematoma. Duration. Concurrent medication/care: Fracture reduction was performed after 5 minutes or once the analgesic effect was achieved Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier (n=33) Intervention 2: Anaesthetic technique - Entonox. Inhaled for 5 minutes or till analgesic effect was achieved before fracture reduction started. Duration. Concurrent medication/care: Entonox inhaled continuously during the fracture reduction. Once the fracture was reduced and no further manipulation of the fracture was needed, the use of Entonox was stopped Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HAEMATOMA BLOCK versus ENTONOX Protocol outcome 1: Pain - Actual outcome: Pain perception during reduction ; Group 1: mean 2.8 (SD 2.2); n=34, Group 2: mean 7.19 (SD 2.76); n=33; Visual Analogue Scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation - Actual outcome: Failed reduction; Group 1: 0/34, Group 2: 0/33; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

Table 29: Wardrope 1985[148]

Study	Wardrope 1985[148]

Study type	Quasi-RCT
Number of studies (number of participants)	(n=79)
Countries and setting	Conducted in United Kingdom; Setting: Accident & emergency
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People (>45 years) with Colles' fractures requiring manipulation
Exclusion criteria	Previous wrist fracture on the injured side. Contra-indications to Bier's block or to local anaesthesia
Age, gender and ethnicity	Age - Mean (SD): Unknown. Gender (M:F): Unknown. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=42) Intervention 1: Anaesthetic technique - IV regional anaesthesia. Bier's block. 0.5% plain prilocaine (Citanest) was used in a dose of 0.6 ml/kg. Duration. Concurrent medication/care: Reduction carried out after 5 minutes Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier (n=37) Intervention 2: Anaesthetic technique - Haematoma block. 1% plain lignocaine was used in a dose of 0.2 ml/kg. About four-fifths of the total dose was given through the dorsum of the wrist into the fracture haematoma given in this site; the rest was injected into the area of the ulnar styloid. Duration. Concurrent medication/care: Reduction carried out after 5 minutes Further details: 1. Timing: on day of injury 2. Use of image intensifier: no image intensifier
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA versus HAEMATOMA BLOCK

Protocol outcome 1: Pain
- Actual outcome: Painful/very painful reduction ; Group 1: 11/42, Group 2: 16/37; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Need for re-operation
- Actual outcome: Re-manipulation (during 1st anaesthetic); Group 1: 6/45, Group 2: 12/36; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Mortality; Quality of life; Patient-reported functional score; Laryngospasm/Respiratory depression; Cardiac arrhythmias; Infection; Nerve damage; Nausea/vomiting; Hallucinations/emergent phenomena; Return to normal activities

G.3.1.2 Adverse events review

Table 30: Andolfatto 2011[9]

Study	Andolfatto 2011[9]
Study type	Case series
Number of studies (number of participants)	(n=728)
Countries and setting	Conducted in Canada; Setting: Emergency department
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults given procedural sedation with ketafol in the emergency department
Exclusion criteria	None detailed
Recruitment/selection of patients	Prospective observational case series from July 2005 to December 2009
Age, gender and ethnicity	Age - Median (IQR): 53 (36–70). Gender (M:F): 342/386. Ethnicity:
Further population details	
Extra comments	ASA class 1+2: 653 (90%) patients, class 3+4: 75 (10%) patients. 68% of procedures were orthopaedic. Co-morbidities included: hypertension, dysrhythmia, coronary artery disease, asthma, multisystem trauma, psychiatric disease, cerebrovascular disease, drug intoxification, GERD, seizure disorder.
Indirectness of population	No indirectness
Interventions	(n=728) Intervention 1: Anaesthetic technique - Conscious sedation. Ketofol was prepared as a 1:1 mixture of 10 mg/ml ketamine and 10 mg/ml propofol, drawn into a single 20- or 10-ml polypropylene syringe. Thus, each millilitre of solution contained 5 mg each of ketamine and propofol. PSA with ketofol was performed using titrated aliquots of 0.025 to 0.05 ml/kg of solution, constituting 0.125 to 0.25 mg/kg each of ketamine and propofol. Aliquots were given at 30-second to 1-minute intervals at the discretion of the treating physician with a target of deep or dissociative

	sedation. The procedure was begun when the treating physician determined that the patient had achieved the targeted sedation depth. All procedures were performed in the ED, The only absolute contraindication being known allergy to relevant medications. Duration. Concurrent medication/care: All procedures were performed in the ED in an area equipped with a complete airway and resuscitation cart. All patients received continuous oxygen saturation and cardiac monitoring and were placed on oxygen delivered at 2 to 3 L per minute delivered by nasal prongs. In accordance with regional PSA guidelines, all sedations required the attendance of an EP (the treating physician), nurse, and respiratory therapist. During times when more than one EP was on site, a second EP dedicated to the administration of PSA medications was also present (the sedation physician). It is estimated that 80% of PSAs performed involved two EPs. Vital signs were recorded by the assisting nurse before, at 2- to 5-minute intervals during, and after each procedure
Funding	No funding (The authors have no relevant financial information or potential conflicts of interest to disclose)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY Protocol outcome 1: Cardiac arrhythmias - Actual outcome: Dysrhythmia; Group 1: 1/728, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Compromised airway/respiration - Actual outcome: Bag valve mask ventilation; Group 1: 15/728, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Convulsions/seizure - Actual outcome: Seizure at; Group 1: 0/728, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Other serious adverse event - Actual outcome: Hypotension; Group 1: 1/728, Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Hypertension/tachycardia; Group 1: 2/728, Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Death; Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Nerve damage; Aspiration of gastric contents; Methaemoglobinaemia

Table 31: Bou-merhi 2007[21]

Study	**Bou-merhi 2007[21]**
Study type	Case series
Number of studies (number of participants)	(n=479 operations (448 patients))

Countries and setting	Conducted in Canada; Setting: Hospital
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients who underwent a surgical procedure and were administered IVRA
Exclusion criteria	None detailed
Recruitment/selection of patients	Between January 2000 and December 2004
Age, gender and ethnicity	Age - Mean (range): 44 (12–85). Gender (M:F): 246/202. Ethnicity:
Further population details	
Extra comments	99.6% of procedures performed on upper extremities
Indirectness of population	Serious indirectness: Some children included and anaesthetic administered by plastic surgeon rather than emergency physician
Interventions	(n=479) Intervention 1: Anaesthetic technique - IV regional anaesthesia. Double pneumatic cuff used. Cuff inflated to 250 or 100 mmHg greater than SBP. IVRA established using 40 ml of a solution containing 0.5% (200 mg) lidocaine. Duration. Concurrent medication/care: Patients were monitored: ECG, non-invasive blood monitoring, pulse oximetry. Administering surgeon had basic or advanced cardiac life support qualification. A nurse whose only responsibility was to continuously monitor the patient's vital signs and to operate and monitor the pneumatic cuff.
Funding	No funding ("None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this article")

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA [INTERVENTION 1] ONLY

Protocol outcome 2: Cardiac arrest
- Actual outcome: Major cardiac event; Group 1: 0/479, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 3: Other serious adverse event
- Actual outcome: Operations cancelled due to tourniquet related technical problems; Group 1: 4/479, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcomes not reported by the study	Quality of life; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric

	contents; Compromised airway/respiration; Methaemoglobinaemia; Convulsions/seizure

Table 32: Burton 2006[24]

Study	Burton 2006[24]
Study type	Case series
Number of studies (number of participants)	(n=792)
Countries and setting	Conducted in USA; Setting: Multicentre (three emergency departments) prospective consecutive case series of ED patients receiving propofol for PSA
Line of therapy	1st line
Duration of study	Intervention and follow up: Until completion of ED PSA encounter
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	All patients presenting to the ED with an injury or illness requiring PSA and who were treated with propofol as the PSA sedative agent were included
Exclusion criteria	None detailed
Recruitment/selection of patients	Overall the recruitment took place between 2001 and 2005. However The investigational period was unique to each study site, with no attempt to standardise the periods of data collection
Age, gender and ethnicity	Age - Mean (SD): 41 (22). Gender (M:F): 444/348. Ethnicity:
Further population details	
Extra comments	73% of procedures were orthopaedic
Indirectness of population	Serious indirectness: 8% of patients were younger than twelve years old
Interventions	(n=792) Intervention 1: Anaesthetic technique - Conscious sedation. Propofol dosing: 1 mg/kg as an initial bolus dose, supplemented by 0.5 mg/kg as needed. The physician administering propofol was allowed to increase or decrease the dose of propofol in accordance with the needs of the patient or the deemed risk/benefit of the selected PSA dosing strategy for the clinical encounter. Depth of sedation was monitored by physician and nursing personnel. Duration Concurrent medication/care: A standardized PSA monitoring protocol was in place at each institution during the study period. The monitoring and patient sedation practices were unique to each practice setting. All study sites continuously monitored patients undergoing PSA for changes in blood pressure, heart rate, and oxygen saturation

	(SpO2). A standardized ED monitoring flow sheet was used to record vital signs and depth of sedation variables throughout the sedation encounter.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY Protocol outcome 2: Compromised airway/respiration - Actual outcome: Endotracheal intubation; Group 1: 0/792, Risk of bias: Very high; Indirectness of outcome: Serious indirectness - Actual outcome: Bag mask valve ventilation at .; Group 1: 31/792, Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric contents; Methaemoglobinaemia; Convulsions/seizure; Other serious adverse event

Table 33: Campbell 2006[26]

Study	**Campbell 2006[26]**
Study type	Case series
Number of studies (number of participants)	(n=979)
Countries and setting	Conducted in Canada; Setting: Emergency department
Line of therapy	1st line
Duration of study	Not clear:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People who had procedural sedation in the emergency department
Exclusion criteria	None detailed
Recruitment/selection of patients	Chart review of all PSA records from 1st August 2004 to 3rd July 2005. 80% of procedures were orthopaedic
Age, gender and ethnicity	Age - Other: 210 people >65 years of age. Gender (M:F): 484/481 - 14 not specified. Ethnicity:
Further population details	
Extra comments	Definition of adverse event included: oxygen saturation (SaO 2) of <90% at any time during the procedure in any patient with a baseline SaO 2 of ≥95%; systolic blood pressure (SBP) of <85 mm Hg in any patient with a baseline (pre-

	procedure) systolic blood pressure of 100 mm Hg or greater; evidence of aspiration; endotracheal intubation; or death
Indirectness of population	No indirectness
Interventions	(n=979) Intervention 1: Anaesthetic technique - Conscious sedation. Procedural sedation drugs used: propofol and fentanyl in 487 (49.7%) of cases, midazolam and fentanyl in 324 (33.1%) of cases, fentanyl was used in combination with both midazolam and propofol in 71 (7.3%) cases. Drug administration and patient monitoring is conducted by advanced level paramedics (Advanced Care Paramedics [ACPs]) trained in PSA, under the supervision of an emergency physician. Duration. Concurrent medication/care: The ACP was present to document the procedure and assist with the monitoring
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY Protocol outcome 1: Death - Actual outcome: Death; Group 1: 0/979, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Aspiration of gastric contents - Actual outcome: Aspiration; Group 1: 0/979, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Compromised airway/respiration - Actual outcome: Endotracheal intubation; Group 1: 0/979, Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Methaemoglobinaemia; Convulsions/seizure

Table 34: Jacques 2011[67]

Study	**Jacques 2011[67]**
Study type	Case series
Number of studies (number of participants)	(n=1402)
Countries and setting	Conducted in United Kingdom; Setting: Adult, principally urban, teaching hospital emergency department
Line of therapy	1st line
Duration of study	Not clear

Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	All patients requiring PSA
Exclusion criteria	Patients requiring sedation for other reasons, such as to control delirium were excluded
Recruitment/selection of patients	Consecutive patients from 4th September 2006 to 3rd September 2008 were consecutively enrolled onto the Registry of Emergency Procedural Sedation (REPS)
Age, gender and ethnicity	Age - Mean (range): 50 (13–101). Gender (M:F): 1.2:1. Ethnicity:
Further population details	
Extra comments	597 (43%) had moderate sedation, 401 (29%) had deep sedation, the rest had light sedation. Most senior doctor: consultant or equivalent: 399 patients, other grades: 1003 patients. 96% underwent orthopaedic procedures
Indirectness of population	Serious indirectness: Some children included in the study. The total number of children was not reported however there were 144 patients <20 years of age
Interventions	(n=1402) Intervention 1: Anaesthetic technique - Conscious sedation. PSA was delivered in one of the resuscitation rooms with at least two doctors and one nurse present. All patients received supplemental oxygen. Drugs used for sedation: no propofol or midazolam: 82 patients, propofol: 307 patients, midazolam: 982 patients, propofol and midazolam: 29 patients, not known: 2 patients. Most senior doctor present: consultant or equivalent: 399 patients, other grades: 1003.Maximum sedation score: 1–3: 875 patients, 4 (deep): 370 patients, 5 (unresponsive): 31 patients, Unknown: 126 patients. Duration. Concurrent medication/care: New doctors to the department must initially deliver sedation under direct senior supervision until judged competent. At the time of the study there was no formal assessment of competence. Only doctors who had completed an approved anaesthetic placement could use propofol, etomidate or ketamine. Otherwise, no restrictions were placed on the choice of drugs.
Funding	No funding (No competing interests)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY

Protocol outcome 1: Cardiac arrest
- Actual outcome: Cardiac arrest; Group 1: 0/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Laryngospasm/respiratory depression
- Actual outcome: Laryngospasm; Group 1: 3/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Bronchospasm; Group 1: 2/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Cardiac arrhythmias - Actual outcome: Arrhythmia; Group 1: 3/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Aspiration of gastric contents - Actual outcome: Aspiration; Group 1: 0/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: Compromised airway/respiration - Actual outcome: reversal agent used; Group 1: 22/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 6: Other serious adverse event - Actual outcome: Oversedation; Group 1: 4/1402, Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Death; Quality of life; Nerve damage; Methaemoglobinaemia; Convulsions/seizure

Table 35: Jakeman 2013[68]

Study	**Jakeman 2013[68]**
Study type	Case series
Number of studies (number of participants)	(n=416)
Countries and setting	Conducted in United Kingdom; Setting: Emergency department
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients over 16 years who were admitted to the emergency department with wrist trauma
Exclusion criteria	None detailed
Recruitment/selection of patients	Retrospective patient database review from April 2008 to June 2010
Age, gender and ethnicity	Age - Mean (SD): 65. Gender (M:F): 360/56. Ethnicity:
Further population details	

Extra comments	All procedures were orthopaedic
Indirectness of population	No indirectness
Interventions	(n=416) Intervention 1: Anaesthetic technique - IV regional anaesthesia. Bier's block: 0.5% plain lidocaine at a dose of 3 mg/kg, up to a maximum of 200 mg. Cuff pressure was 100 mmHg above systolic blood pressure. Duration. Concurrent medication/care: Patient had cardiac monitoring, pulse oximetry and BP monitoring throughout.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA [INTERVENTION 1] ONLY Protocol outcome 1: Death - Actual outcome: Death; Group 1: 0/416, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Cardiac arrhythmias - Actual outcome: Arrhythmia; Group 1: 0/416, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Convulsions/seizure - Actual outcome: Convulsions; Group 1: 0/416, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Other serious adverse event - Actual outcome: Cuff failure (asymptomatic); Group 1: 1/416, Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Nerve damage ; Aspiration of gastric contents; Compromised airway/respiration; Methaemoglobinaemia

Table 36: Newstead 2013[102]

Study	**Newstead 2013[102]**
Study type	Case series
Number of studies (number of participants)	(n=1008)
Countries and setting	Conducted in United Kingdom; Setting: Emergency department
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People requiring procedural sedation within the emergency department
Exclusion criteria	None detailed
Recruitment/selection of patients	Departmental sedation database. Records from December 2006 to March 2012. 77% of procedures were manipulation under anaesthesia.
Age, gender and ethnicity	Age - Mean (range): 58 (15–97). Gender (M:F): Not reported. Ethnicity:
Further population details	
Extra comments	Failed to retrieve the original sedation chart in 132 cases, either because the chart had not been completed, had not been scanned, or incorrect patient details had been recorded on the database. None of these patients had any adverse event recorded in the electronic database or in the clinical notes.
Indirectness of population	Serious indirectness: Children included in the study
Interventions	(n=1008) Intervention 1: Anaesthetic technique - Conscious sedation. Propofol was used under the direct observation of senior emergency physicians in whom advanced airway management was part of their training. Procedure: 1mg/kg IV of propofol as a bolus (though less for DC cardioversion procedures). Perform the procedure when patient unconscious i.e. not responding to command. Give incremental top ups of 0.25mg/kg of propofol prn. Gently ventilate if the patient remains apnoeic and O2 sats fall <94% until saturation reads >94%. Duration. Concurrent medication/care: The ASA's guideline on fasting requirements for elective surgery was used. Flexibility was allowed in clinically urgent cases (e.g. unstable patient requiring cardioversion, joint dislocation with neuropraxia) Patient's airway was routinely risk assessed. Risks and benefit of procedural sedation with propofol, versus other options, including minimal/moderate sedation with other agents (including 70% nitrous oxide) and general anaesthesia in theatre were considered. Those patients receiving propofol were continuously monitored with pulse oximetry, respiratory rate (via transthoracic impedance trace) and ECG, and non-invasive blood pressure is measured every 5 min. Nasal capnography was introduced in late 2011.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY

Protocol outcome 1: Compromised airway/respiration
- Actual outcome: Bag valve mask ventilation; Group 1: 32/1008, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Other serious adverse event

- Actual outcome: Hypotension; Group 1: 11/1008, Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Death; Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric contents; Methaemoglobinaemia; Convulsions/seizure

Table 37: Rodgers 2011[119] (Rodgers 2005[120])

Study (subsidiary papers)	**Rodgers 2011[119] (Rodgers 2005[120])**
Study type	Case series
Number of studies (number of participants)	(n=6209)
Countries and setting	Conducted in USA; Setting: Oral surgical practice
Line of therapy	1st line
Duration of study	--: Until discharge from oral surgical practice
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People undergoing procedural sedation for various oral surgical procedures
Exclusion criteria	None detailed
Recruitment/selection of patients	Medical files of people undergoing procedural sedation over a 14 year period
Age, gender and ethnicity	Age - Other: Not reported. Gender (M:F): Not reported. Ethnicity:
Further population details	
Extra comments	ASA class I: 2800 patients, ASA class II: 3319 patients, ASA class III: 90 patients, ASA class IV: 0 patients. Procedures included: extractions, impactions, dental implants, bone grafts, exposure and bonding of unerupted teeth, surgically assisted rapid palatal expansions, closed reduction of fractures, biopsies and treatment of pathologies.
Indirectness of population	Serious indirectness: Sedation administered by surgeon rather than emergency physician
Interventions	(n=6209) Intervention 1: Anaesthetic technique - Conscious sedation. Sedation was typically performed using midazolam and fentanyl. Other drugs used were propofol, methohexital, dexamethasone, diphenhydramine, and meperidine. Duration. Concurrent medication/care: Surgeon was a diplomate of the American Board of Oral and Maxillofacial Surgery and the National Dental Board of Anesthesia. All assistants were either licensed registered nurses or anaesthesia assistants. All patients were monitored with continuous pulse oximetry and ECG monitoring, as well as noninvasive blood pressure monitoring every 5 minutes.

Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY Protocol outcome 1: Death - Actual outcome: Death; Group 1: 0/6209, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 2: Cardiac arrest - Actual outcome: Cardiac arrest; Group 1: 0/6209, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 3: Cardiac arrhythmias - Actual outcome: Cardiac dysrhythmia; Group 1: 9/6209, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 4: Aspiration of gastric contents - Actual outcome: Aspiration of foreign body; Group 1: 0/6209, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 6: Convulsions/seizure - Actual outcome: Seizure; Group 1: 1/6209, Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Quality of life; Laryngospasm/respiratory depression; Nerve damage; Methaemoglobinaemia

Table 38: Sacchetti 2007[126] (Hogan 2006[58])

Study (subsidiary papers)	**Sacchetti 2007[126] (Hogan 2006[58])**
Study type	Case series
Number of studies (number of participants)	(n=1028 sedations on 980 patients)
Countries and setting	Conducted in USA; Setting: Multicentre study of 14 community emergency departments
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Emergency department patients for whom a sedation-related PI recording form was generated and the sedation for

	the procedure was directed by an emergency physician.
Exclusion criteria	Sedation to facilitate intubation or in intubated patients
Recruitment/selection of patients	Data from the ProSCED registry, an observational database comprised of consecutive EP-directed procedural sedation cases.
Age, gender and ethnicity	Age - Median (range): 31 (0–95). Gender (M:F): Not reported. Ethnicity:
Further population details	
Extra comments	Over 60% of procedures were orthopaedic. 719 (70%) ASA I, 267 (26%) ASA II, 42 (4%) ASA III or higher.
Indirectness of population	Serious indirectness: Children were included in the study, approximately 25% of data are from children. Sedations performed by emergency physicians but not necessarily within the ED
Interventions	(n=1028) Intervention 1: Anaesthetic technique - Conscious sedation. Procedural sedation. Breakdown of sedation drugs administered (number of patients and % of total): etomidate 241 (23%), fentanyl 253 (25%), hydromorphone 62 (6%), ketamine 145 (14%), meperidine 24 (2%), midazolam 423 (41%), morphine 104 (10%), pentobarbital 1 (0.1%), propofol 253 (25%), other 35 (3%). Duration. Concurrent medication/care: None detailed
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY

Protocol outcome 1: Death
- Actual outcome: Death; Group 1: 0/1028, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Compromised airway/respiration
- Actual outcome: Bag valve mask ventilation; Group 1: 5/1028, Risk of bias: Very high; Indirectness of outcome: Serious indirectness
- Actual outcome: Reversal agent used; Group 1: 4/1028, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 3: Convulsions/seizure
- Actual outcome: Seizure; Group 1: 0/1028, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 4: Other serious adverse event
- Actual outcome: Hypotension; Group 1: 1/1028, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcomes not reported by the study	Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric contents; Methaemoglobinaemia

Table 39: Taylor 2011[141]

Study	Taylor 2011[141]
Study type	Case series
Number of studies (number of participants)	(n=2623)
Countries and setting	Conducted in Australia; Setting: Multi-centre study in 11 emergency departments.
Line of therapy	1st line
Duration of study	Follow up (post intervention): Until hospital discharge
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adult and paediatric patients who received parenteral sedation for a procedure in the ED
Exclusion criteria	None detailed
Recruitment/selection of patients	Consecutive patients between January 2006 and December 2008. 50% of procedures were for either dislocated shoulder, fractured wrist, fractured ankle
Age, gender and ethnicity	Age - Median (IQR): 34 (20–60). Gender (M:F): 1306/840. Ethnicity:
Further population details	
Extra comments	Level of sedation using Observer's assessment of alertness/sedation (OAA/S) scale: level 1: 274 patients, level 2: 340 patients, level 3: 237 patients, level 4: 331 patients, level 5: 454 patients, level 6: 510 patients. The sedation-related events examined included respiratory events that required an intervention, vomiting, aspiration of stomach contents, hypotension (systolic BP <80 mmHg) or hypertension (systolic BP >180 mmHg), bradycardia (HR <60 /min) or tachycardia (HR >120 /min), and 'other' events. A respiratory event was defined as hypoventilation (<10 breaths/min) and/or oxygen desaturation (<90% mmHg) and/or an obstructed airway (partial/complete). Interventions for respiratory events included painful stimuli, chin lift or jaw thrust, insertion of an oro/nasopharyngeal airway, bag and mask ventilation, endotracheal intubation and the administration of flumazenil or naloxone.
Indirectness of population	Serious indirectness: Study included children
Interventions	(n=2146) Intervention 1: Anaesthetic technique - Conscious sedation. Sedation drug(s): propofol (1350 patients), midazolam (523 patients), fentanyl (642 patients), morphine (170 patients), nitrous oxide (184 patients), ketamine (354 patients) Person in charge of sedation: consultant (1259 patients), registrar (852 patients), resident (20 patients), other (15 patients). Duration. Concurrent medication/care: Pre-medication drug(s): morphine (711 patients), fentanyl (304 patients), anti-emetic (83 patients)

Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY Protocol outcome 1: Laryngospasm/respiratory depression - Actual outcome: Laryngospasm; Group 1: 2/2146, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 2: Aspiration of gastric contents - Actual outcome: Pulmonary aspiration at .; Group 1: 1/2146, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 3: Compromised airway/respiration - Actual outcome: Bag ventilation; Group 1: 66/2146, Risk of bias: Very high; Indirectness of outcome: Serious indirectness - Actual outcome: Reversal agents administered; Group 1: 15/2146, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 4: Convulsions/seizure - Actual outcome: Seizure; Group 1: 2/2146, Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Death; Quality of life; Cardiac arrest; Cardiac arrhythmias; Nerve damage; Methaemoglobinaemia

Table 40: Thamizhavell 1996[142]

Study	**Thamizhavell 1996[142]**
Study type	Case series
Number of studies (number of participants)	(n=915)
Countries and setting	Conducted in United Kingdom; Setting: Emergency department
Line of therapy	1st line
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients having various manipulative surgical procedures
Exclusion criteria	Patient cannot understand procedure, known hypersensitivity to local anaesthesia, peripheral vascular disease, sickle

	cell disease - were not given Bier's block
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Range: 17–92. Gender (M:F): Not reported. Ethnicity:
Further population details	
Indirectness of population	No indirectness
Interventions	(n=915) Intervention 1: Anaesthetic technique - IV regional anaesthesia. Bier's block: weight related dose of 0.5% prilocaine, not exceeding 40 ml. Upper cuff inflated to 100 mmHg above SBP. After 7 minutes, lower cuff is inflated and upper cuff deflated. Tourniquet is not deflated until for at least 20 minutes after injection. Duration. Concurrent medication/care: ECg and pulse oximetry monitored during the procedure
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IV REGIONAL ANAESTHESIA [INTERVENTION 1] ONLY Protocol outcome 1: Death - Actual outcome: Death; Group 1: 0/915, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Convulsions/seizure - Actual outcome: Seizure at .; Group 1: 1/915, Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Cardiac arrest; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric contents; Compromised airway/respiration; Methaemoglobinaemia; Other serious adverse event

Table 41: Vinson 2013[146]

Study	**Vinson 2013[146]**
Study type	Case series
Number of studies (number of participants)	(n=442)
Countries and setting	Conducted in USA; Setting: Multicentre: 3 suburban community hospital emergency departments
Line of therapy	1st line
Duration of study	Follow up (post intervention): Until hospital discharge
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall

Subgroup analysis within study	Not applicable
Inclusion criteria	ED patients who received procedural sedation for reduction of one of the following four orthopaedic diagnoses: shoulder dislocation, elbow dislocation, hip dislocation, and forearm fracture
Exclusion criteria	The ED patients who underwent their sedation-assisted orthopaedic procedure without resident assistance during the study period constitute the study population. Cases that required immediate operative reduction without intervening ED sedation were not included.
Recruitment/selection of patients	18-month retrospective health records review between November 2007 and April 2009. Consecutive patients.
Age, gender and ethnicity	Age - Median (IQR): Shoulder reduction group: 32 (19–58), elbow reduction group 21 (16–36), hip reduction group 75 (65–83), forearm reduction group 12 (7–32). Gender (M:F): 257/185. Ethnicity:
Further population details	
Extra comments	ASA physical status classification system: class I: 172, class II: 69, class III: 5 (some data missing). Most reductions carried out using 1 physician, 1 nurse model. All procedures were orthopaedic
Indirectness of population	Serious indirectness: Children were included in this study
Interventions	(n=457) Intervention 1: Anaesthetic technique - Conscious sedation. Carried out by an emergency physician and emergency nurse specifically trained and certified in procedural sedation. The choice and dose of sedative, as well as the use of adjunct medications, were at the physician's discretion. Supplemental oxygen was administered, intravenous access secured. Continuous cardiac and transcutaneous oxygen saturation were in place throughout the procedure until complete recovery monitoring had been achieved. Blood pressure, pulse rate, respiratory rate, cardiac rhythm, oxygen saturation and level of consciousness were measured and documented serially a minimum of every 5 minutes during the procedure, then after the procedure every 15 minutes, for at least 30 minutes, or until vital signs stabilised near pre-sedation levels. Duration. Concurrent medication/care: The emergency physician conducted a history and physical examination, including an airway assessment and an ASA score, prior to the procedure to determine the patient's eligibility for ED procedural sedation.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: CONSCIOUS SEDATION [INTERVENTION 1] ONLY

Protocol outcome 1: Death
- Actual outcome: Death; Group 1: 0/457, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Cardiac arrest
- Actual outcome: Cardiopulmonary arrests; Group 1: 0/457, Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 3: Compromised airway/respiration - Actual outcome: Reversal agents administered; Group 1: 1/457, Risk of bias: Very high; Indirectness of outcome: Serious indirectness - Actual outcome: Endotracheal intubation; Group 1: 0/457, Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 4: Other serious adverse event - Actual outcome: Hypotension; Group 1: 2/457, Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Quality of life; Laryngospasm/respiratory depression; Cardiac arrhythmias; Nerve damage; Aspiration of gastric contents; Methaemoglobinaemia; Convulsions/seizure

G.3.2 Treatment of torus fractures

Table 42: Karimi 2012[78]

Study	Karimi 2012[78]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=142)
Countries and setting	Conducted in Iran; Setting: Orthopaedic clinic of a provincial hospital in Iran
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Method of assessment/diagnosis not stated: It was stated that the participants were 'recognised distal forearm torus fracture patients'
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	distal forearm torus fracture
Exclusion criteria	None stated
Recruitment/selection of patients	All those with the diagnosis were approached (and enrolled)
Age, gender and ethnicity	Age - Mean (SD): 9.5(1.9). Gender (M:F): 103:39. Ethnicity: Iran
Sub-group categorisation	Age: 2–15 (range was 1.2 to 17 but vast majority were in the 2–15 group)
Indirectness of population	No indirectness

Study	Karimi 2012[78]
Interventions	(n=77) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). short arm cast. Duration 3 weeks. Concurrent medication/care: No details given (n=65) Intervention 2: Removable splint. Removable wrist splint. Duration 3 weeks. Concurrent medication/care: No details given
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus REMOVABLE SPLINT AEs - Skin problems skin rash at 3 weeks (but unclear); Rigid cast: 0/73, Removable splint: 11/64; Risk of bias: Very high; Indirectness of outcome: No indirectness edema at 3 weeks (but unclear); Rigid cast: 5/73, Removable splint: 0/64; Risk of bias: Very high; Indirectness of outcome: No indirectness Pain or discomfort mild to moderate pain with activity at 3 weeks (but unclear); Rigid cast: 24/73, Removable splint: 28/64; Risk of bias: Very high; Indirectness of outcome: No indirectness Patient experience proportion finding treatment convenient at 3 weeks (but unclear); Rigid cast: 66/73, Removable splint: 58/64; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; return to normal activities; AEs – re-fracture; Number of outpatient visits; need to change cast; Length of stay

Table 43: Khan 2007[80]

Study	Khan 2007[80]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=117)
Countries and setting	Conducted in Irish Republic; Setting: A&E department in Children's hospital in Dublin
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: AP and lateral X-rays

Study	Khan 2007[80]
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	X-ray-diagnosed buckle fractures of the distal radius
Exclusion criteria	None given
Recruitment/selection of patients	Unclear
Age, gender and ethnicity	Age - Mean (range): 5 (2–12). Gender (M:F): 68:49. Ethnicity: Irish
Subgroup categorisation	Age: 2–15 (range 2–12) so comfortably in this sub-group
Indirectness of population	No indirectness
Interventions	(n=48) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). Rigid cast. Duration 3 weeks. Concurrent medication/care: No details given (n=69) Intervention 2: Softcast. Soft Cast. Duration 3 weeks. Concurrent medication/care: No details given
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus SOFTCAST Patient experience Actual outcome: Parental 'problems' with the casts at 3 weeks (but unclear); Rigid cast: 5/48, Soft-cast: 1/69; Risk of bias: Very high; Indirectness of outcome: No indirectness Actual outcome: Proportion of parents who would choose that treatment in future at 3 weeks (but unclear); Rigid cast: 3/48, Soft-cast: 68/69; Risk of bias: Very high; Indirectness of outcome: No indirectness Adverse events 'cast complications' at 3 weeks (but unclear); Rigid cast: 5/48, Soft-cast: 1/69; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; AEs - skin problems; pain or discomfort; return to normal activities; AEs – re-fracture; Number of outpatient visits; need to change cast; Length of stay

Table 44: Oakley 2008[106]

Study	Oakley 2008[106]
Study type	RCT (randomised; Parallel)

Study	Oakley 2008[106]
Number of studies (number of participants)	1 (n=42)
Countries and setting	Conducted in Australia; Setting: Emergency department of a large urban children's hospital
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Age up to 18 years; torus fracture
Exclusion criteria	Other injuries to upper limb or other serious injury
Recruitment/selection of patients	Consecutive patients with inclusion criteria
Age, gender and ethnicity	Age - Other: Not given. Gender (M:F): Not given. Ethnicity: Unclear
Subgroup categorisation	Age: 2–15 (Likely majority would be in this category given inclusion criterion)
Indirectness of population	No indirectness
Interventions	(n=47) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). below-elbow POP cast. Duration 2 weeks. Concurrent medication/care: All patients placed in a broad arm sling and given information on home care of the plaster (n=48) Intervention 2: Removable splint. Dynacast Prelude Volar slab, attached by bandage and removable. Duration 2 weeks. Concurrent medication/care: All patients were placed in a broad arm sling and given information on home care of the slab
Funding	Other (Some donation from a cast company)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus REMOVABLE SPLINT Pain or discomfort median (IQR) of daily dairy pain scores(VAS) for those with score >50 at baseline at 2 weeks; Rigid cast: 40 (25–50), n=19, Removable splint: 40(20–60), n=24; Risk of bias: High; Indirectness of outcome: No indirectness median (IQR) of daily dairy pain scores(VAS) for those with score < or =50 at baseline at 2 weeks; Rigid cast: 30 (10–30), n=23, Removable splint: 20(10–40), n=18; Risk of bias: High; Indirectness of outcome: No indirectness median (IQR) duration of pain for those with score >50 at baseline at 2 weeks; Rigid cast: 5 (2–11), n=19, Removable splint: 8(5–11), n=24; Risk of bias: High; Indirectness of outcome: No indirectness	

Study	Oakley 2008[106]
median (IQR) duration of pain for those with score < or =50 at baseline at 2 weeks; Rigid cast: 2 (1–4), n=23, Removable splint: 2 (1–5), n=18; Risk of bias: High; Indirectness of outcome: No indirectness Patient experience proportion who would continue same form of immobilisation at 2 weeks; Rigid cast: 30/42, Removable splint: 31/42; Risk of bias: High; Indirectness of outcome: No indirectness Return to normal activities proportion resuming normal activities at 2 weeks; Rigid cast: 40/42, Removable splint: 28/42; Risk of bias: High; Indirectness of outcome: No indirectness Need to change cast Need for re-immobilisation at 2 weeks; Rigid cast: 3/42, Removable splint: 6/42; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; AEs - skin problems; AEs – re-fracture; Number of outpatient visits; Length of stay

Table 45: Plint 2006[113]

Study	Plint 2006[113]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=113)
Countries and setting	Conducted in Canada; Setting: Academic tertiary care children's hospital in Ontario, Canada
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 6–15; buckle fracture of radius or ulna
Exclusion criteria	Other fractures requiring immobilisation in the same limb; bilateral fractures; metabolic bone disease
Recruitment/selection of patients	Consecutive

Age, gender and ethnicity	Age - Range of means: 9.5 to 9.9. Gender (M:F): 57:30. Ethnicity: Unclear
Sub-grouping categorisation	Age: 2–15
Indirectness of population	No indirectness
Interventions	(n=56) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). short arm cast. Duration 3 weeks. Concurrent medication/care: Patients given usual cast-care instructions about keeping it dry, etc. All told to avoid contact sports. (n=57) Intervention 2: Removable splint. individually fitted plaster splint (composed of 12 plaster layers) fitted with tensor bandage. Duration 3 weeks. Concurrent medication/care: Patients told to use the splint for comfort only, to remove as desired for activities, and to discontinue completely when desired. All told to avoid contact sports.
Funding	Academic or government funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus REMOVABLE SPLINT Pain or discomfort median (IQR) VAS pain score at 4 weeks; Rigid cast: 0 (0–0.5); n=25, Removable splint: 0 (0–0); n=18, Risk of bias: Very high; Indirectness of outcome: No indirectness Patient experience Proportion who would have same treatment in future at 4 weeks; Rigid cast: 5/23, Removable splint: 20/21; Risk of bias: Very high; Indirectness of outcome: No indirectness AEs – re-fracture re-fracture at 4 weeks; Rigid cast: 0/45, Removable splint: 0/42; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; AEs - skin problems; return to normal activities; Number of outpatient visits; need to change cast; Length of stay

Table 46: West 2005[151]

Study	**West 2005[151]**
Study type	RCT (randomised; Parallel)

Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in United Kingdom; Setting: A&E department in Wales
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Define
Exclusion criteria	Define
Recruitment/selection of patients	Unclear
Age, gender and ethnicity	Age - Other: categorical: 1 <5 years; 26 5–10years; 12 >10 years. Gender (M:F): Define. Ethnicity: Unclear
Subgrouping category	Age: 2–15 (Majority were in this range)
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). plaster cast. Duration 4 weeks. Concurrent medication/care: Initially placed in a below-elbow back-slab cast (n=19) Intervention 2: Bandaging. Orthopaedic wool applied, covered with a layer of ordinary commercial cotton crepe bandage, held with tape. Duration 4 weeks. Concurrent medication/care: None
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus BANDAGING

Pain or discomfort
Existence of pain at 4 weeks; Rigid cast: 15/21, Bandaging: 4/18; Risk of bias: Very high; Indirectness of outcome: No indirectness
Existence of pain lasting for 2 or more days at 4 weeks; Rigid cast: 15/21, Bandaging: 1/18; Risk of bias: Very high; Indirectness of outcome: No indirectness

Patient experience Proportion of patients finding the treatment convenient at 4 weeks; Rigid cast: 3/21, Bandaging: 17/18; Risk of bias: Very high; Indirectness of outcome: No indirectness Proportion of patients with discomfort during treatment at 4 weeks; Rigid cast: 12/21, Bandaging: 1/18; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; AEs - skin problems; return to normal activities; AEs – re-fracture; Number of outpatient visits; need to change cast; Length of stay

Table 47: Williams 2013[154]

Study	**Williams 2013[154]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=84)
Countries and setting	Conducted in USA; Setting: Emergency department of an academic tertiary care paediatric hospital in USA
Line of therapy	1st line
Duration of study	Follow up (post intervention): 3 weeks follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Radiographically confirmed
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 2–17; radiographically confirmed distal radial torus fractures
Exclusion criteria	Skeletal maturity; previous torus #s; concurrent other fractures except ipsilateral ulnar torus #; osteogenesis imperfecta; other metabolic bone diseases
Recruitment/selection of patients	Not clear
Age, gender and ethnicity	Age - Other: range of medians: 9–9.5. Gender (M:F): 51:43. Ethnicity: 52.5% white
Subgroup categorisation	Age: 2–15 (very few aged 16 but vast majority 2–15 years)
Indirectness of population	No indirectness: All direct evidence
Interventions	(n=51) Intervention 1: Rigid non removal cast (fibreglass or POP) - Rigid non removable cast (fibreglass or POP). Short arm cast. Application of the cast performed or supervised by an attending physician or paediatric

	emergency medicine fellow in the paediatric ED. All casts were constructed of fibreglass with protective layers of stockingette underneath. Duration 3 weeks. Concurrent medication/care: patients were given advice on how to care for the cast, including keeping it dry. (n=43) Intervention 2: Removable splint. Volar removable wrist splint. This was a prefabricated cock-up wrist splint with a Velcro closure system available in various sizes for both right and left hands. Duration 3 weeks. Concurrent medication/care: Patients were advised to wear the splint as much as possible, but that it was normal to remove the splint more frequently as pain improved.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RIGID NON REMOVABLE CAST (FIBREGLASS OR POP) versus REMOVABLE SPLINT Pain or discomfort median pain immediately after application; Rigid cast: 0, Removable splint:3 ;Risk of bias: High; Indirectness of outcome: No indirectness median pain at 3 days; Rigid cast: 1.5, Removable splint:3.5 ; Risk of bias: High; Indirectness of outcome: No indirectness median pain at 7 days; Rigid cast: 1, Removable splint:2.5 ; Risk of bias: High; Indirectness of outcome: No indirectness median pain at 21days; Rigid cast: 0, Removable splint:1 ; Risk of bias: High; Indirectness of outcome: No indirectness Patient experience parental preference to use same method in future immediately; Rigid cast: 39/51, Removable splint: 41/43; Risk of bias: High; Indirectness of outcome: No indirectness parental preference to use same method in future at 3 days; Rigid cast: 28/51, Removable splint: 36/43; Risk of bias: High; Indirectness of outcome: No indirectness parental preference to use same method in future at 7 days; Rigid cast: 33/51, Removable splint: 36/43; Risk of bias: High; Indirectness of outcome: No indirectness parental preference to use same method in future at 21 days; Rigid cast: 25/51, Removable splint: 36/43; Risk of bias: High; Indirectness of outcome: No indirectness Median perception of convenience at 1 day after application; Rigid cast: 6, Removable splint:9 ; Risk of bias: High; Indirectness of outcome: No indirectness Median perception of convenience at 3 days; Rigid cast: 5, Removable splint:8.5 ; Risk of bias: High; Indirectness of outcome: No indirectness Median perception of convenience at 7 days; Rigid cast: 6, Removable splint:9 ; Risk of bias: High; Indirectness of outcome: No indirectness Median perception of convenience at 21 days; Rigid cast: 3, Removable splint:9 ; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Hospitalisation; AEs - skin problems; return to normal activities; AEs – re-fracture; Number of outpatient visits; need to change cast; Length of stay

G.3.3 Referral for ongoing management from the emergency department

G.3.3.1 Referral pathway decision-makers (MDT)

Table 48: East 2014[36]

Study	East 2014[36]
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=101)
Countries and setting	Conducted in Irish Republic; Setting: A&E
Line of therapy	1st line
Duration of study	Intervention + follow up: Until first fracture clinic appointment
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients referred from an A&E to orthopaedic fracture clinics
Exclusion criteria	None detailed
Recruitment/selection of patients	Retrospective chart review. Consecutive patients between September 2012 and October 2012
Age, gender and ethnicity	Age - Other: Unknown. Gender (M:F): Unknown. Ethnicity:
Further population details	1. Diagnosis: Not applicable / Not stated / Unclear
Extra comments	Injuries of false positive referrals: metatarsal fracture: 5, soft tissue elbow: 3, radial fracture: 3, metacarpal fracture: 3, scaphoid fracture: 1, acromioclavicular sprain: 1, ankle sprain: 1, achilles sprain: 1, clavicle fracture: 1, wrist sprain: 1. . Injury by anatomical site: metacarpal fracture: 14, radial fracture: 12, clavical fracture: 11, humerus fracture: 10, metatarsal fracture: 7, scaphoid fracture: 5, shoulder dislocation: 5, fibula fracture: 4, vertebrae fracture: 3, ankle sprain: 3, ulna fracture: 2, acromioclavicular sprain: 2.
Indirectness of population	No indirectness
Interventions	(n=6) Intervention 1: Decision-makers - ED consultant. Consultant. (n=56) Intervention 2: Decision-makers - Registrar. Registrar. (n=16) Intervention 3: Decision-makers - Junior doctor or SHO. SHO.

	(n=10) Intervention 4: Decision-makers - Nurse. Clinical nurse specialist.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ED CONSULTANT versus REGISTRAR

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic at .; Group 1: 1/6, Group 2: 10/56; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ED CONSULTANT versus JUNIOR DOCTOR OR SHO

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic at .; Group 1: 1/6, Group 2: 1/16; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ED CONSULTANT versus NURSE

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic at .; Group 1: 1/6, Group 2: 4/10; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: REGISTRAR versus JUNIOR DOCTOR OR SHO

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic; Group 1: 10/56, Group 2: 1/16; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: REGISTRAR versus NURSE

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic; Group 1: 10/56, Group 2: 4/10; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: JUNIOR DOCTOR OR SHO versus NURSE

Protocol outcome 1: Unnecessary attendances at a clinic
- Actual outcome: No intervention after first attendance at fracture clinic at .; Group 1: 1/16, Group 2: 4/10; Risk of bias: Very high; Indirectness of outcome: No indirectness

Level of referring health professional				Number of referrals	Incorrect referrals	PPV
Consultant	6	1	83%			
Registrar	56	10	82%			
SHO	16	1	94%			
Clinical nurse specialist	10	4	60%			
Undocumented	20	3	85%			

Protocol outcomes not reported by the study	Quality of life ; Time to definitive management plan ; Patients recalled for change in management ; Number of referrals to a specialist clinic ; Patient satisfaction ; Other measure of efficiency of management plan process

Table 49: Snaith 2014[136,136]

Study	**Snaith 2014[136,136]**
Study type	Observational data drawn from a larger RCT
Number of studies (number of participants)	(n=598)
Countries and setting	Conducted in the UK; Setting: A&E
Line of therapy	1st line
Duration of study	Intervention + follow up: Until discharge from A&E
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients discharged from A&E who were imaged

Exclusion criteria	None detailed
Age, gender and ethnicity	Age - Other: Unknown. Gender (M:F): Unknown. Ethnicity:
Indirectness of population	No indirectness
Interventions	(n=254) Intervention 1: Decision-makers - Nurse. ENP (n=80) Intervention 2: Decision-makers - Junior doctor or SHO. Junior doctor (n=220) Intervention 3: Decision-makers - ED consultant. Senior doctor (n=44) Intervention 4: Decision-makers - ED consultant. ED consultant
Funding	NIHR funding

Level of referring health professional	Discharges total	Specialist referrals	% specialist referrals
ENP	234	103	44%
Junior doctor	70	24	34%
Senior doctor	200	73	37%
Consultant	42	15	36%

Protocol outcomes not reported by the study	Quality of life; Time to definitive management plan; Patients recalled for change in management ; Number of referrals to a specialist clinic ; Patient satisfaction ; Other measure of efficiency of management plan process

G.3.3.2 Referral to virtual clinics versus face to face clinics

Table 50: Jenkins 2014[72]

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
Jenkins, PJ et al. The Glasgow Fracture Pathway: a virtual clinic.	Historical Cohort study	598	This paper looked at a wide sample of 6285 people with fractures, who	A new virtual clinic protocol was set up, whereby two components existed.	Standard face to face fracture clinics, which existed prior to the setting up of the virtual clinic	Unclear	Number of appointments per patient	Face to face: 1.76 Virtual clinics: 0.32	None.	Risk of bias: Very serious for both outcomes as no information
							Subsequent open reduction and	Face to face versus virtual: OR 0.72 (0.17-		

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
BJJ news 2014; 22-24			were either given direct ED discharge or a virtual fracture clinic review. The analysis of most of these data was not compared to standard fracture clinics. For example, data on patient satisfaction with the virtual clinic strategy were collected, but there was no comparison with people on a traditional face to face clinic regime. There was, however, a short report within the paper of a	1. patients with simple self-limiting stable fractures (5th meta-tarsal, 5th meta-carpal, distal radius, torus, minor radial head/elbow fat pad sign, mallet finger, child's clavicle) were given structured verbal advice and an information leaflet at their original ED presentation and not automatically followed up (ED direct discharge). This was backed up by telephone support staffed by the orthopaedic department during working hours and the the Ed at other times. 2. Patients with	protocol.		internal fixation for non-union:	3.07)		allowing any assessment of selection, performance, attrition or detection bias. The available data only exists for a sub-set of people who had ED direct discharge, not virtual fracture clinics.

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
			comparison done between virtual clinics and traditional face to face clinics for people with fractures of the fifth metatarsal. No patient characteristics are given.	other fractures not requiring immediate admission were referred to the virtual fracture clinic. This is a regular multidisciplinary meeting, led by an orthopaedic consultant, where the history, examination and ED radiographs are reviewed. The resulting management plan is outlined and agreed with the patient by telephone immediately afterwards. This can lead to telephone advice along with discharge from follow up, review in a nurse-led clinic or r**eview in a sub-specialty**						

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
				clinic Patients with simple						

Table 51: Beiri 2006[16,16]

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
Beiri et al. Trauma rapid review process: efficient out-patient fracture management. Trauma and Orthopaedics 2006; 88: 408-411	Historical cohort study.	N=1364 (797 in intervention and 567 in comparator group) Inclusion: all patients at Leicester Royal Infirmary with musculoskeletal	No details given	Consultant review process at LRI for 4 weeks in May 2004. X rays and notes of all patients with MSK injury reviewed in the rapid review process by the on-call consultant surgeon the following morning. During this meeting decisions were made whether	Routine out-patient fracture clinics over a 2 week period in September 2004 at the same hospital.	Not clear	Average time in minutes to review a patient [mean(range)]	Ix: 1(0.42 – 1.86) Comp: 11 (8.2-14.1)	None reported	Risk of bias: Very serious for all outcomes as all had unadjusted selection bias, there was potential attrition bias from incomplete data and there was no assessor

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
		injuries and all sources of referrals (ie A&E, GP, other hospital, in-patients). Exclusion: Not reported.		the patient is referred to a routine outpatient fracture clinic, nurse led fracture clinic, recalled for further review or change of management or discharged back to GP care. Nurse-led # clinics review patients who have injuries that would be expected to require one follow-up appointment and be discharged. The reviewing consultant specifies the time interval for when patients are to be seen in an out-patient fracture clinic or nurse-led clinic. Clerical staff in the fracture clinic						blinding. Other outcomes (ie recall of patients) were reported, but only for the intervention group.

Reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect sizes	Source of funding	Comments
				send out appointments to patients via mail the same day the case notes are reviewed by the orthopaedic surgeon on-call.						

G.4 On-going management

G.4.1 Timing of surgery – ankle fractures

Table 52: Breederveld 1988[22]

Study	Breederveld 1988[22]
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=92)
Countries and setting	Conducted in Netherlands; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable

Inclusion criteria	Patients admitted between January 1983 and December 1984 with a unilateral fracture requiring surgery. Weber C, Weber C, bimalleolar, trimalleolar and medial malleolus fractures were included.
Exclusion criteria	None specified
Recruitment/selection of patients	All patients admitted to the participating hospital during the study
Age, gender and ethnicity	Age - Range of means: Mean in group 1 = 39 years; Mean in group 2 = 44. Gender (M:F): 49 male; 43 women. Ethnicity: not reported
Further population details	
Indirectness of population	Serious indirectness: Population includes unknown number of patients who have experienced an open ankle fracture
Interventions	(n=72) Intervention 1: Ankle surgery - </= 24 hours. Open reduction and internal fixation following the principles of AO/ASIE within 24 hours of admission. Duration Unclear. Concurrent medication/care: All ruptured ligaments were sutured. Post-operatively, the ankle was elevated and immobilised in a splint for 5 days. If the fracture was considered stable after operation, the ankle was mobilised. Full weight bearing began 5–7 weeks after operation. When the fracture was considered to be too unstable for partial weight bearing, the ankle was immobilised in a short leg plaster cast for minimum 6 weeks in the case of a unimalleolar fracture and 8-weeks in the case of a bimalleolar fracture. Follow-up at 6–8 weeks sometimes led to longer immobilisation. The ankle joint was also immobilised in cases of ligamentous rupture or those with trimalleolar fracture without fixation of the posterior fragment. Further details: 1. Time of admission: Not applicable / Not stated / Unclear (Not stated). (n=20) Intervention 2: Ankle surgery - 2–7 days post injury. Open reduction and internal fixation following the principles of AO/ASIE 5–8 days following admission. Duration Unclear. Concurrent medication/care: All ruptured ligaments were sutured. Post-operatively, the ankle was elevated and immobilised in a splint for 5 days. If the fracture was considered stable after operation, the ankle was mobilised. Full weight bearing began 5–7 weeks after operation. When the fracture was considered to be too unstable for partial weight bearing, the ankle was immobilised in a short leg plaster cast for minimum 6-weeks in the case of a unimalleolar fracture and 8-weeks in the case of a bimalleolar fracture. Follow-up at 6–8 weeks sometimes led to longer immobilisation. The ankle joint was also immobilised in cases of ligamentous rupture or those with trimalleolar fracture without fixation of the posterior fragment. Further details: 1. Time of admission: Not applicable/Not stated/Unclear (Not stated). Comments: The author was contacted to acquire details on the mean time to surgery in this group of patients, but due to the age of this study, the author was unable to access this data
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 24 HOURS versus 2–7 DAYS POST INJURY Protocol outcome 1: Length of stay - Actual outcome: Hospital length of stay at Until discharge; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - Wound infection - Actual outcome: Superficial wound infection at Until discharge; Group 1: 1/72, Group 2: 2/20; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Deep wound infection at Until discharge; Group 1: 2/72, Group 2: 0/20; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; AE - skin breakdown; Physiotherapy appointments

Table 53: Hoiness 2000[59]

Study	**Hoiness 2000[59]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=84)
Countries and setting	Conducted in Norway; Setting: Emergency department
Line of therapy	1st line
Duration of study	Intervention and follow up: Patient records examined up until 6-week follow-up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Radiographs re-examined by research team and incorrect diagnoses excluded (.61 kappa intra-observer agreement)
Stratum	Young people and adults (17 years and over): 18+ years
Subgroup analysis within study	Post-hoc subgroup analysis: Time of surgery (daytime, evening, weekend)
Inclusion criteria	Surgically treated ankle surgery for closed ankle fracture, admission within 8 hours
Exclusion criteria	Incorrect diagnosis, age <18 years, fractures of the tibial plafond, patient lost to 6-week follow-up, primary treatment in another hospital
Recruitment/selection of patients	Consecutive patients diagnosed with an ankle fracture at the participating hospital between 01/01/1995–31/12/1995.

	Patient records reviewed for inclusion criteria and available data
Age, gender and ethnicity	Age - Mean (SD): Early surgery = 52 (18.4); Delayed surgery 56.1 (14). Gender (M:F): 54 male, 30 female. Ethnicity: Not reported
Further population details	
Indirectness of population	No indirectness
Interventions	(n=67) Intervention 1: Ankle surgery - </= 24 hours. Ankle surgery within 8 hours of injury. Open reduction and internal fixation performed according to AO-principles. Duration 6 weeks. Concurrent medication/care: AO-ASIF-group recommendations followed. Severely dislocated fractures were reduced on admission. All fractures were immobilised in a plaster cast or in traction and elevation on a braun's frame until surgery. A tourniquet was used during surgery in most cases. Antibiotics (Cefalotin 2g) given intravenously, and 40mgs of low molecular heparin administered subcutaneously daily. After surgery, the ankle was immobilised in a semi-circular plaster cast for 2–3 days with the ankle in a neutral position and elevated on a Braun's frame. Careful movement and light weight bearing was then usually followed. Patients with unstable fixation were given an additional 6-week cast. All syndesmotic positioning screws were removed after 8–12 weeks. Further details: 1. Time of admission: Not applicable/Not stated/Unclear (n=17) Intervention 2: Ankle surgery - 8–13 days post injury. Surgery after a minimum of 5 days (mean = 8.2 days) due to a lack of capacity. Duration 6 weeks. Concurrent medication/care: AO-ASIF-group recommendations followed. Severely dislocated fractures were reduced on admission. All fractures were immobilised in a plaster cast or in traction and elevation on a braun's frame until surgery. A tourniquet was used during surgery in most cases. Antibiotics (Cefalotin 2g) given intravenously, and 40mgs of low molecular heparin administered subcutaneously daily. After surgery, the ankle was immobilised in a semi-circular plaster cast for 2–3 days with the ankle in a neutral position and elevated on a Braun's frame. Careful movement and light weight bearing was then usually followed. Patients with unstable fixation were given an additional 6-week cast. All syndesmotic positioning screws were removed after 8–12 weeks. Further details: 1. Time of admission: Not applicable/Not stated/Unclear
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 8 HOURS versus 8–13 DAYS POST INJURY

Protocol outcome 1: Length of stay
- Actual outcome for Young people and adults (17 years and over): Mean duration of inpatient stay at 6-weeks post-injury; Group 1: mean 7.2 days (SD 4.1); n=67, Group

2: mean 19.6 days (SD 10.3); n=17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - VTE - Actual outcome for Young people and adults (17 years and over): VTE at 6-weeks post-injury; Group 1: 0/67, Group 2: 0/67; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - Wound infection - Actual outcome for Young people and adults (17 years and over): Patients who developed at least one wound infection at 6-weeks post-injury; Group 1: 2/67, Group 2: 3/17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - skin breakdown - Actual outcome for Young people and adults (17 years and over): Patients who developed wound margin necrosis at 6-weeks post-injury; Group 1: 3/67, Group 2: 4/17; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; Physiotherapy appointments

Table 54: James 2001[70]

Study	**James 2001[70]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=87)
Countries and setting	Conducted in United Kingdom; Setting: ED
Line of therapy	1st line
Duration of study	Not clear: Retrospective review of patient records
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: No demographic data reported
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients admitted to participating hospital with a fractured ankle requiring surgery
Exclusion criteria	Ankle fractures managed conservatively, patients referred from other centres, open fractures, fractures where

	conservative treatment had failed, patients presenting >24 hours after injury
Recruitment/selection of patients	Consecutive patients admitted to the participating hospital between 01/01/1998–31/12/1998 meeting inclusion criteria
Age, gender and ethnicity	Age - Other: Not reported. Gender (M:F): No demographic data reported. Ethnicity: Not reported
Further population details	
Indirectness of population	No indirectness
Interventions	(n=47) Intervention 1: Ankle surgery - </= 24 hours. Surgery within 24 hours of injury. Duration Unclear. Concurrent medication/care: No details provided Further details: 1. Time of admission: (n=40) Intervention 2: Ankle surgery - 2–7 days post injury. Delayed surgery (mean = 5.5 days; median = 4, range 2–15). Duration Unclear. Concurrent medication/care: No details reported Further details: 1. Time of admission:
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 24 HOURS versus 2–7 DAYS POST INJURY Protocol outcome 1: Length of stay - Actual outcome: Mean inpatient stay at Unclear; Group 1: mean 7.1 days (SD not reported); Group 2: mean 10.6 days (SD not reported); p<.004; n=47; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; AE - VTE; AE - Wound infection; AE - skin breakdown; Physiotherapy appointments

Table 55: Konrath 1995[82]

Study	**Konrath 1995[82]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=202)
Countries and setting	Conducted in USA; Setting: ED

Line of therapy	1st line
Duration of study	Intervention and follow up: Last post-operative follow-up (range 2–38 months)
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: No age range reported
Subgroup analysis within study	Not applicable
Inclusion criteria	Define
Exclusion criteria	Define
Recruitment/selection of patients	Consecutive patients admitted to the participating hospital between 01/01/1991–01/01/1994 meeting inclusion criteria
Age, gender and ethnicity	Age - Other: Early surgery mean = 45 years; Delayed surgery mean = 43 years. Gender (M:F): Define. Ethnicity: Not reported
Further population details	
Indirectness of population	Serious indirectness: Does not stratify by age
Interventions	(n=105) Intervention 1: Ankle surgery - 24–48 hours post injury. Surgery <5 days post-injury (mean 1.5 days). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: (n=97) Intervention 2: Ankle surgery - >/= 14 days post injury. Surgery > 5 days post-injury (mean = 13.6 days; range 6–35 days). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission:
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: 24–48 HOURS POST INJURY versus >/= 14 DAYS POST INJURY

Protocol outcome 1: Length of stay
- Actual outcome: Median length of inpatient stay at final follow-up; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - Wound infection
- Actual outcome: Patients developing major wound complications (deep infection, osteomyelitis, or major wound dehiscence requiring soft-tissue coverage or

reoperation) at Until final follow-up; Group 1: 0/105, Group 2: 0/97; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Patients developing minor wound complications (stitch abscesses, superficial infections, minor wound breakdown) at Until final follow-up; Group 1: 5/105, Group 2: 6/97; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; AE - VTE; AE - skin breakdown; Physiotherapy appointments

Table 56: Manoukian 2013[90]

Study	**Manoukian 2013[90]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=98)
Countries and setting	Conducted in United Kingdom; Setting: In hospital
Line of therapy	1st line
Duration of study	Not clear:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: Children, young people and adults
Subgroup analysis within study	Not stratified but pre-specified
Inclusion criteria	Patients requiring operative fixation for an ankle fracture
Exclusion criteria	Patients treated non-operatively
Recruitment/selection of patients	All patients admitted to the participating hospital between 11 July 2010 and 13 September 2011 and meeting inclusion criteria
Age, gender and ethnicity	Age - Mean (range): 47.8 years (13–90). Gender (M:F): 51 male; 47 female. Ethnicity: Not reported
Further population details	
Indirectness of population	--
Interventions	(n=57) Intervention 1: Ankle surgery - </= 24 hours. Open fixation of ankle fracture within 24 hours post-admission.

	Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: Not applicable/Not stated/Unclear (Not stated). (n=41) Intervention 2: Ankle surgery - 2–7 days post injury. Open fixation of ankle fracture >24 hours post-admission (mean time to surgery = 3.7 days). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: (n=76) Intervention 3: Ankle surgery - </= 24 hours. Operative fixation <48 hours post-admission (mean time to surgery = 0.95 days). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: Not applicable/Not stated/Unclear (Not stated) (n=22) Intervention 4: Ankle surgery - 2–7 days post injury. Open fixation > 48 hours post-admission (mean time to surgery = 5.04 days). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission:
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 24 HOURS versus MEAN 3.7 DAYS Protocol outcome 1: Length of stay - Actual outcome: Hospital length of stay at until discharge; Group 1: mean 4.61 days (SD 6.93); n=57, Group 2: mean 8.1 days (SD 6.43); n=41; Risk of bias: Very high; Indirectness of outcome: No indirectness RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 48 HOURS versus 5 DAYS POST INJURY Protocol outcome 1: Length of stay - Actual outcome: Hospital length of stay at until discharge; Group 1: mean 4.61 days (SD 6.08); n=76, Group 2: mean 11.14 days (SD 7.35); n=22; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life at Define; Patient reported outcomes at Define; AE - VTE at Define; AE - Wound infection at Define; AE - skin breakdown at Define; Physiotherapy appointments at Define

Table 57: Saithna 2009[127]

Study	**Saithna 2009[127]**

Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=85)
Countries and setting	Conducted in United Kingdom; Setting: Trauma unit
Line of therapy	1st line
Duration of study	Intervention and follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (17 years and over): Age range 16.4–82.2 years
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients who underwent open reduction and internal fixation surgery for closed ankle fracture.
Exclusion criteria	Patients with an additional ipsilateral lower limb fracture. Patients with incomplete follow-up data
Recruitment/selection of patients	Retrospective review of records of consecutive patients admitted to the participating hospital meeting the inclusion criteria
Age, gender and ethnicity	Age - Mean (range): 46.6 years (16.4–82.2 years). Gender (M:F): Male = 33; Female = 52. Ethnicity: not reported
Further population details	
Extra comments	Five patients had a history of diabetes mellitus, but unknown proportion within each intervention group
Indirectness of population	No indirectness
Interventions	(n=56) Intervention 1: Ankle surgery - 24–48 hours post injury. Surgery within 6 days (mean time to surgery = 1.98 days). Duration unclear. Concurrent medication/care: No prophylactic antibiotics were administered prior to surgery Further details: 1. Time of admission: Not applicable/Not stated /Unclear (Not stated). (n=29) Intervention 2: Ankle surgery - 8–13 days post injury. Surgery >/= 6 days following injury (mean time to surgery = 9.46 days). Duration unclear. Concurrent medication/care: No prophylactic antibiotics were administered prior to surgery Further details: 1. Time of admission: Not applicable/Not stated/Unclear (not stated).
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: 24–48 HOURS POST INJURY versus 8–13 DAYS POST INJURY Protocol outcome 1: AE - Wound infection - Actual outcome for Young people and adults (17 years and over): Infection (superficial and deep) at unclear; Group 1: 2/56, Group 2: 6/29; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; Length of stay; AE - VTE; AE - skin breakdown; Physiotherapy appointments

Table 58: Schepers 2013[128]

Study	**Schepers 2013[128]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n= unclear, 205 ankle fractures)
Countries and setting	Conducted in Netherlands; Setting: Unclear
Line of therapy	1st line
Duration of study	Not clear:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Assessed by hospital clinicians
Stratum	Overall: No population demographics provided
Subgroup analysis within study	Not applicable
Inclusion criteria	Closed ankle fractures treated using plating of the fibula
Exclusion criteria	None stated
Recruitment/selection of patients	Consecutive patients admitted between Jan 2004 and December 2009 meeting inclusion criteria were included in the study
Age, gender and ethnicity	Age - Other: Not stated. Gender (M:F): Not stated. Ethnicity:
Further population details	
Indirectness of population	--

Interventions	(n=60) Intervention 1: Ankle surgery - 24–48 hours post injury. Surgery within 24 hours. Duration not stated. Concurrent medication/care: All patients received antibiotic prophylaxis (third generation cephalosporin). Tourniquets were used based on surgeon's preference Further details: 1. Time of admission: Not applicable/Not stated/Unclear Comments: Unclear if timeframe refers to time following injury or admission (n=98) Intervention 2: Ankle surgery - 2–7 days post injury. Surgery within 0–6 days. Duration not stated. Concurrent medication/care: All patients received antibiotic prophylaxis (third generation cephalosporin). Tourniquets were used based on surgeon's preference Further details: 1. Time of admission: Not applicable/Not stated/Unclear (Not stated). Comments: Unclear if timeframe refers to time following injury or admission (n=145) Intervention 3: Ankle surgery - 2–7 days post injury. Surgery within 1–11 days. Duration not stated. Concurrent medication/care: All patients received antibiotic prophylaxis (third generation cephalosporin). Tourniquets were used based on surgeon's preference Further details: 1. Time of admission: Not applicable/Not stated/Unclear (not stated). Comments: Unclear if timeframe refers to time following injury or admission (n=107) Intervention 4: Ankle surgery - 8–13 days post injury. Ankle surgery within 7–11 days. Duration not stated. Concurrent medication/care: All patients received antibiotic prophylaxis (third generation cephalosporin). Tourniquets were used based on surgeon's preference Further details: 1. Time of admission: Comments: Unclear if timeframe refers to time following injury or admission
Funding	--

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: <24 HOURS POST INJURY versus 1–11 DAYS POST INJURY

Protocol outcome 1: AE - Wound infection at Define
- Actual outcome: Minor infection complications (defined as requiring conservative management, e.g. oral antibiotics) at Unclear; Group 1: 0/60, Group 2: 10/145; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Major infection complications (defined as deep infection in need of re-admission or intervention, e.g. intravenous antibiotics, removal of hardware, wound debridement) at Unclear; Group 1: 0/60, Group 2: 6/145; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: 0–6 DAYS POST INJURY versus 7–11 DAYS POST INJURY

Protocol outcome 1: AE - Wound infection - Actual outcome: Minor infection complications (defined as requiring conservative management, e.g. oral antibiotics) at Unclear; Group 1: 0/98, Group 2: 10/107; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Major infection complications (defined as deep infection in need of re-admission or intervention, e.g. intravenous antibiotics, removal of hardware, wound debridement) at Unclear; Group 1: 2/98, Group 2: 4/107; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; Length of stay; AE - VTE; AE - skin breakdown; Physiotherapy appointments

Table 59: Singh 2005[134]

Study	**Singh 2005[134]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=62)
Countries and setting	Conducted in United Kingdom; Setting: ED
Line of therapy	1st line
Duration of study	Not clear:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Young people and adults (17 years and over): Adults (all skeletally mature)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients requiring ankle surgery and with complete documentation covering data and time of injury, pre- and post-operative radiographs, date and time of operation, follow-up wound data.
Exclusion criteria	Patients with fractures into the tibial plafond, those undergoing percutaneous fixation.
Recruitment/selection of patients	Consecutive patients undergoing open reduction and internal fixation for an ankle fracture admitted to the participating hospital between 01/01/2001–31/12/2001
Age, gender and ethnicity	Age - Mean (range): 45 years (19–90). Gender (M:F): 31 male, 31 female. Ethnicity: Not reported
Further population details	

Extra comments	Two patients with open fractures were included
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Ankle surgery - </= 24 hours. Surgery within 24 hours of injury. Duration Unclear. Concurrent medication/care: The majority of patients received peri-operative antibiotics intravenously, and a tourniquet applied during surgery. Post-operatively, all patients were immobilised in a below-knee plaster cast for 4–6 weeks and allowed non-weight bearing mobilisation Further details: 1. Time of admission: (n=40) Intervention 2: Ankle surgery - 2–7 days post injury. Surgery longer than 24 hours after injury (mean 3.1 days). Duration unclear. Concurrent medication/care: The majority of patients received peri-operative antibiotics intravenously, and a tourniquet applied during surgery. Post-operatively, all patients were immobilised in a below-knee plaster cast for 4–6 weeks and allowed non-weight bearing mobilisation Further details: 1. Time of admission:
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 24 HOURS versus 2–7 DAYS POST INJURY Protocol outcome 1: Length of stay - Actual outcome for Young people and adults (17 years and over): Mean length of inpatient stay at Unclear; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - Wound infection - Actual outcome for Young people and adults (17 years and over): Incidences of infection at Unclear; Group 1: 0/22, Group 2: 6/40; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - skin breakdown - Actual outcome for Young people and adults (17 years and over): Delayed wound healing at Unclear; Group 1: 1/22, Group 2: 2/40; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Young people and adults (17 years and over): Skin blisters at Unclear; Group 1: 2/22, Group 2: 0/40; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; AE - VTE; Physiotherapy appointments

Table 60: Westacott 2010[152]

Study	Westacott 2010[152]
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=71)
Countries and setting	Conducted in United Kingdom; Setting: ED department
Line of therapy	1st line
Duration of study	Intervention and follow up: up to 21 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: Children and adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients admitted to the ED of the participating hospital with an isolated, closed injury sustained on the day of presentation
Exclusion criteria	Patients who received conservative treatment, were referred from other centres, with delayed presentation, whose conservative treatment had failed, and patients with pilon or salter-harris type fractures.
Recruitment/selection of patients	All patients admitted to the ED between 01/01/2008–31/12/2008
Age, gender and ethnicity	Age - Range: 13–88 years. Gender (M:F): Not reported. Ethnicity: Not stated
Further population details	
Indirectness of population	No indirectness
Interventions	(n=38) Intervention 1: Ankle surgery - </= 24 hours. Surgery </= 24 hours following presentation at ED. Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: Mixed (Dedicated trauma theatre and orthopaedic physiotherapists available 7 days a week). (n=33) Intervention 2: Ankle surgery - 2–7 days post injury. Surgery between 28–151 hours after presentation at the ED (mean = 63 hours). Duration Not reported. Concurrent medication/care: Not reported Further details: 1. Time of admission: Mixed (Dedicated trauma theatre and orthopaedic physiotherapists available 7

	days a week).
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: </= 24 HOURS versus 2–7 DAYS POST INJURY Protocol outcome 1: Length of stay - Actual outcome: Number of days spent in an acute hospital bed after surgery at up to 21 days; Group 1: mean 3.7 days (SD 4.4); n=38, Group 2: mean 7.2 days (SD 8.8); n=33; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes; AE - VTE; AE - Wound infection; AE - skin breakdown; Physiotherapy appointments

G.4.2 Definitive treatment - distal radial fractures

Table 61: Abbaszadegan 1990[1]

Study	Abbaszadegan 1990[1]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=47)
Countries and setting	Conducted in Sweden
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Severely displaced (defined as >5 mm radial shortening) Colles' fractures, Older type III and IV
Exclusion criteria	Adults aged 75 or over, people with addictions, people with dementia, neuromuscular disorders, warfarin treatment
Recruitment/selection of patients	Consecutively recruited
Age, gender and ethnicity	Age - Mean (range): 63 (22–75). Gender (M:F): 11/36. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated /Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3 Children:

	Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: External fixation - Bridging ex-fix. Following initial closed reduction and temporary plaster cast immobilisation, external fixation with a Hoffmann device was carried out on the first to third day under regional intravenous anaesthetic. Two pairs of self-tapping 3 mm Hoffmann half-pins were inserted through a 1 cm incision through the second metacarpal and two in the radius. Duration 4 weeks. Concurrent medication/care: not reported (n=24) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction under local anaesthetic and below-elbow plaster cast applied. Duration 4 weeks. Concurrent medication/care: not reported
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain (VAS 0–10) at 1 year; Other: Median values (Cast = 1, ex-fix = 0) (p value 0.002); Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Lidstrom grade - fair or poor at 1 year; Group 1: 3/22, Group 2: 7/19; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin-site infection at 8 weeks; Group 1: 3/23, Group 2: 0/24; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Need for further surgery - Actual outcome for Adults (16+ years): Re-displacement (need for further procedure at 8 weeks; Group 1: 0/23, Group 2: 5/24; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 62: Abramo 2009[3] (Landgren 2011[85])

Study (subsidiary papers)	Abramo 2009[3] (Landgren 2011[85])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Sweden
Line of therapy	1st line
Duration of study	Intervention and follow up: 5 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 28–65, Frykman type I-VIII fracture impossible to reduce or retain in an acceptable position in cast after closed reduction, injury less than 10 days old, incongruence in RC or DRU joint and/or axial compression >2 mm and/or dorsal angulation >20 degrees
Exclusion criteria	Fracture volarly displaced, fracture in the contralateral side or other fracture in need of treatment, open fracture previous ipsilateral fracture, ongoing radiotherapy or chemotherapy, metabolic disease affecting the bone, medication affecting the bone, dementia, alcohol abuse or other psychiatric disorder
Recruitment/selection of patients	Patients recruited between May 2002 and December 2005
Age, gender and ethnicity	Age - Mean (range): 48 (20–65). Gender (M:F): 14/36. Ethnicity: not reported
Further population details	1. Adults: Adults aged 16–50 (Adults aged 18–65). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=24) Intervention 1: External fixation - Bridging ex-fix. Hoffman type1 bridging external fixator (Stryker, Hopkinton MA) used for first 20 consecutive patients. Radiolucent Wrist Fixator (OrthofixF, SRL, Bussolegno, Italy) used for the next four consecutive patients. Pins inserted into the second metacarpal and into the radius proximal to the fracture line. Duration 6 weeks. Concurrent medication/care: Supplemental Kirschner wires or percutaneous bone cement used at surgeon's discretion (n=26) Intervention 2: Internal fixation - Mixed methods of internal fixation. Two incisions made through the first and fourth extensor compartments. Fracture was reduced and two pins introduced at the tip of the radial styloid,

	obliquely in a proximal direction leaving the radial cortex ulnarly and proximally. Stabilizing pin-plate was threaded onto the styloid pins and the plate was secured to the radial side of the radius by 3–5 screws. Norian SRS (Synthese GmbH Switzerland) used at the surgeons discretion. Forearm plaster cast was applied and removed 2 weeks later. Duration Remained in situ. Concurrent medication/care: not reported
Funding	Academic or government funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus BRIDGING EX-FIX Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Bodily pain (SF36) at 1 year 3–7 years (mean follow-up = 5 years); Other: Median (range): Open = 84 (22–100); Closed = 100 (0–100) (p value 0.2); Risk of bias: Very high ; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Function - DASH score at 1 year; Group 1: mean 8.7 (SD 8.9); n=26, Group 2: mean 14 (SD 13); n=24; DASH 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - post traumatic osteoarthritis - Actual outcome for Adults (16+ years): Osteoarthritis at 3–7 years (mean follow-up = 5 years); Group 1: 2/26, Group 2: 4/24; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 1 year; Group 1: 1/26, Group 2: 2/24; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: AE - pin site infection - Actual outcome for Adults (16+ years): pin tract infection at 1 year; Group 1: 0/26, Group 2: 1/24; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 6: Need for further surgery - Actual outcome for Adults (16+ years): Re-operation due to malunion at 3–7 years (mean follow-up = 5 years); Group 1: 1/26, Group 2: 5/24; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Need for further surgery; Number of hospital attendances/bed days

Table 63: Arora 2011[10]

Study	Arora 2011[10]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=90)
Countries and setting	Conducted in Austria; Setting: Level 1 trauma centre
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years): Adults 65 years and over
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with displaced and unstable distal radius fractures. Detailed inclusion criteria were made available in supplementary material at the time of publication, but were no longer accessible. The lead author of the study was emailed, but did not reply
Exclusion criteria	As above
Recruitment/selection of patients	Patients aged 65 years or over treated at the participating institution were evaluated for eligibility for the study between 2005 and 2008. Those patients meeting inclusion criteria were invited to participate
Age, gender and ethnicity	Age: mean age = 76.7 years. Gender (M:F): 18 male/55 female. Ethnicity: Not reported
Further population details	1. Adults: Adults aged >70 (Adults aged >65 years (mean age = 76.7 years)). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra-articular and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults)
Indirectness of population	Serious indirectness: Full inclusion and exclusion criteria were not available
Interventions	(n=45) Intervention 1: Internal fixation - Volar/palmar plating. Volar fixed-angle plate placed on the volar radial cortex and fixed using image-controlled subchrondrial placement of interlocking screws. Surgery performed <14 days post-injury. Duration Surgery + 17 days immobilisation. Concurrent medication/care: Fracture reduction with an image intensifier. After surgery, the wrist was immobilised in a below the elbow splint. Active digital range of motion was started immediately. Ten days after surgery, the sutures were removed and the wrist placed in a removeable splint or another week. After that, patients received physiotherapy (n=45) Intervention 2: Conservative treatment - Plaster cast or splint. All wrists were immobilised in a short arm case

	in a neutral position for five weeks. Duration 5 weeks. Concurrent medication/care: No further reduction. Active digital motion was started immediately. After the case was removed, patients received physiotherapy
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus PLASTER CAST OR SPLINT Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain at rest at 12 weeks; Group 1: mean 0.2 (SD 0.7); n=36, Group 2: mean 0.3 (SD 0.8); n=37; VAS 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): Pain under stress at 12 weeks; Group 1: mean 1.4 (SD 2); n=36, Group 2: mean 1.8 (SD 2); n=37; VAS 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): PRWE at 12 months; Group 1: mean 12.8 (SD 23.2); n=36, Group 2: mean 14.6 (SD 22.8); n=37; PRWE 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 12 months; Group 1: 2/36, Group 2: 5/37; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 64: Azzopardi 2005[11]

Study	Azzopardi 2005[11]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=57)
Countries and setting	Conducted in Unknown
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Adults (16+ years):
Subgroup analysis within study	Not applicable
Inclusion criteria	Age >60 years , unstable dorsally angulated extra-articular fracture of the distal radial metaphysis (AO A3 or Frykman types I and II)
Exclusion criteria	Dementia, psychiatric illness, previous fractures of either wrist, intra-articular fractures, volar angulated fractures (Smith's fracture), open fractures and stable fractures with dorsal angulation <30 degrees and minimal dorsal comminution
Recruitment/selection of patients	Patients recruited between August 1997 and December 2000
Age, gender and ethnicity	Age - Mean (SD): Conservative treatment 71(9); percutaneous wiring 72(8). Gender (M:F): Define. Ethnicity: not reported
Further population details	1. Adults: Adults aged >70 (Adults >60). 2. Articular involvement: Extra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=27) Intervention 1: Conservative treatment - Plaster cast or splint. Short arm cast. Duration 5 weeks. Concurrent medication/care: following closed reduction under fluoroscopic guidance (n=30) Intervention 2: Percutaneous wiring - K-wires. Two crossed smooth Kirschner wires, one inserted through the styloid process of the radius and the other through the dorso-ulnar border of the distal fragment. Duration 5 weeks. Concurrent medication/care: Closed reduction under fluoroscopic guidance
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SHORT ARM PLASTER CAST versus K-WIRES

Protocol outcome 1: Quality of life
- Actual outcome for Adults (16+ years): SF-36 physical score at 1 year; Group 1: mean 38.2 (SD 11.2); n=27, Group 2: mean 42.2 (SD 9.7); n=27; SF-36 0–100 Top=High is good outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Patient outcomes - Pain
- Actual outcome for Adults (16+ years): Pain at 1 year; Group 1: mean 1.2 (SD 1.6); n=27, Group 2: mean 0.7 (SD 1.3); n=27; Visual analogue scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Patient outcomes - return to normal activities
- Actual outcome for Adults (16+ years): Activities of daily living (ADL) bilateral at 1 year; Group 1: mean 9.4 (SD 2.5); n=27, Group 2: mean 9.7 (SD 2.2); n=27; Risk of

bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): Pin track infection at 1 year; Group 1: 0/27, Group 2: 1/27; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: Need for further surgery - Actual outcome for Adults (16+ years): Need for re-manipulation and wire fixation at 1 year; Group 1: 1/27, Group 2: 0/27; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 65: Bahari-kashani 2012[12]

Study	**Bahari-kashani 2012[12]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=114)
Countries and setting	Conducted in Iran
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 40–60, Fernandez type III distal radial fracture
Exclusion criteria	Specific diseases including malignancy, upper limb vascular disorders, hyperparathyroidism, multiple trauma, osteoarthritis, rheumatoid arthritis; pathological fracture; open fracture; concomitant fracture of the carpal bones and distal ulna; history of ipsilateral distal radial fracture
Recruitment/selection of patients	Patients recruited between 2009 and 2011
Age, gender and ethnicity	Age - Median (IQR): Percutaneous pins 41.7 (1.7); locking plate 42.4 (2.5). Gender (M:F): 76/38. Ethnicity: not reported
Further population details	1. Adults: Adults aged 50–70 (Adults aged 40–60). 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness

Interventions	(n=57) Intervention 1: Percutaneous wiring - K-wires. pin and plaster fixation. Duration unclear. Concurrent medication/care: not detailed (n=57) Intervention 2: Internal fixation - Volar/palmar plating. Volar locking plate. Duration unclear. Concurrent medication/care: not reported
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus VOLAR/PALMAR PLATING Protocol outcome 1: Quality of life - Actual outcome for Adults (16+ years): SF-36 at 1 year; Group 1: mean 42.1 (SD 22.3); n=57, Group 2: mean 66.5 (SD 27.4); n=57; SF-36 0–100 Top=High is good outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain (SF-36 subscale) at 1 year; Group 1: mean 54.3 (SD 7.7); n=57, Group 2: mean 62.8 (SD 14.1); n=57; SF-36 1–100 Top=High is good outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Hand and wrist function - Actual outcome for Adults (16+ years): MAYO score at 1 year; Group 1: mean 60.7 (SD 11.3); n=57, Group 2: mean 75.2 (SD 19.5); n=57; MAYO scale 0–100 Top=High is good outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 1 year; Group 1: 1/57, Group 2: 0/57; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 66: Bartl 2014[15]

Study	**ORCHID trial: Bartl 2014[15]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=185)
Countries and setting	Conducted in Germany; Setting: Twelve trauma centres in Germany

Study	ORCHID trial: Bartl 2014[15]
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	aged >65; radiologically confirmed closed unstable intra-articular fracture of distal radius according to AO criteria (fracture types 23-C1 to C3).
Exclusion criteria	None specified
Recruitment/selection of patients	Not clear but appears to be consecutive
Age, gender and ethnicity	Age - Range of means: 75.3 and 74.4. Gender (M:F): 17/157. Ethnicity:
Further population details	1. Adults: Adults aged >70 2. Articular involvement: Intra-articular 3. Children: Not applicable / Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=94) Intervention 1: Internal fixation - Volar/palmar plating. Treated primarily or after soft tissue conditioning by open reduction with volar lockling plate fixation via the volar henry approach. Duration NA. Concurrent medication/care: All fractures initially treated with closed reduction and immobilisation in a dorsoradial plaster cast. Physiotherapy presecribed 2 weeks after surgery. (n=91) Intervention 2: Conservative treatment - Plaster cast or splint. Closed forearm cast . Duration 6 weeks. Concurrent medication/care: Followed by physiotherapy according to local standards. Conversion to surgery allowed by protocol if required.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus PLASTER CAST OR SPLINT

Protocol outcome 1: Quality of life at Define
- Actual outcome for Adults (16+ years): SF-36-PCS at 3 months; Group 1: mean 44.5 (SD 8.4); n=73, Group 2: mean 42 (SD 10.6); n=82; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for Adults (16+ years): SF-36-PCS at 12 months; Group 1: mean 48.6 (SD 10.4); n=68, Group 2: mean 45.3 (SD 11.3); n=81; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for Adults (16+ years): SF-36-MCS at 3 months; Group 1: mean 53.7 (SD 8.7); n=73, Group 2: mean 54 (SD 10.1); n=82; Risk of bias: Very high;

Study	ORCHID trial: Bartl 2014[15]
Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): SF-36-MCS at 12 months; Group 1: mean 53.8 (SD 7.6); n=68, Group 2: mean 53.6 (SD 9.1); n=81; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): EQ5D utility at 3 months; Group 1: mean 0.9 (SD 0.14); n=73, Group 2: mean 0.87 (SD 0.18); n=78; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): EQ5D utility at 12 months; Group 1: mean 0.89 (SD 0.21); n=68, Group 2: mean 0.89 (SD 0.18); n=81; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function at Define - Actual outcome for Adults (16+ years): DASH at 3 months; Group 1: mean 22.7 (SD 16.7); n=73, Group 2: mean 28.2 (SD 20.5); n=82; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): DASH at 12 months; Group 1: mean 14 (SD 16.1); n=68, Group 2: mean 19 (SD 21.3); n=81; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - Pain at Define; Patient outcomes - return to normal activities at Define; Patient outcomes - psychological wellbeing at Define; AE - post traumatic osteoarthritis at Define; AE - complex regional pain syndrome at Define; AE - pin site infection at Define; Need for revision surgery at Define; Need for further surgery at Define; Number of hospital attendances/bed days at Define; Radiological measures at Define

Table 67: Belloti 2010[18] (Belloti 2010[17])

Study (subsidiary papers)	Belloti 2010[18] (Belloti 2010[17])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=100)
Countries and setting	Conducted in Brazil
Line of therapy	1st line
Duration of study	Follow up (post intervention): 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable

Inclusion criteria	Adults aged >40 years, displaced fracture up to 10 days old without previous treatment, fracture type - unstable and displaced (Universal classification IIb and IVb). Fractures considered unstable if 3+ of the following factors: shortening of radius by >5 mm, dorsal angulation >20 degrees, joint incongruence, association with ulnar styloid, dorsal comminution of the metaphysis, age>60. Fractures considered reducible if presenting the following features post closed reduction: shortening of radius <3 mm, joint fragment displacement <2 mm, dorsal displacement <10 degrees
Exclusion criteria	Volar angulation (Smith's fracture), joint margin fractures (Barton's fracture), open or bilateral fractures, fractures that could not be reduced, previous history of degenerative disease, wrist joint trauma or traumatic injuries associated with the fracture
Recruitment/selection of patients	Patients recruited between August 2002 and June 2004
Age, gender and ethnicity	Age - Mean (SD): 58.3. Gender (M:F): 27/73. Ethnicity: not reported
Further population details	1. Adults: 2. Articular involvement: Not applicable/Not stated/Unclear (both intra and extra articular). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=51) Intervention 1: Percutaneous wiring - K-wires. Modified De Palma technique using 2–4 Kirschner wires, introduced under fluoroscopy guidance by stab incision. Pins curved and cut close to the skin. Duration 4–8 weeks. Concurrent medication/care: Above elbow POP cast (n=49) Intervention 2: External fixation - Bridging ex-fix. Biomechanical bridging external fixation. Two proximal pins in dorsal face of radius and two distal pins in the dorsal face of the diaphysis of the second metacarpal bone. Duration 6 weeks. Concurrent medication/care: Bandaged with sterilized gauze and instruction to clean pins and pin sites with chlorhexidine daily
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus BRIDGING EX-FIX Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain (visual analogue scale) at 2 years; Group 1: mean 1.2 cm (SD 1.4); n=45, Group 2: mean 1.4 cm (SD 1.5); n=46; Visual analogue scale 0–10 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 2 years; Group 1: mean 9.4 % (SD 12.9); n=45, Group 2: mean 12.9 % (SD 15.2); n=46; DASH score 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need

	for further surgery; Number of hospital attendances/bed days

Table 68: Colaris 2013[29]

Study	Colaris 2013[29]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=128)
Countries and setting	Conducted in Netherlands
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children
Subgroup analysis within study	Not applicable
Inclusion criteria	Children aged <16 years, displaced metaphyseal radial + ulnar fracture (displaced defined as angulation of >15 degrees for children aged <10 years and >10 degrees for children aged between 10 and 16 years), stable after closed reduction in the operating room under general anaesthesia and fluoroscopic guidance
Exclusion criteria	Fractures older than 1 week. Severe open fractures (Gustillo Anderson II and III), re-fractures
Age, gender and ethnicity	Age - Mean (SD): 8.8 (3.1). Gender (M:F): 83/45. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	--
Interventions	(n=61) Intervention 1: Percutaneous wiring - K-wires. Closed reduction under general anaesthetic and fluoroscopic guidance. After optimal reduction, the fracture was tested for stability by moving the wrist through full range of pronation and supination (any fractures re-displaced after stability testing were excluded from analysis and treated with percutaneous wires). K wire directed proximally and ulnarly across the fracture site engaging the opposite cortex with a second k-wire inserted from dorsal to volar across the fracture site through a small incision between the fourth and fifth dorsal compartments. An above-elbow cast was applied. Duration 4 weeks. Concurrent medication/care: not reported (n=67) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction under general anaesthetic and fluoroscopic guidance. After optimal reduction, the fracture was tested for stability by moving the wrist through full

	range of pronation and supination (any fractures re-displaced after stability testing were excluded from analysis and treated with percutaneous wires). Above elbow cast applied. Duration 4 weeks. Concurrent medication/care: not reported
Funding	Other (Anna Foundation Grant)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Children: Parent-completed ABILHAND functional questionnaire at 6 months; Group 1: mean 41.9 (SD 0.4); n=60, Group 2: mean 41.5 (SD 1.6); n=63; ABILHAND-kids 0–42 Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: AE - pin site infection - Actual outcome for Children: pin site infection at 6 months; Group 1: 2/60, Group 2: 0/63; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain ; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 69: Costa 2014[31,32]

Study	**Costa 2014[31,32]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=461)
Countries and setting	18 centres in the UK (including major trauma centres and smaller emergency hospitals)
Line of therapy	1st line
Duration of study	Intervention and follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Age: <50 years and >50 years
Inclusion criteria	Adults (aged 18 years and over) with a dorsally displaced fracture of the distal radius within 3 cm of the radiocarpal joint. Patient whom the treating surgeon believe surgical fixation of the fracture would be beneficial
Exclusion criteria	Fractures older than 2 weeks, if the fracture extended >3 cm from the radiocarpal joint, if the fracture was open (Gustilo grading >1[12]), if the articular surface of the fracture could not be reduced by indirect techniques, if there was

	a contra-indication to anaesthesia, or if the patient was unable to complete questionnaires
Age, gender and ethnicity	Age - Mean (SD): Internal fixation = 58.3 years (14.9), K-wires = 59.7 years (16.4). Gender (M:F): 79/385. Ethnicity: not reported
Further population details	1. Adults: Overall 2. Articular involvement: Overall 3. Children: Not applicable
Indirectness of population	--
Interventions	(n=231) Intervention 1: Internal fixation - Volar/palmar plating. Locking plate applied through an incision over the volar aspect of the wrist. The details of the surgical approach, type of plate, the number and configuration of the screws, and whether a cast was applied, were decided by the surgeon. The only stipulation was that the screws in the distal portion of the bone were 'fixed angle' (i.e. screwed into the plate). Patients received standard written physiotherapy advice. Patients were encouraged to begin exercised immediately if they did not have a plaster cast or as soon as the cast was removed. Any other rehabilitation input was at the discretion of the surgeon (n=) Intervention 2: Percutaneous wiring - K-wires. Wires passed through the skin over the dorsal aspect of the distal radius and into the bone to hold the fracture in the correct position. The size and number of wires, the insertion technique, and the configuration of wires were decided by the surgeon. A plaster cast was applied to supplement the wire fixation. Patients received standard written physiotherapy advice. Patients were encouraged to perform range of movement exercises at the wrist as soon as their plaster cast was removed. Any other rehabilitation input was at the discretion of the surgeon
Funding	Academic or government funding (NIHR health technology assessment scheme)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INTERNAL FIXATION versus K-WIRES

Protocol outcome 1: Health related quality of life
- Actual outcome for Adults (18+ years): EQ-5D at 12 months; Group 1: mean 0.85 (SD 0.19); n=194, Group 2: mean 0.83 (SD 0.19); n=204; EQ-5D 0–1 Top=High is good outcome; Risk of bias**:** Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Hand and wrist function
- Actual outcome for Adults (18+ years): PRWE score at 1 year; Group 1: mean 13.9 (SD 17.1); n=204, Group 2: mean 15.3 (SD 15.8); n=211; PRWE score 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Need for further surgery
- Actual outcome for Adults (18+ years): Revision surgery at 1 year; Group 1: 2/228, Group 2: 5/230; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further

	surgery; Number of hospital attendances/bed days

Table 70: Cui 2011[34]

Study	**Cui 2011[34]**
Study type	Systematic review
Number of studies (number of participants)	10 (n=738)
Countries and setting	-
Line of therapy	1st line
Duration of study	--:
Method of assessment of guideline condition	Adequate
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	RCTs comparing internal fixation with external fixation; Arbeitsgemeinshaft für Osteosynthesefragen (AO) type A-C3 fractures or Frykman type I-VIII fractures impossible to reduce or retain in an acceptable position in a cast after closed reduction; skeletally mature patients; patients with an unstable distal radius fracture of >14 days or axial compression >2 mm; dorsal angulation >20 degrees; reported clinical outcomes, such as complication, clinical results, radiological outcomes and DASH score; patients who had received oral and written information and signed an informed consent. All studies included patients having appropriate therapy for the first time
Exclusion criteria	If patients had any of the following conditions; fracture of the contralateral side, or other fracture in need of treatment; open fracture; ongoing radiotherapy or chemotherapy; metabolic disease affecting the bone; medication affecting the bone
Age, gender and ethnicity	Age range = 18–87 years. Gender (M:F): not reported. Ethnicity: not reported
Further population details	1. Adults: 2. Articular involvement: 3. Children:
Indirectness of population	None
Interventions	(n=365) Intervention 1: Internal fixation - mixed methods of internal fixation (n=373) Intervention 2: External fixation - mixed methods of external fixation
Funding	Funding not reported
Outcomes	Protocol outcome 1: AE - pin site infection Protocol outcome 2: AE - Complex regional pain syndrome
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes -

	psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 71: Egol 2008[37]

Study	Egol 2008[37]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=88)
Countries and setting	Conducted in USA
Line of therapy	1st line
Duration of study	Intervention and follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Fracture of the distal radius requiring operative repair (due to loss of initial reduction or unstable due to any of the following features: dorsal angulation >20 degrees, initial shortening >5 mm, dorsal comminution >50, intra-articular fractures, associated ulnar fracture in those >60 years or fracture-dislocation), amenable to either open reduction and internal fixation or external fixation and Kirschner wires
Exclusion criteria	Volar and dorsal shear fractures, skeletal immaturity
Recruitment/selection of patients	Patients recruited over three years, presenting to one of four consultants
Age, gender and ethnicity	Age - Mean (range): 51.05 (18–87). Gender (M:F): 41/47. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear (all adults). 2. Articular involvement: Not applicable/Not stated/Unclear (both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=44) Intervention 1: External fixation - Bridging ex-fix. Brand of fixator chosen by surgeon, two pins inserted in base of second metacarpal and two pins in the proximal radius, then percutaneous Kirschner wires inserted to hold the reduction. Duration 6 weeks. Concurrent medication/care: Volar plaster cast. From 6 months to 1 year group received average of 45.3 physiotherapy sessions (n=44) Intervention 2: Internal fixation - Volar/palmar plating. Brand of locked pre-contoured volar plate chosen by surgeon. Duration Permanently in situ. Concurrent medication/care: Volar plaster cast. Average of 20.4 physiotherapy sessions

Funding	Other (Industry funding other research in institutions that authors are affiliated to)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus VOLAR/PALMAR PLATING Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain at 1 year; Group 1: mean 2.1 cm (SD 2.7); n=38, Group 2: mean 2.5 cm (SD 2.9); n=39; Visual analogue scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 1 year; Group 1: mean 17.2 (SD 33.7); n=38, Group 2: mean 13 (SD 30.9); n=39; DASH score 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Pin track infection at 1 year; Group 1: 2/38, Group 2: 0/39; Risk of bias: Very high ; Indirectness of outcome: No indirectness Protocol outcome 4: Need for further surgery - Actual outcome for Adults (16+ years): Further surgery at 1 year; Group 1: 2/38, Group 2: 5/39; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 72: Foldhazy 2010[42]

Study	**Foldhazy 2010[42]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=59)
Countries and setting	Conducted in Sweden
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Distal radial fracture following a low-energy trauma (in most cases a simple fall from standing),either intra or extra

	articular, not older than 3 days and dorsal angulation radiographically of at least 40 degrees from normal or shortening of radius of at least 5 mm in relation to the ulna
Exclusion criteria	Concomitant conditions that might influence hand function, concomitant fracture of the distal ulna (apart from ulnar styloid), paretic arm, earlier fracture of the same wrist, pre-existing joint disease, unable to perform basic ADLs, cognitive dysfunction, unable to understand written information
Age, gender and ethnicity	Age - Mean (range): 71 (60–85). Gender (M:F): 6/53. Ethnicity:
Further population details	1. Adults: Adults aged 50–70 (Adults aged 60–85 years). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra- and extra-articular). 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=28) Intervention 1: External fixation - Bridging ex-fix. Fractures were reduced immediately in the emergency department and immobilised in a dorsal elbow splint to be operated on at the next available opportunity. External fixator applied with two pins inserted into the distal radius and two into the second metacarpal. Duration 5 weeks. Concurrent medication/care: physiotherapy only prescribed when needed (n=31) Intervention 2: Conservative treatment - Plaster cast or splint. Treated in the emergency department by an orthopaedic registrar or specialist with closed reduction using regional anaesthesia (haematoma block in three patients and IVRA in 28 patients) and wrists were immobilised with a dorsal plaster splint reaching below the elbow. Duration 5 weeks. Concurrent medication/care: physiotherapy only prescribed when needed
Funding	Academic or government funding (Grants from Karolinska Institute)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Green & O'Brien - Fair or Poor at 1 year; Group 1: 13/22, Group 2: 19/29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - post traumatic osteoarthritis - Actual outcome for Adults (16+ years): Post-traumatic arthritis grade 1 at 1 year; Group 1: 6/28, Group 2: 8/31; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 1 year; Group 1: 2/28, Group 2: 2/31; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital

	attendances/bed days

Table 73: Gradl 2013[48]

Study	**Gradl 2013[48]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=102)
Countries and setting	Conducted in Unknown
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Dorsal displacement (>20 degrees), extra articular fracture (AO type A3) and intra articular (AO type C1–3)
Exclusion criteria	dorsal or volar shearing fracture, AO type B fracture or patients with previous history of wrist fracture
Recruitment/selection of patients	Patients recruited between January 2005 and May 2006
Age, gender and ethnicity	Age - Mean (range): 63 (18–88). Gender (M:F): 13/89. Ethnicity: not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear (mixed). 2. Articular involvement: Not applicable/Not stated/Unclear (mixed). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=52) Intervention 1: Internal fixation - Volar/palmar plating. Volar fixed angle plate (2.4 mm synthes, Mathys Medical, Bettlach, Swizerland) through standard Henry approach. Duration 39 remained in situ permanently. Concurrent medication/care: volar splint for 3 days (n=50) Intervention 2: External fixation - Non-bridging ex-fix. Non-bridging external fixation (AO small fixator, Mathys Medical, Bettlach, Swizerland). Preliminary joint bridging construction used to refrain and maintain radial length, after second step of reduction and fixation of distal segment the bridging elements were removed. Duration 7 weeks. Concurrent medication/care: bandaging not documented
Funding	Academic or government funding (AO grant)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: NON-BRIDGING EX-FIX versus VOLAR/PALMAR PLATING	

Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain at 1 year; Group 1: mean 0.1 cm (SD 0.1); n=44, Group 2: mean 0 cm (SD 0); n=44; Visual analogue scale 0–10 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Clinician-based function - Gartland and Werley Score at 1 year; Group 1: mean 1.18 (SD 1.99); n=44, Group 2: mean 1.4 (SD 2.32); n=44; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 74: Grewal 2005[49]

Study	**Grewal 2005[49]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=62)
Countries and setting	Conducted in Canada; Setting: Royal Columbian Hospital (Level I Trauma Centre)
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	AO type C intra-articular distal radius fractures with 2 mm or more of intra-articular step deformity on either pre-reduction or post-reduction film, skeletal maturity, age <70 years
Exclusion criteria	Associated soft tissue or skeletal injuries to the same limb, pre-existing wrist arthrosis, >14 days between injury and surgery, isolated radial styloid or volar Barton's fracture, any fractures with gross palmar displacement of the articular fragments, distal ulnar fractures proximal to the ulnar styloid fractures with comminution extending into the diaphysis, active infection or any premorbid medical condition precluding surgery
Recruitment/selection of patients	Between November 1998 and May 2002
Age, gender and ethnicity	Age - Mean (SD): ORIF 46 (2.7) Ex-fix 45 (2.7). Gender (M:F): 29/33. Ethnicity:

Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: External fixation - Non-bridging ex-fix. External fixation and K-wires. Duration Unclear. Concurrent medication/care: use of iliac crest bone graft at discretion of surgeon (n=33) Intervention 2: Internal fixation - Dorsal plating. Mini open reduction and dorsal plating. Duration Unclear. Concurrent medication/care: use of iliac crest bone graft at discretion of surgeon
Funding	Study funded by industry (Grant from Zimmer Canada)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DORSAL PLATING versus NON-BRIDGING EX-FIX Protocol outcome 1: Quality of life - Actual outcome for Adults (16+ years): SF-36 at 2 years; Mean "not significant"; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain at 2 years; Group 1: mean 2.21 (SD 3.4); n=24, Group 2: mean 10 (SD 3.4); n=30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 2 years; Mean "not significant"; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 2 years; Group 1: 3/24, Group 2: 2/30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: AE - pin site infection - Actual outcome for Adults (16+ years): Pin-site infection at 2 years; Group 1: 0/24, Group 2: 2/30; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 75: Grewal 2011[50]

Study	Grewal 2011[50]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=53)
Countries and setting	Conducted in Canada
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged between 18 and 75, unstable distal radius fractures (inadequate initial reduction or loss of reduction defined as >20 degrees dorsal angulation, >5 mm ulnar positive variance and/or >2 mm intra-articular step)
Exclusion criteria	Volar shear fractures, open fractures, other associated ipsilateral upper extremity injuries, acute carpal tunnel syndrome, medical comorbidities precluding surgery
Age, gender and ethnicity	Age - Mean (SD): Internal fixation 58 (9.9), External fixation 54 (11.7). Gender (M:F): 12/38. Ethnicity:
Further population details	1. Adults: Adults aged 16–50 (Adults aged 18–75). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular fractures). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=26) Intervention 1: Internal fixation - Dorsal plating. Second generation Synthes dorsal Pi plate. Duration remained in situ. Concurrent medication/care: Intra-operative fluoroscopy to confirm reduction and verify positioning of hardware. Volar plaster cast applied. (n=24) Intervention 2: External fixation - Bridging ex-fix. 1.6 mm smooth Kirschner wires and a bridging external fixator (small AO external fixatori, Synthes). Duration 6 weeks. Concurrent medication/care: Intra-operative fluoroscopy to confirm reduction and verify positioning of hardware
Funding	Academic or government funding (Physician Services Incorporated Foundation grant)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DORSAL PLATING versus BRIDGING EX-FIX

Protocol outcome 1: Hand and wrist function
- Actual outcome for Adults (16+ years): PRWE at 1 year; Mean "not significant"; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 1 year; Group 1: 0/26, Group 2: 1/24; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin tract infection at 1 year; Group 1: 0/26, Group 2: 8/24; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 76: Gupta 1999[51]

Study	**Gupta 1999[51]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in India
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Colles' fracture in participants with a fuse epiphysis
Exclusion criteria	Not reported
Age, gender and ethnicity	Age - Mean (range): 55.6 (22–80). Gender (M:F): 13/37. Ethnicity: not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Extra-articular (No description - only described as "Colles" fractures). 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Percutaneous wiring - K-wires. Closed reduction under local anaesthesia maintained by crossed-pin fixation. The first wire was inserted at the tip of the radial styloid process at a 45 degree angle to the long axis of the radius. The second k-wire was introduced through the dorso ulnar corner of the distal radius at a 45 degree angle to the long axis of the radius, keeping the angle 30 degrees volar. Duration Until fracture union. Concurrent

	medication/care: Below-elbow plaster cast placed with the wrist in a functional position (approximately 10 degrees extension and neutral deviation at wrist) for 6 weeks (n=25) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction maintained by plaster of paris cast immobilisation with the wrist in palmar flexion and ulnar deviation for the first 3 weeks. The cast was then changed with the wrist in a neutral position for the next 3 weeks. Duration 6 weeks. Concurrent medication/care: No further detail provided
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Sarmiento et al functional score - fair or poor at 8 weeks; Group 1: 2/25, Group 2: 6/25; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 77: Handoll 2007[53]

Study	**Handoll 2007[53]**
Study type	Systematic review
Number of studies (number of participants)	15 (n=1022)
Countries and setting	-
Line of therapy	1st line
Duration of study	--
Method of assessment of guideline condition	Adequate
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Any randomised or quasi-randomised controlled clinical trial comparing external fixation with conservative methods for treating distal radial fractures in adults; patients of either sex who have completed skeletal growth, with a fracture of the distal radius. External fixation as primary treatment or take place after the failure of initial conservative

	management, generally within two to three weeks. Augmented external fixation in the form of supplementary percutaneous pinning was also included. Trials with a mixed population of adults and children were included provided the proportion of children was clearly small (<5%)
Exclusion criteria	Trials comparing different methods, including techniques and devices, of external fixation; or trials comparing external fixation with other methods of surgical fixation, such as percutaneous pinning, or trials evaluating the use of supplementary methods, such as bone grafts and substitutes, other than percutaneous pinning, to external fixation compared with conservative treatment
Age, gender and ethnicity	Age range of means = 36–72 years. Gender: range of female participants = 17–91%. Ethnicity: not reported
Further population details	
Indirectness of population	None
Interventions	(n=unclear) Intervention 1: External fixation – Mixed methods of external fixation (n=unclear) Intervention 2: Conservative treatment – Plaster cast or splint
Funding	No funding
Outcomes	Protocol outcome 1: Quality of life Protocol outcome 2: Hand and wrist function Protocol outcome 3: Pain Protocol outcome 4: AE - complex regional pain syndrome Protocol outcome 5: AE - pin site infection
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 78: Harley 2004[57]

Study	**Harley 2004[57]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Canada; Setting: Major teaching hospital and trauma referral centre
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 18–65, unstable (defined as initial dorsal angulation of >20 degrees, initial shortening >5 mm, displaced intra-articular component, loss of reduction with closed casting technique) closed fracture of the distal radius
Exclusion criteria	Previous injury or surgery to the involved wrist, severe underlying medical illness, primary shear fractures (AO type B fractures)
Recruitment/selection of patients	Patients recruited between May 2009 and February 2002
Age, gender and ethnicity	Age - Mean (range): 42 (19–62). Gender (M:F): 22/28. Ethnicity:
Further population details	1. Adults: Adults aged 16–50 (Adults aged 18–65). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Percutaneous wiring - K-wires. Three smooth K-wires drilled from distal to proximal, not in an intrafocal Kapandji technique. Two pins were placed from the darial styloid region directed ulnarly, the third placed from the distal dorsal surface of the lunate facet. Duration 6 weeks. Concurrent medication/care: Fluoroscopic guided closed reduction. Below-elbow cast (n=25) Intervention 2: External fixation - Bridging ex-fix. Augmented external fixation system (Howmedica Hoffman II Compact; Stryker-Howmedica-Osteonics, Allendale, NJ) with 3 mm self-tapping Shantz pins placed through predrilled 2 mm holes in both dorso-radial aspect of second metacarpal and radial diaphysis proximal to fracture line. Duration 6 weeks. Concurrent medication/care: Closed reduction using multiplanar ligamenotaxis principles. Daily pin care advised
Funding	Other (Commercial funding has been received by the foundation or educational institution one or more of the authors are affiliated with)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus BRIDGING EX-FIX

Protocol outcome 1: Quality of life
- Actual outcome for Adults (16+ years): SF-36 physical component at 1 year; Group 1: mean 48 % (SD 11); n=17, Group 2: mean 45 % (SD 11); n=17; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Hand and wrist function
- Actual outcome for Adults (16+ years): DASH score at 1 year; Group 1: mean 15 % (SD 18); n=17, Group 2: mean 23 % (SD 23); n=17; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 1 year; Group 1: 0/17, Group 2: 3/17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): Pin drainage requiring antibiotics at 1 year; Group 1: 2/17, Group 2: 4/17; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 79: Hollevoet 2011[60]

Study	**Hollevoet 2011[60]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=42)
Countries and setting	Conducted in Belgium
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults aged >50 years, dorsally displaced fracture of the distal radius following a simple fall
Exclusion criteria	Associated ulnar head fracture, previous wrist fracture, high energy fractures
Recruitment/selection of patients	Patients recruited between September 2006 and February 2008
Age, gender and ethnicity	Age - Mean (SD): K-wires: 66 Plate: 67. Gender (M:F): 4/36. Ethnicity: not reported
Further population details	1. Adults: Adults aged 50-70 (Adults aged >50). 2. Articular involvement: Not applicable / Not stated / Unclear (both intra and extra-articular). 3. Children: Not applicable / Not stated / Unclear (adults only).
Indirectness of population	No indirectness

Interventions	(n=20) Intervention 1: Percutaneous wiring - K-wires. Two or three 1.6 mm Kirschner wires inserted according to the Kapandji method. Duration 5 weeks. Concurrent medication/care: forearm plaster cast (n=20) Intervention 2: Internal fixation - Volar/palmar plating. 2.4 mm LCP distal radius plate with locking screws (Synthes) via Henry approach. Duration remained in situ. Concurrent medication/care: forearm plaster cast
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus VOLAR/PALMAR PLATING Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 1 year; Group 1: mean 13 % (SD 20); n=18, Group 2: mean 14 % (SD 16); n=15; DASH score 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - pin site infection - Actual outcome for Adults (16+ years): Deep and superficial infection at 1 year; Group 1: 3/15, Group 2: 1/16; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Need for further surgery - Actual outcome for Adults (16+ years): Additional surgery to remove metalwork at 1 year; Group 1: 1/15, Group 2: 3/16; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 80: Howard 1989[62]

Study	**Howard 1989[62]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	severely displaced (>30 degrees of dorsal angulation, >1 cm radial shortening) comminuted Colles' fractures
Exclusion criteria	Patients over 75 years
Recruitment/selection of patients	Consecutive patients
Age, gender and ethnicity	Age - Other: external fixation group mean 49.2 years; plaster cast immobilisation mean 45.3 years. Gender (M:F): not reported. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	--
Interventions	(n=25) Intervention 1: External fixation - Bridging ex-fix. Medium-C-Hoffman external fixator applied with two pairs of self-tapping 2 mm pins inserted into the radius and two distal pins inserted in the index and middle metacarpals. Fracture was then reduced and fixator locked with the position being checked on an image intensifier and pin depth adjusted as necessary. Duration 5–6 weeks. Concurrent medication/care: Immobilisation for five to six weeks followed by physiotherapy (n=25) Intervention 2: Conservative treatment - Plaster cast or splint. Fracture manipulated under a Bier's block and supported by a moulded below-elbow plaster backslab, which was completed to a full cast the next day (with three point fixation). Check radiographs taken ant one and two weeks after reduction: re-manipulation was arranged if there had been significant loss of position. Duration 5–6 weeks. Concurrent medication/care: immobilisation for five to six weeks followed by physiotherapy
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT

Protocol outcome 1: Hand and wrist function
- Actual outcome for Adults (16+ years): Gartland and Werley score - fair or poor at 6 months; Group 1: 6/25, Group 2: 7/25; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - complex regional pain syndrome
- Actual outcome for Adults (16+ years): Complex regional pain syndrome at 6 months; Group 1: 0/25, Group 2: 0/25; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 6 months; Group 1: 2/25, Group 2: 0/25; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain ; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 81: Hutchinson 1995[64]

Study	**Hutchinson 1995[64]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=89)
Countries and setting	Conducted in USA
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Closed fractures, radiographic instability defined as dorsal angulation greater than 20 degrees (in Colles' fractures), extensive articular involvement and/or severe comminution), adequate reduction of fracture (incongruity less than 2 mm)
Exclusion criteria	Internal fixation required
Age, gender and ethnicity	Age - Mean (range): 65 (14–93). Gender (M:F): 22/68. Ethnicity: not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear (Adults and children aged 14–93). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Both adults and children)
Indirectness of population	Serious indirectness: Children and adults (mean = 65 years, range = 14–93)
Interventions	(n=46) Intervention 1: Percutaneous wiring - K-wires. Threaded dorsal pin placed in the radius proximal to the fracture site and a smaller pin placed in the metacarpals in the plane of the palm. Pins distracted and cast applied incorporating both pins. Duration 4 months. Concurrent medication/care: Closed reduction under regional or general anaesthesia

	(n=44) Intervention 2: External fixation - Bridging ex-fix. Unilateral four-pin AO small external fixator with tow 4 mm pins placed dorso-radially in the radius proximal to the fracture and two 2.5 mm pins placed in the second metacarpal along the dorso-radial border directed towards each other at 45 degrees to the skin. Limited open dissection technique used at discretion of surgeon. Duration 4 months. Concurrent medication/care: Closed reduction under regional or general anaesthesia carried out first
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus BRIDGING EX-FIX Protocol outcome 1: Hand and wrist function - Actual outcome: Gartland Demerit Criteria - poor or fair at 2 years; Group 1: 2/26, Group 2: 1/26; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome: Reflex sympathetic dystrophy at 1 year; Group 1: 6/26, Group 2: 5/26; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome: Pin tract infections at 1 year; Group 1: 2/26, Group 2: 11/26; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 82: Ismatullah 2012[66]

Study	**Ismatullah 2012[66]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=30)
Countries and setting	Conducted in Pakistan
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not stratified but pre-specified: <40 years of age >40 years of age
Inclusion criteria	Adults >20 years of age with comminuted distal radial fractures

Exclusion criteria	Open fractures, fractures with previous deformity of the wrist, paralysis, tendon or ligament injury or nerve injury, serious systemic ailments
Recruitment/selection of patients	Participants recruited from February 2009 to September 2010
Age, gender and ethnicity	Age - Mean (SD): External fixation: 51.47 (15) Plaster cast: 49.8 (16). Gender (M:F): 13/17. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated /Unclear
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: External fixation - Bridging ex-fix. AO-ASIF external fixator applied under general anaesthesia. 4 pins inserted, with distal pins placed in the second metacarpal and fracture reduced by the principle of ligamentotaxis. Duration Unclear. Concurrent medication/care: Not reported (n=15) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction and above-elbow plaster casting under haematoma block and sedation with midazolam. Duration Unclear. Concurrent medication/care: Not reported
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Green & O'Brien Scoring system - fair or poor at 3 months; Group 1: 4/15, Group 2: 8/15; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 3 months; Group 1: 1/15, Group 2: 3/15; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Pin-site infection at 3 months; Group 1: 2/15, Group 2: 0/15; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 83: Jenkins 1988[71]

Study	Jenkins 1988[71]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=106)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Colles' fracture sufficiently displaced to require manipulative reduction
Exclusion criteria	Aged 60 or over
Age, gender and ethnicity	Age - Mean (SD): External fixator 34.5 years; Plaster cast 40.1 years. Gender (M:F): not reported. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=59) Intervention 1: External fixation - Non-bridging ex-fix. AO/ASIF mini-fixator applied under general anaesthesia using image intensifier control. Two proximal K-wires inserted into the radial shaft whilst two distal wires transfixed the comminuted distal fragment the two sets of wires being connected by a Z-type configuration external frame. No additional splintage used therefore potentially full wrist movements allowed. Duration 4 weeks+. Concurrent medication/care: X-ray check at 1 week and any fracture requiring re-manipulation excluded from further analysis. (n=47) Intervention 2: Conservative treatment - Plaster cast or splint. Following reduction, the fractures were splinted in a dorsal plaster slab in a pronated position with approximately 10 degrees of flexion. Duration 4 weeks+. Concurrent medication/care: X-ray check at 1 week and any fracture requiring re-manipulation excluded from further analysis
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: NON-BRIDGING EX-FIX versus PLASTER CAST OR SPLINT	

Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Function - fair or poor (Stewart) at 1 year; Group 1: 15/59, Group 2: 9/41; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 84: Jeudy 2012[73]

Study	**Jeudy 2012 [73]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=75)
Countries and setting	Conducted in France
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults >40 years old (
Subgroup analysis within study	Not stratified but pre-specified: <40 years of age >40 years of age
Inclusion criteria	Patients (aged 40-80) with a recent (>48h), isolated fracture of the distal radius, joint involvement, ulnar integrity (except distal styloid) and impaction of the distal radius >3mm based on the ulnar variance compared with the healthy side.
Exclusion criteria	Existence of contralateral radial malunion, stages lesions of the ipsilateral upper limb, open fractures or association with nerve or intracarpral joint lesions.
Recruitment/selection of patients	Participants recruited from 2006 to 2009
Age, gender and ethnicity	Age - Mean (SD): 64.7 (3.6) Gender (M:F): 18/57. Ethnicity: Not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated /Unclear
Indirectness of population	No indirectness
Interventions	(n=39) Intervention 1: External fixation – EF was prolonged over 6 weeks and associated with intra-focal percutaneous pinning to control posterior tilts. EF used Hoffman II, Stryker) (n=36) Intervention 2: Open reduction and plate fixation: Trans-articular radio-metacarpal distraction was performed

	under flyoroscopic control and maintained by 2mm diameter sticks. ORIF groups used volar fixed angle plate (titanium 2.4 DRP Synthes).
Funding	Direction Generale de la Sante
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: External fixation versus Internal fixation Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Green and O'Brien Scoring system - fair or poor at 6 months; Group 1: 28/39, Group 2: 17/36; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): CRPS at 6months; Group 1: 12/39, Group 2: 7/36; Risk of bias: Very high; Indirectness of outcome: Some indirectness Protocol outcome 3: AE – Return to normal activity - Actual outcome for Adults (16+ years): Return to normal activity at 6 months; Group 1: 21/39, Group 2: 22/36; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - psychological wellbeing; AE - post traumatic; Number of hospital attendances/bed days; Osteoarthritis; Pin site infection

Table 85: Kapoor 2000[75]

Study	Kapoor 2000[75]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=90)
Countries and setting	Conducted in India
Line of therapy	1st line
Duration of study	Intervention and follow up: 4 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years): Adults

Subgroup analysis within study	Not applicable
Inclusion criteria	Adults with acute displaced intra-articular fractures of the lower end of the radius
Exclusion criteria	None reported
Recruitment/selection of patients	Recruited between July 1991 and July 1996
Age, gender and ethnicity	Age - Mean (SD): 39. Gender (M:F): Define. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=33) Intervention 1: Conservative treatment - Plaster cast or splint. Closed reduction and plaster immobilisation (up to two attempts if the first attempt had failed). Duration 6–7 weeks. Concurrent medication/care: not reported (n=28) Intervention 2: External fixation - Bridging ex-fix. Roger and Anderson external fixator applied. Duration 6–7 weeks. Concurrent medication/care: patients advised on pin care (n=29) Intervention 3: Internal fixation - Mixed methods of internal fixation. Open reduction and internal fixation with small T-plates, k-wires or both. Duration Unclear. Concurrent medication/care: mobilisation encouraged from 2 weeks
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT

Protocol outcome 1: Hand and wrist function
- Actual outcome: Sarmiento et al. functional score - fair or poor at 6–7 weeks; Group 1: 4/18, Group 2: 13/23; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - complex regional pain syndrome
- Actual outcome: Reflex sympathetic dystrophy at 6–7 weeks; Group 1: 1/28, Group 2: 0/33; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 3: AE - pin site infection
- Actual outcome: superficial infection at 6–7 weeks; Group 1: 1/28, Group 2: 0/33; Risk of bias: High; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus PLASTER CAST OR SPLINT

Protocol outcome 1: Hand and wrist function

- Actual outcome: Sarmiento et al. functional score - fair or poor at 6–7 weeks; Group 1: 7/19, Group 2: 13/23; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome: Reflex sympathetic dystrophy at 6–7 weeks; Group 1: 0/29, Group 2: 0/33; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome: superficial infection at 6–7 weeks; Group 1: 1/29, Group 2: 0/33; Risk of bias: High; Indirectness of outcome: No indirectness RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus BRIDGING EX-FIX Protocol outcome 1: Hand and wrist function - Actual outcome: Sarmiento et al. functional score - fair or poor at 6–7 weeks; Group 1: 7/19, Group 2: 4/18; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome: Reflex sympathetic dystrophy at 6–7 weeks; Group 1: 0/29, Group 2: 1/28; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome: superficial infection at 6–7 weeks; Group 1: 1/29, Group 2: 1/28; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain ; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 86: Karantana 2013[76]

Study	**Karantana 2013[76]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=135)
Countries and setting	Conducted in United Kingdom; Setting: Tertiary care institution
Line of therapy	1st line
Duration of study	Follow up (post intervention): 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Adults (16+ years): Adults (aged 18–73 years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with a displaced distal radial fracture. Further information not accessible
Exclusion criteria	Information not accessible
Recruitment/selection of patients	All skeletally mature patients who presented to the participating trauma service were eligible. The attending physician screened patients according to the inclusion criteria and referred eligible patients to the research team
Age, gender and ethnicity	Age - Range: 18-73 years. Gender (M:F): Information not accessible. Ethnicity: Not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear (All adults (18–73 years)). 2. Articular involvement: Not applicable/Not stated/Unclear (Mixed intra-/extra-articular fractures). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=68) Intervention 1: Internal fixation - Volar/palmar plating. Volar locking plate inserted using fluoroscopic guidance. Duration Surgery + 2-weeks immobilisation. Concurrent medication/care: Wrist was immobilised post-operatively in either a plaster splint or a removable velcro splint. Patients were instructed in active and passive finger motion exercises. After 2 weeks, splints were removed and patients received physiotherapy (n=67) Intervention 2: Percutaneous wiring - K-wires. Smooth 1.6 mm kirschner wires and a supplemental standard AO/ASIF external fixator if required as decided by the operating surgeon. Duration Surgery + 6-week immobilisation. Concurrent medication/care: Postoperatively, the wrist was immobilised in a plaster cast splint for 6 weeks, and patients were instructed in passive and active finger motion exercises. Patients with external fixation did not require plaster support. K-wires and external fixation were removed at 6-weeks, after which patients received physiotherapy
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus K-WIRES

Protocol outcome 1: Quality of life
- Actual outcome for Adults (16+ years): EQ-5D (index score) at 1 year; Group 1: mean 0.87 (SD 0.20); n=66, Group 2: mean 0.89 (SD 0.16); n=64; EQ-5D 0–1 Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 2: Patient outcomes - Pain
- Actual outcome for Adults (16+ years): Pain (ulnar styloid or unspecified wrist pain) at 1 year; Group 1: 3/66, Group 2: 3/64; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 3: Hand and wrist function

- Actual outcome for Adults (16+ years): QuickDASH at 1 year; Group 1: mean 9 (SD 12); n=66, Group 2: mean 12 (SD 15); n=64; QuickDASH 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): Superficial infection at 1 year; Group 1: 2/66, Group 2: 5/64; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 5: Need for further surgery - Actual outcome for Adults (16+ years): Further surgery (removal of plate, carpal tunnel decompression, extensor pollicus longus reconstruction, removal of buried k-wires) at 1 year; Group 1: 2/66, Group 2: 8/64; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 87: Kreder 2006[83]

Study	Kreder 2006[83]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=113)
Countries and setting	Conducted in Canada, USA
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged between 16 and 75 years, distal radius fracture with metaphyseal comminution and displacement and a stable congruous joint.
Exclusion criteria	Comminution of >1/3 the anterior-posterior diameter of the radius and pre-reduction dorsal tilt of >10 degrees or a detectable step or gap at the distal radius joint surface, history of a previous wrist fracture, congenital anomaly or other sever wrist problem, not fit for surgery, unable to read English, open fractures, associated upper ipsilateral extremity injuries or other significant systemic injuries.
Recruitment/selection of patients	Patients recruited between February 1994 and April 1998

Age, gender and ethnicity	Age - Mean (SD): Conservative treatment: 53.4 (17.7) External fixation: 52.4 (16.3). Gender (M:F): 39/74. Ethnicity:
Further population details	1. Adults: Adults aged 16–50 (Adults aged 16–75). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=59) Intervention 1: Conservative treatment - Plaster cast or splint. Above elbow backslab with wrist in neutral and the elbow flexed to 90 degrees with neutral rotation. Converted to full cast within 2 weeks and reduced to a below elbow cast at 4 weeks. Duration 6-8 weeks. Concurrent medication/care: Closed reduction performed under haematoma block and fluoroscopy guidance (n=54) Intervention 2: External fixation - Bridging ex-fix. Small AO fixator used in conjunction with 2.5 mm threaded pins inserted into the second metacarpal and 4 mm pins inserted into the radius via a 1 cm skin incision. Additional smooth Kirschner wires (1.6 mm) inserted at the surgeon's discretion. Duration 6–8 weeks. Concurrent medication/care: Closed reduction under regional anaesthesia in the operating room under fluoroscopic guidance
Funding	Academic or government funding (Grant from the Orthopaedic Research & Education Foundation)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PLASTER CAST OR SPLINT versus BRIDGING EX-FIX Protocol outcome 1: Pain - Actual outcome for Adults (16+ years): Change in SF-36 bodily pain from premorbid level at 2 years; Group 1: mean 0.1 (SD 1.1); n=59, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 2 years; Group 1: 2/36, Group 2: 1/43; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Pin site infection at 2 years; Group 1: 1/36, Group 2: 6/43; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 88: Lagerstrom 1999[84]

Study	Lagerstrom 1999[84]

Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=68)
Countries and setting	Conducted in Sweden
Line of therapy	1st line
Duration of study	Follow up (post intervention): 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years): Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Adult patients, aged 45–75 years, with displaced intra-articular Colles' fractures of the distal radio-ulnar joint. The required degree of displacement was >/= 3 mm shortening, >/= 10 degrees dorsal, and/or >/= 10 degrees radial angulation of the radius. The fractures should be clinically feasible to immobilise either with a cylindrical below-elbow plaster cast (p-group) or with a light weight non-cylindrical external fixator
Exclusion criteria	Patients with medical conditions or language difficulties that might interfere with the results of the study
Recruitment/selection of patients	Consecutive patients admitted to the participating institution
Age, gender and ethnicity	Age - Range: 45–72 years. Gender (M:F): 5 male, 30 female. Ethnicity: Not reported
Further population details	1. Adults: Adults aged 50–70 (Adults aged 45–75). 2. Articular involvement: Intra-articular (Intra-articular). 3. Children: Not applicable/Not stated/Unclear (No children)
Indirectness of population	--
Interventions	(n=18) Intervention 1: External fixation - Mixed methods of external fixation. Non-cylindrical AO external fixator. Duration 6 weeks. Concurrent medication/care: Immobilisation and physiotherapy (n=17) Intervention 2: Conservative treatment - Plaster cast or splint. Cylindrical below-elbow plaster cast. Duration 6 weeks. Concurrent medication/care: Physiotherapy
Funding	Academic or government funding (Funding from the County Council of Uppsala and the Trygg-Hansa Foundation Fund)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF EXTERNAL FIXATION versus PLASTER CAST OR SPLINT

Protocol outcome 1: Patient outcomes - Pain
- Actual outcome for Adults (16+ years): Pain performing grip strength test at unclear; RR 'not significant'; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 89: Leung 2008[86]

Study	**Leung 2008 [86]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=144)
Countries and setting	Conducted in Hong Kong
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16- 60 years)
Subgroup analysis within study	Not stratified but pre-specified: <40 years of age >40 years of age
Inclusion criteria	Adults >16 years of age with an acute intra-articular fracture, AO group-C1, C2, or C3 distal radial fracture
Exclusion criteria	Open fractures, patients who presented more than 8 hours after injury. Patients with pathological fractures and those with a history of premature osteoporosis, drug abuse or alcohol abuse.
Recruitment/selection of patients	Participants recruited from March2002 to March 2005
Age, gender and ethnicity	Age - Mean (range): 42 (17-60) Gender (M:F): 85/52. Ethnicity: Not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated /Unclear
Indirectness of population	No indirectness
Interventions	(n=74) Intervention 1: External fixation – A small AO/ASIF external fixator (Synthes) was used. Two half pins were inserted in the second metacarpal through stab incisions and two pins were placed in the radial aspect of the shaft of the radius. Reduction was achieved with ligamentotaxis and percutaneous fracture fragment manipulation with Kirschner wires. (n=70) Intervention 2: Open reduction and plate fixation: A combined volar and dorsal approach was used. When metaphyseal support of the articular fragments was compromised by communication, autogenous cancellous bone graft was used to support articular fragments. Conventional, non-locking stainless steel 3.5mm T plates (Synthes,

	Bettlach, Switzerland) were used.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: External fixation versus Internal fixation Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Gartland and Werely Scoring system - fair or poor at 2 years; Group 1: 3/49, Group 2: 2/54; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): CRPS at 3years; Group 1: 1/49, Group 2: 0/54; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Pin-site infection at 2 years; Group 1: 5/49, Group 2: 0/54; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Osteoarthritis - Actual outcome for Adults (16+ years): Knirk Jupiter Scoring system – classification above 1; Group 1: 40/49, Group 2: 30/54; Risk of bias: Very high; Indirectness of outcome: Some indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain;; Patient outcomes - psychological wellbeing; AE - post traumatic; Number of hospital attendances/bed days

Table 90: Ludvigsen 1997[87]

Study	Ludvigsen 1997[87]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=74)
Countries and setting	Conducted in Norway
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged over 20 years, Colles' fracture Older type 3 with more than 5 mm of radial shortening or Older type 4
Exclusion criteria	Previous injuries of the wrist or hand
Recruitment/selection of patients	Patients recruited between 1992 and 1994
Age, gender and ethnicity	Age - Mean (range): 61 (30–80). Gender (M:F): 7/53. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear (adults aged >20). 2. Articular involvement: Not applicable/Not stated/Unclear (both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=31) Intervention 1: Percutaneous wiring - K-wires. Three 1.6 mm Kirschner wires inserted. Two from the radial styloid process (from dorsal and ventral aspects), the third from the dorsal ulnar corner of the radius. Duration 6 weeks. Concurrent medication/care: Plaster cast (n=29) Intervention 2: External fixation - Bridging ex-fix. Two 3 mm self-drilling and self-tapping half pins placed in radius proximal to fracture and two pins inserted in index metacarpal. Duration 6 weeks. Concurrent medication/care: Not detailed
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus BRIDGING EX-FIX Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Patients with Gartland Werley Score >9 (fair or poor outcome) at 6 months; Group 1: 4/31, Group 2: 5/29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 6 months; Group 1: 1/31, Group 2: 3/29; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain ; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 91: Marcheix 2010[91]

Study	Marcheix 2010[91]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=110)
Countries and setting	Conducted in France
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients aged >50 years with a dorsally displaced fracture of the distal radius
Exclusion criteria	Patients with a palmar tilted distal radius fracture, open fractures, patients with polytrauma, patients living outside the local area
Recruitment/selection of patients	Patients recruited from May 2007 to March 2008
Age, gender and ethnicity	Age - Mean (SD): K-wires 73 (11) Palmar Plates 75 (11). Gender (M:F): Define. Ethnicity: not reported
Further population details	1. Adults: Adults aged 50-70 (Aged >50 years). 2. Articular involvement: Not applicable/Not stated/Unclear (both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=56) Intervention 1: Percutaneous wiring - K-wires. Fracture reduced by manual traction, then four Kirschner wires (1.8 mm or 2 mm) used to stabilise the fracture. Two dorsal and one radial wire inserted into the fracture gap, the last wire inserted through the radial styloid. Duration 6 weeks. Concurrent medication/care: Below elbow plaster cast. 15 physiotherapy sessions (n=54) Intervention 2: Internal fixation - Volar/palmar plating. Palmar fixed angle plate with four or five locking screws, approached via palmar incision. Duration remained in situ. Concurrent medication/care: Below elbow plaster cast. 15 physiotherapy sessions
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus VOLAR/PALMAR PLATING	

Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 6 months; Group 1: mean 22 % (SD 22); n=53, Group 2: mean 10 % (SD 14); n=50; DASH score 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 92: Mardani 2011[93]

Study	**Mardani 2011[93]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=198)
Countries and setting	Conducted in Iran
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Skeletally mature, aged between 16 and 75 years, displaced but stable distal radius fracture with congruous joint with less than 2 mm joint gap (type I Fernandez classification)
Exclusion criteria	Open physis, open fracture, dorsal comminution, dorsal tilt more than 20 degrees, history of previous wrist of forearm fractures, congenital or other forearm or other anomalies, previous history of wrist operations, history of psychiatric problems, fractures in other parts of upper limb
Age, gender and ethnicity	Age - Mean (SD): 50.8 (15). Gender (M:F): 111/87. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=99) Intervention 1: Percutaneous wiring - K-wires. Closed reduction under general anaesthesia and percutaneous pinning with smooth unthreaded 1.5 mm or 2 mm pins, then immobilised in short-arm cast. Duration Unclear. Concurrent medication/care: not reported

	(n=99) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction under general anaesthetic with long-arm cast applied. Duration Unclear. Concurrent medication/care: not reported
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT Protocol outcome 1: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 3 months; Group 1: 15/99, Group 2: 0/99; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Need for further surgery - Actual outcome for Adults (16+ years): re-reduction and fixation required at 1 week; Group 1: 0/99, Group 2: 6/99; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 93: Mcfadyen 2011[94]

Study	**Mcfadyen 2011[94]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=56)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Closed unilateral dorsally displaced unstable extra-articular distal radial fractures (AO Classification type A), instability defined as dorsal angulation >20 degrees, dorsal comminution and radial shortening >4 mm
Exclusion criteria	AO Classification type B and C fractures, bilateral fractures, multiple injuries, radiographic evidence of pre-existing hand and wrist arthritis, dementia and open fractures
Recruitment/selection of patients	Patients recruited over 3 years from two district general hospitals

Age, gender and ethnicity	Age - Median (range): Internal fixation: 61 (26–80) Percutaneous wiring 65 (18–80). Gender (M:F): 23/33. Ethnicity: not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear (all adults). 2. Articular involvement: Extra-articular 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=27) Intervention 1: Internal fixation - Volar/palmar plating. Volar approach. Choice of either Hand Innovations DVR-Anatomic plate and Synthes LCP T-plate. Duration remained in situ for 6 months. Concurrent medication/care: below elbow cast 6 weeks (n=29) Intervention 2: Percutaneous wiring - K-wires. Three 1.6 mm percutaneous pins. Two pins placed in the styloid process, one dorsally one volarly, the third pin placed in the most ulnar corner of the radius. Duration 6 weeks. Concurrent medication/care: below elbow plaster cast
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus K-WIRES Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 6 months; Group 1: mean 15.89 (SD 8.44); n=27, Group 2: mean 21.45 (SD 8.44); n=29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 6 months; Group 1: 0/27, Group 2: 0/29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin-site infection at 6 months; Group 1: 0/27, Group 2: 5/29; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Need for further surgery - Actual outcome for Adults (16+ years): Need for second surgical procedure at 6 months; Group 1: 0/27, Group 2: 3/29; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Number of hospital attendances/bed days

Table 94: Mclauchlan 2002[95] (Mclauchlan 2002[96])

Study (subsidiary papers)	Mclauchlan 2002[95] (Mclauchlan 2002[96])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=68)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged between 4 and 14 with completely displaced metaphyseal fracture of the distal radius with or without a fracture of the ulna
Exclusion criteria	Physeal injuries,
Recruitment/selection of patients	Recruited between May 1997and October 1999
Age, gender and ethnicity	Age - Mean (SD): 7.9 (2.7). Gender (M:F): 42/26. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Younger child (1–10 years)
Indirectness of population	No indirectness
Interventions	(n=33) Intervention 1: Conservative treatment - Plaster cast or splint. Closed reduction under general anaesthetic and image intensification followed by immobilisation in a long-arm plaster cast. Duration 4–6 weeks. Concurrent medication/care: Not reported (n=35) Intervention 2: Percutaneous wiring - K-wires. Closed reduction under general anaesthetic and image intensification followed by insertion of a single K-wire. Wire introduced across the fracture to the radial side of Lister's tubercle avoiding thee extensor tendons. Participants then immobilised in a long-arm plaster cast. Duration 4–6 weeks. Concurrent medication/care: not reported
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT	

Protocol outcome 1: Need for further surgery - Actual outcome for Children: Re-operation for an unacceptable deformity at 3 months; Group 1: 0/35, Group 2: 7/33; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Number of hospital attendances/bed days

Table 95: Mcqueen 1996[97]

Study	**Mcqueen 1996[97]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=120)
Countries and setting	Conducted in United Kingdom
Line of therapy	2nd line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Unstable distal radial fractures (defined as failure to hold a reduced position with a forearm cast of dorsal angulation ≤10 degrees and radial shortening ≤3 mm)
Exclusion criteria	Inadequate primary reduction, displacement of articular fragments requiring open reduction, previous malunion, physical or mental incapacity
Recruitment/selection of paients	Between December 191 and December 1993
Age, gender and ethnicity	Age - Mean (range): 63 (16–86). Gender (M:F): 13/107. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Conservative treatment - Plaster cast or splint. Closed reduction under general or regional anaesthesia with application of a forearm cast. Duration 6 weeks. Concurrent medication/care: not reported

	(n=30) Intervention 2: External fixation - Bridging ex-fix. Penning external fixator with two pins in the second metacarpal and two in the shaft of the radius, all inserted by an open technique (joint of fixator locked). Duration 6 weeks. Concurrent medication/care: Pin care instruction provided (n=30) Intervention 3: Internal fixation - Mixed methods of internal fixation. Open reduction and bone grafting. Transverse dorsal skin incision used. Distal radius exposed by sub-periosteal dissection ad fracture was reduced. The resulting defect in the dorsal surface was filled with a wedge of corticocancellous bone from the iliac crest held in place by a single Kirschner wire inserted diagonally across the fracture from the radial styloid. Forearm cast applied. Duration Unclear. Concurrent medication/care: not reported (n=30) Intervention 4: External fixation - Bridging ex-fix. Penning external fixator with two pins in the second metacarpal and two in the shaft of the radius, all inserted by an open technique (joint of fixator locked, then unlocked after 3 weeks in situ to allow wrist movement). Duration 6 weeks. Concurrent medication/care: Pin care instruction provided
Funding	Equipment / drugs provided by industry (Orthofix)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT

Protocol outcome 1: AE - complex regional pain syndrome
- Actual outcome for Adults (16+ years): reflex sympathetic dystrophy at 1 year; Group 1: 4/30, Group 2: 1/30; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - pin site infection
- Actual outcome for Adults (16+ years): pin-site infection at 1 year; Group 1: 7/30, Group 2: 1/30; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus PLASTER CAST OR SPLINT

Protocol outcome 1: AE - complex regional pain syndrome
- Actual outcome for Adults (16+ years): reflex sympathetic dystrophy at 1 year; Group 1: 1/30, Group 2: 1/30; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - pin site infection
- Actual outcome for Adults (16+ years): pin-site infection at 1 year; Group 1: 1/30, Group 2: 0/30; Risk of bias: Very high; Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus BRIDGING EX-FIX

Protocol outcome 1: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): reflex sympathetic dystrophy at 1 year; Group 1: 1/30, Group 2: 4/30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - pin site infection - Actual outcome for Adults (16+ years): pin-site infection at 1 year; Group 1: 1/30, Group 2: 7/30; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 96: Merchan 1992[98]

Study	**Merchan 1992[98]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=70)
Countries and setting	Conducted in Spain
Line of therapy	1st line
Duration of study	Follow up (post intervention): 1 year
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients who had sustained a comminuted distal radius fracture of types III to VIII severity (according to Frykman); these are fractures that involve the distal radiocarpal and/or radioulnar joints. Patients treated between 1988–1990.
Exclusion criteria	None reported
Recruitment/selection of patients	No details reported
Age, gender and ethnicity	Age - Range: 20–45 years. Gender (M:F): 58 men: 12 women. Ethnicity: Not reported
Further population details	1. Adults: Adults aged 16–50 (Adults aged 20–45years). 2. Articular involvement: Intra-articular (Intra-articular fractures that involve the distal radiocarpal and/or radioulnar joints). 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=35) Intervention 1: External fixation - Bridging ex-fix. A Clyburn dynamic external fixator was applied; two pins were applied to the radius diaphysis and to pins were introduced into the diaphysis of the second metacarpal. If

	instability of the radioulnar joint was detected, the forearm was supinated and the wrist viewed using fluoroscopy. If the joint was unstable, a transverse pin was inserted. All patients received a posterior plaster splint. The splint and transverse pin were removed after three weeks. Duration 7 weeks. Concurrent medication/care: Prior to fixation, fractures were reduced under general anaesthesia or brachial block. The arm was elevated overnight and the patient discharged the next day. Patients were given instructions to mobilise the fingers and shoulder; however extension was not permitted until 4 weeks (n=35) Intervention 2: Conservative treatment - Plaster cast or splint. Split forearm cast. Duration up to 7 weeks. Concurrent medication/care: Patients were given instructions to mobilise the fingers and shoulder. Comments: Length of time in cast determined by further displacement of fracture. Vague description of 7 week maximum
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Functional results (fair or poor; Stewart et al) at 7-weeks post-injury; Group 1: 7/35, Group 2: 15/35; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy syndrome at unclear; Group 1: 0/35, Group 2: 2/35; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 97: Miller 2005[99]

Study	Miller 2005[99]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=25)
Countries and setting	Conducted in USA; Setting: 25 children consented to randomisation and randomised to the two groups, nine further participants met inclusion criteria but refused randomisation and so were treated according to clinician preference. All 43 participants analysed together

Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Children
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 10 or older, skeletal immaturity, complete fracture of the distal radius metaphysis (defined as within 4 cm of the distal radial physis), angulation greater than 30 degrees or complete displacement
Exclusion criteria	Open fractures, history of injury or surgery of the affected wrist, fracture requiring open reduction, swelling or neurovascular compromise precluding circumferential cast immobilisation
Recruitment/selection of patients	Recruited between June 1995 and July 1997
Age, gender and ethnicity	Age - Mean (range): 12.4 (10–14). Gender (M:F): 31/3. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Extra-articular 3. Children: Older child/young person (11–16 years) (Aged over 10 but skeletally immature)
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Percutaneous wiring - K-wires. Reduction under general anaesthesia and fluoroscopic guidance. 0.045–0.625 inch C-wire inserted and directed proximally and ulnarly across the fracture site engaging the opposite cortex. If stability not achieved with a single wire (37.5%), a second C-wire was inserted from dorsal to volar across the fracture site through a 5–10 mm incision over the interval between fourth and fifth dorsal extensor compartments. Duration 4 weeks. Concurrent medication/care: long-arm plaster cast applied and overwrapped with fiberglass for 4 weeks, followed by a short arm cast for 2 weeks. Follow-up X-rays at 1 week, 2 weeks, 4 weeks, 6 weeks and 6 months (n=18) Intervention 2: Conservative treatment - Plaster cast or splint. Reduction under general anaesthesia and fluoroscopic guidance. Long-arm plaster cast applied and overwrapped with fiberglass for 4 weeks, followed by a short arm cast for 2 weeks. Duration 6 weeks. Concurrent medication/care: Follow-up X-rays at 1 week, 2 weeks, 4 weeks, 6 weeks and 6 months
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT

Protocol outcome 1: AE - pin site infection
- Actual outcome for Children: Pin site infection at 4 weeks; Group 1: 2/16, Group 2: 0/18; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Need for further surgery - Actual outcome for Children: Loss of reduction at 4 weeks; Group 1: 0/16, Group 2: 7/18; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 98: Moroni 2004[100]

Study	**Moroni 2004[100]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in Italy
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Female, aged>65 AP type A2 or A3, fracture due to a major trauma, ability to communicated, bone mineral density <-2.5 in the contralateral radius.
Exclusion criteria	Open fractures, fracture secondary to malignant tumour one or soft tissue infection at the fracture site, chemotherapy, multiple fractures, or systematic disease
Age, gender and ethnicity	Age - Mean (SD): Gender (M:F): 0/40. Ethnicity:
Further population details	1. Adults: Adults aged >70 2. Articular involvement: Extra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: External fixation - Bridging ex-fix. Orthofix Pennin II (Orthofix, Bussolengo, Italy) external fixator. Two 3.3–3 mm diameter HA coated screws implanted in the radius and two in the second metacarpal. The screws implanted in the radius were implanted into diaphyseal bone. All screws were implanted after pre-drilling with a 2.6 mm drill. Reduction of the fracture was performed under fluoroscopic guidance and the fixator locked. Brachial nerve block used. . Duration 6 weeks. Concurrent medication/care: Unclear

	(n=20) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction under fluoroscopic guidance and local anaesthesia with application of a forearm plaster cast positioned in flexion and ulnar deviation. Duration 6 weeks. Concurrent medication/care: Unclear
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Quality of life - Actual outcome for Adults (16+ years): SF-36 overall score at 3 months; Group 1: mean 67.1 (SD 13.2); n=20, Group 2: mean 66.2 (SD 13.1); n=20; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Need for further surgery - Actual outcome for Adults (16+ years): Re-manipulation at 3 months; Group 1: 0/20, Group 2: 4/20; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Number of hospital attendances/bed days

Table 99: Pring 1988[115]

Study	**Pring 1988[115]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=75)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Follow up (post intervention): 6 months
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	Adults (16+ years): Unclear if children included in sample
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with a displaced fracture of the distal radius
Exclusion criteria	None reported
Recruitment/selection of patients	Consecutive patients admitted to the participating hospital between 01/1985–07/1986

Age, gender and ethnicity	Age - Range of means: 59.3–64 years. Gender (M:F): 14 male, 61 female. Ethnicity: not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear (Mean age = 59.3 years, no range). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra- and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Not clear if children included in the sample)
Indirectness of population	No indirectness
Interventions	(n=36) Intervention 1: External fixation - Bridging ex-fix. Bipolar fixation, as described by Rauis et al. (1979), with modifications; two percutaneous half pins were aseptically drilled through both cortices of the radius and a third pin inserted through the metacarpal of the thumb at a plane of 90 degrees to the radial pins with thumb widely abducted. A padded forearm cast was applied that incorporated the pins. Duration 5 weeks. Concurrent medication/care: Infiltration of the fracture haematoma with local anaesthetic. Reduction was achieved using controlled traction (chines finger traps). Following fixation, the wrist was immobilised in a functional position. Early function of the hand was encouraged, and all patients attended daily physiotherapy before and after cast removal (n=39) Intervention 2: Conservative treatment - Plaster cast or splint. Forearm plaster cast. Duration 5 weeks. Concurrent medication/care: Infiltration of the fracture haematoma with local anaesthetic. Reduction was achieved using controlled traction (chines finger traps). Following fixation, the wrist was immobilised in a functional position. Early function of the hand was encouraged, and all patients attended daily physiotherapy before and after cast removal
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Need for further surgery - Actual outcome for Adults (16+ years): Re-manipulation at 6-months; Group 1: 0/36, Group 2: 9/39; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Number of hospital attendances/bed days

Table 100: Rodriguez-merchan 1997[121]

Study	**Rodriguez-merchan 1997[121]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)

Countries and setting	Conducted in Spain
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Unstable (Frykman II-VIII) distal radius fracture as a result of a fall. Fractures considered unstable if dorsal angulation>10 degrees and/or radial shortening >3 mm
Exclusion criteria	not reported
Recruitment/selection of patients	Participants recruited between January 1992 and December 1994
Age, gender and ethnicity	Age - Mean (range): 58 (46–65). Gender (M:F): 6/14. Ethnicity:
Further population details	1. Adults: Adults aged 50–70 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Percutaneous wiring - K-wires. Under either general anaesthesia or brachial nerve block closed reduction of the fracture followed by percutaneous fixation with k-wires under fluoroscopic guidance. Two 0.45 mm k-wires inserted from the radial styloid proximally toward the ulna then an additional k-wire inserted from the ulnar side of the radius proximally toward the radius. Placement of wires checked with X-ray. Duration 7 weeks. Concurrent medication/care: Forearm plaster cast applied. Patient admitted for arm elevation overnight and discharged the following day (n=20) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction of the fracture under local anaesthetic and application of a split below-elbow cast. Duration 7 weeks. Concurrent medication/care: Check X-rays following procedure identified some displacement of the intra-articular aspect of the radius in every case. Patients were instructed to mobilise their fingers and discharged home after the radiographic examination
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT

Protocol outcome 1: Hand and wrist function
- Actual outcome for Adults (16+ years): Horne et al. scoring - fair or poor (9-15) at 7 weeks; Group 1: 2/20, Group 2: 9/20; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy syndrome at 7 weeks; Group 1: 1/20, Group 2: 1/20; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 7 weeks; Group 1: 2/20, Group 2: 0/20; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Need for further surgery - Actual outcome for Adults (16+ years): Re-operation due to loss of reduction at 1 week; Group 1: 0/20, Group 2: 15/20; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Number of hospital attendances/bed days

Table 101: Roh 2015[122]

Study	**Roh 2015[122]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=74)
Countries and setting	Conducted in South Korea; Setting: Tertiary care university hospital
Line of therapy	1st line
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	AO type C2 or C3 DRFs confirmed by CT; age <70 years; treated <2 weeks post injury
Exclusion criteria	Systemic, multiorgan, or head injuries; concomitant wrist or upper extremity injuries; bilateral fractures; open fractures or associated nerve lesions
Recruitment/selection of patients	Unclear but probably consecutive
Age, gender and ethnicity	Age - Range of means: 54.4 and 55.3. Gender (M:F): 30:15. Ethnicity: Korean
Further population details	1. Adults: Adults aged 15-70 2. Articular involvement: intra-articular 3. Children: Not applicable

Study	Roh 2015[122]
Indirectness of population	No indirectness
Interventions	(n=48) Intervention 1: Internal fixation - Volar/palmar plating. Performed through FCR approach. Short arm orthosis for 2 weeks. (n=62) Intervention 2: External fixation Closed or limited open reduction used with image intensification. Short arm orthosis for 2 weeks.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus MIXED METHODS OF EXTERNAL FIXATION Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Michigan hand questionnaire score score - ; Group 1: 81 (sd 15) post surgery , Group 2: 79 (sd 14) post surgery; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome at Define - Actual outcome for Adults (16+ years): Number with complex regional pain syndrome at post surgery; Group 1: 1/36, Group 2: 1/38; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: AE – pin site infection - Actual outcome for Adults (16+ years): pin site infection or superficial wound infection; Group 1: 1/36, Group 2: 3/38; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life at Define; Patient outcomes – pain; Patient outcomes - return to normal activities at Define; Patient outcomes - psychological wellbeing at Define; AE - post traumatic osteoarthritis at Define; AE - pin site infection at Define; Need for revision surgery at Define; Need for further surgery at Define; Number of hospital attendances/bed days at Define; Radiological measures at Define

Table 102: Roumen 1991[123]

Study	Roumen 1991[123]
Study type	RCT (Patient randomised; Parallel)

Number of studies (number of participants)	1 (n=43)
Countries and setting	Conducted in Netherlands
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Displaced Colles' fracture sustained in a simple fall that on closed reduction and plaster immobilisation had dorsal angulation of more than 10 degrees and radial shortening of more than 5 mm at check-up within 2 weeks of injury
Exclusion criteria	not reported
Age, gender and ethnicity	Age - Mean (SD): not reported. Gender (M:F): not reported. Ethnicity:
Further population details	1. Adults: Adults aged 50–70. 2. Articular involvement: Not applicable/Not stated/Unclear 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: External fixation - Bridging ex-fix. ACE Colles fixator applied after re-manipulation under general anaesthetic within 2 weeks of injury. Duration 5 weeks. Concurrent medication/care: not reported (n=22) Intervention 2: Conservative treatment - Plaster cast or splint. Fracture manipulated under local anaesthetic and stabilised in a plaster backslab. Duration 5 weeks. Concurrent medication/care: not reported
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Lidstrom classification - fair or poor at 6 months; Group 1: 9/21, Group 2: 3/22; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 6 months; Group 1: 4/21, Group 2: 2/22; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - pin site infection; Need for further surgery; Need for

	further surgery; Number of hospital attendances/bed days

Table 103: Rozental 2009[124]

Study	Rozental 2009[124]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in USA
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 18 years or over, living and functioning independently, dorsally displaced extra-articular fracture or simple intra-articular fracture with a single split between the scaphoid and lunate facets, isolated injury, substantial initial displacement, inadequate initial reduction or loss of reduction within 3 weeks after injury as defined by one or more of the following: >20 degrees of dorsal angulation of the articular surface on lateral X-ray view, >100% loss of apposition, >5 mm of shortening by ulnar variance on the posteroanterior radiographic view, both dorsal and volar comminution
Exclusion criteria	Multiple trauma or other injuries, patients who rely on others for basic activities, volarly displaced fractures (Smith and AO type B fractures), complex articular fractures with more than a sagittal split between the scaphoid and lunate facets or articular depression, open fractures, fractures associated with neurovascular injury, associated injuries that inhibit the ability to a participate in a structured rehabilitation program, associated musculoskeletal injuries to the same arm, inflammatory arthritis
Recruitment/selection of patients	Patients recruited between February 2006 and September 2007
Age, gender and ethnicity	Age - Mean (range): 51 (19–79). Gender (M:F): 11/34. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear (Adults aged 19–79). 2. Articular involvement: Not applicable/Not stated/Unclear (both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults only).
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Percutaneous wiring - K-wires. 1.6 mm Kirschner wire placed through a small stab incision obliquely through the radial styloid, two additional wires placed in a similar fashion along the ulnar aspect of the ulnar

	aspect of the distal radius. Duration 6 weeks. Concurrent medication/care: Reduction under fluoroscopic guidance with ligamentotaxis. Below elbow cast applied until removal of wires. Standardised outpatient occupational therapy commenced at 6 weeks (n=23) Intervention 2: Internal fixation - Volar/palmar plating. VLS plate (Wright Medical) or DVR plate (Hand innovation) used, with choice of implant left at discretion of operating surgeon. No bone grafting used. Duration remained in situ. Concurrent medication/care: Reduction and verification of placement of hardware under fluoroscopic guidance. Volar plaster splint for one week, then transferred to Orthoplast custom made splint with standardised outpatient occupational therapy commenced at 1 week.
Funding	Other author(s) funded by industry (Wright Medical)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus VOLAR/PALMAR PLATING Protocol outcome 1: Patient outcomes - return to normal activities - Actual outcome for Adults (16+ years): Return to work at 1 year; Group 1: mean 26 days (SD 27); n=21, Group 2: mean 17 days (SD 21); n=21; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 1 year; Group 1: mean 9 (SD 18); n=21, Group 2: mean 4 (SD 8); n=21; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 1 year; Group 1: 3/21, Group 2: 0/21; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 104: Shankar 1992[130]

Study	**Shankar 1992[130]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in United Kingdom

Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Distal radial fractures, Frykman types IV-VIII
Exclusion criteria	none recorded
Age, gender and ethnicity	Age - Range: 17–88. Gender (M:F): 5/40. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Percutaneous wiring - K-wires. Two percutaneous Kirschner wires 1.6 mm thickness inserted from the radial side across the inferior radioulnar joint. Pins driven into the medial cortex of the ulna and were trimmed to 1.5 cm from the skin then held in a plaster cast in slight ulnar deviation and palmar flexion. Duration 5–6 weeks. Concurrent medication/care: Patients admitted overnight for limb elevation. Procedure under image intensifier control and general anaesthetic. Check X-ray performed at 1 week and fracture re-manipulated if necessary. Plaster cast in situ for 5–6 weeks (n=23) Intervention 2: Conservative treatment - Plaster cast or splint. Plaster cast applied in classical Colles' position - slight palmar flexion, ulnar deviation and pronation. Duration 5–6 weeks. Concurrent medication/care: Patients admitted overnight for limb elevation. Procedure under image intensifier control and general anaesthetic. Check X-ray performed at 1 week and fracture re-manipulated if necessary. Plaster cast in situ for 5–6 weeks
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT

Protocol outcome 1: Hand and wrist function
- Actual outcome for Adults (16+ years): McBride system of evaluation of Colles' fracture (Score >10 poor) at 6 months; Group 1: 4/23, Group 2: 10/22; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - complex regional pain syndrome
- Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 6 months; Group 1: 0/23, Group 2: 1/22; Risk of bias: Very high; Indirectness of outcome: No

indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Pin site infection at 6 months; Group 1: 1/23, Group 2: 0/22; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 105: Shukla 2014[133]

Study	**Shukla 2014[133]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=110)
Countries and setting	Conducted in India; Setting: Institutre of medical sciences in India
Line of therapy	1st line
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	>18 years; no other skeletal injuries; Cooney's type IV fracture
Exclusion criteria	bilateral distal radius fractures; open fractures of distal radius; associated head injury
Recruitment/selection of patients	Unclear but probably consecutive
Age, gender and ethnicity	Age - Range of means: 39.33 and 38.95. Gender (M:F): 49:61. Ethnicity:
Further population details	1. Adults: Adults aged 16-50 2. Articular involvement: Not applicable / Not stated / Unclear 3. Children: Not applicable / Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=48) Intervention 1: Internal fixation - Volar/palmar plating. Skin incised longitudinally along course of the flexor carpi radialis tendon. Duration NA. Concurrent medication/care: Discharged home 2 days post surgery (n=62) Intervention 2: External fixation - Mixed methods of external fixation. Used two 2.5 mm Schanz pins in the 2nd MC and two 3.5mm pins in the radius proximal to the fracture. Duration NA. Concurrent medication/care: Below elbow POP applied for 1 weeek

Study	Shukla 2014[133]
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus MIXED METHODS OF EXTERNAL FIXATION Protocol outcome 1: Patient outcomes - Pain at Define - Actual outcome for Adults (16+ years): Pain score at 6 months; Group 1: mean 21.22 (SD 3.71); n=48, Group 2: mean 19.91 (SD 4.6); n=62; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): Pain score at 12 months; Group 1: mean 21.33 (SD 3.5); n=48, Group 2: mean 22.36 (SD 2.86); n=62; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function at Define - Actual outcome for Adults (16+ years): Green and O'Brien score - excellent/good versus not at 12 months; Group 1: 35/48, Group 2: 53/62; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Adults (16+ years): Green and O'Brien score - excellent/good versus not at 6 months; Risk of bias: ; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome at Define - Actual outcome for Adults (16+ years): Number with complex regional pain syndrome at <2 months; Group 1: 1/48, Group 2: 0/62; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life at Define; Patient outcomes - return to normal activities at Define; Patient outcomes - psychological wellbeing at Define; AE - post traumatic osteoarthritis at Define; AE - pin site infection at Define; Need for revision surgery at Define; Need for further surgery at Define; Number of hospital attendances/bed days at Define; Radiological measures at Define

Table 106: Stoffelen 1998[139] (Stoffelen 1999[140])

Study (subsidiary papers)	Stoffelen 1998[139] (Stoffelen 1999[140])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=98)
Countries and setting	Conducted in Belgium
Line of therapy	1st line

Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Frykman type I and type II fractures
Exclusion criteria	Bilateral fractures, severe injuries to the ipsi- or contralateral extremity and multiple injuries, people older than 80 years of age or children
Age, gender and ethnicity	Age - Mean (SD): K-wire fixation 60 years; Plaster cast immobilisation 55.8 years. Gender (M:F): K-wire fixation 42/6 Plaster cast immobilisation 15/35. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Extra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=48) Intervention 1: Percutaneous wiring - K-wires. Triple intra-focal Kapandji-pinning was used and a plaster applied for 1 week until pain subsided. Duration unclear. Concurrent medication/care: not reported (n=50) Intervention 2: Conservative treatment - Plaster cast or splint. Above elbow plaster cast applied for 3 weeks followed by 3 weeks in a below elbow cast. Duration 6 weeks. Concurrent medication/care: not reported
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Improvement in function - Cooney modification of Green & O'Brien Score at 1 year; Group 1: mean 19 (SD 37.4); n=48, Group 2: mean 34 (SD 37.4); n=50; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 107: ur Rahman 2012[144]

Study	**Ur 2012[144]**

Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=60)
Countries and setting	Conducted in Pakistan
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age >30 years, unstable intra-articular distal radial fracture
Exclusion criteria	Presenting >1 week post injury, open fracture, associated fractures
Recruitment/selection of patients	Recruitment between March and August 2007
Age, gender and ethnicity	Age - Mean (SD): 42.7 (7). Gender (M:F): 38/22. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: External fixation - Bridging ex-fix. AO external fixator applied. Two to three schanz pins inserted proximal to the fracture site in the radius while two pins were inserted at the base and shaft of the 2nd metacarpal. Closed reduction of the fracture performed under image intensifier and post-operative radiographs were taken to ensure proper alignment and reduction. Check X-ray at 2 weeks performed to ensure reduction maintained. Duration 6 weeks. Concurrent medication/care: Oral antibiotics 10 days (n=30) Intervention 2: Conservative treatment - Plaster cast or splint. Closed reduction of fracture under sedation and haematoma block in the emergency room. Above-elbow POP cast applied. Duration 6 weeks. Concurrent medication/care: Not reported
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus PLASTER CAST OR SPLINT Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Completely pain free at 3 months; Group 1: 13/30, Group 2: 2/30; Risk of bias: Very high; Indirectness of outcome: No indirectness	

Protocol outcome 2: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 3 months; Group 1: 2/30, Group 2: 3/30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: AE - pin site infection - Actual outcome for Adults (16+ years): Superficial pin-site infection (resolved with oral antibiotics) at 3 months; Group 1: 3/30, Group 2: 0/30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 4: Need for further surgery - Actual outcome for Adults (16+ years): Re-operation due to loss of reduction at 3 months; Group 1: 2/30, Group 2: 18/30; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Hand and wrist function; AE - post traumatic osteoarthritis; Need for further surgery; Number of hospital attendances/bed days

Table 108: Wei 2009[150]

Study	**Wei 2009[150]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in USA
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients aged >18 years and had an unstable distal radial fracture (deemed unstable if they had displaced after initial treatment with closed reduction and splinting or if three of the following criteria were met: (i) dorsal angulation of >20 degrees; (ii) dorsal comminution; (iii) an intra-articular fracture; (iv) an associated ulnar styloid fracture or (v) an age of >60 years)
Exclusion criteria	Patients with an OTA class-B fracture (partial articular), considerable pre-existing arthritis of the hand or wrist that limited grasp, an open or bilateral fracture, a concomitant ulnar shaft fracture, or prior trauma to either hand

Age, gender and ethnicity	Age mean = 58 years (17). Gender (M:F): 13/33. Ethnicity: Not reported
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	None
Interventions	(n=12) Intervention 1: Internal fixation - Mixed methods of internal fixation. Radial column plate. Duration Unclear. Concurrent medication/care: Volar splint for comfort, instructions to immediately begin finger motion and strengthening exercises starting 10 to 14 days post-operatively (n=22) Intervention 2: External fixation - Bridging ex-fix. Intrafocal fracture pinning under fluoroscopic guidance followed by stabilization of fracture fragments with placement of K-wires, usually subchondral or transradial styloid. Two pins then placed in the index metacarpal and two placed in the distal radial shaft before a bridging external fixator applied (Hoffmann II Compact: Stryker). Duration 5–6 weeks. Concurrent medication/care: Instructed on pin care and provided with physiotherapy at 5–6 weeks on removal of external-fixator (n=12) Intervention 3: Internal fixation - Volar/palmar plating. Precontoured locked volar plate (EBI optiLock, Parsippany, New Jersey) inserted via modified Henry approach. Duration Unclear. Concurrent medication/care: Volar splint for comfort, instructions to immediately begin finger motion and strengthening exercises starting 10 to 14 days post-operatively
Funding	Academic or government funding (Doris Duke Clinical Research Fund)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus BRIDGING EX-FIX Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain (VAS 0–10) at 12 months; Group 1: mean 1.8 (SD 1.8); n=9, Group 2: mean 1.8 (SD 1.3); n=17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): DASH score at 1 year; Group 1: mean 4 (SD 5); n=12, Group 2: mean 18 (SD 14); n=22; DASH 0-100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 109: Wilcke 2011[153]

Study	Wilcke 2011[153]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=63)
Countries and setting	Conducted in Sweden
Line of therapy	1st line
Duration of study	Intervention and follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Stratified then randomised: Age under 50 and over 50
Inclusion criteria	Age 20–70 years, acute unilateral dorsally displaced fracture of the distal radius (AO classification extra-articular A and C1 with only one intra-articular fracture line, axial shortening of ≥4 mm, or a dorsal angulation of ≥20 degrees), no previous fracture of either wrist
Exclusion criteria	Concurrent upper limb fracture, warfarin use, open fracture, fracture not amenable to both fixation methods (distal fragment too small i.e. <10 mm volar cortex or too comminuted) inability to cooperate with follow-up (dementia, substance abuse, language barriers)
Recruitment/selection of patients	Patients recruited from January 2006 to May 20008
Age, gender and ethnicity	Age - Mean (range): 55.5 (20–69). Gender (M:F): 15/48. Ethnicity: not reported
Further population details	1. Adults: 2. Articular involvement: Not applicable/Not stated/Unclear (both intra-articular and extra-articular). 3. Children: Not applicable/Not stated/Unclear (adults only)
Indirectness of population	No indirectness
Interventions	(n=33) Intervention 1: Internal fixation - Volar/palmar plating. Volar locked plate with 4 optional distal locked screws without use of cancelous bone graft. Volar flexor carpi radialis approach. Duration unclear when/whether metalwork removed. Concurrent medication/care: Dorsal below-elbow cast 10–12 days (n=30) Intervention 2: External fixation - Bridging ex-fix. Hoffman device (Stryker) using 2 pins in the second metacarpal and 2 pins in the proximal radius. Fluoroscopy guided with supplementary k-wires used at surgeon's discretion. Duration 5 weeks. Concurrent medication/care: External fixation likely to be performed by less experienced surgeons than internal fixation. Bandaging not specified

Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: VOLAR/PALMAR PLATING versus BRIDGING EX-FIX Protocol outcome 1: Hand and wrist function - Actual outcome for Adults (16+ years): Patient-rated wrist evaluation (PRWE) at 1 year; Group 1: mean 11 (SD 14.101); n=33, Group 2: mean 15 (SD 16.0683); n=30; PRWE score 0–100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: AE - pin site infection - Actual outcome for Adults (16+ years): Pin tract infection at 12 months; Group 1: 0/33, Group 2: 4/30; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Need for further surgery - Actual outcome for Adults (16+ years): Need for further surgery (all) at 12 months; Group 1: 3/33, Group 2: 2/30; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; Need for further surgery; Number of hospital attendances/bed days

Table 110: Williksen 2013[155]

Study	**Williksen 2013[155]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=114)
Countries and setting	Conducted in Norway
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged >18 years, AO type A or C fracture, >10 degrees dorsal tilt, >3 mm shortening, >1 mm intra-articular step-off, dorsal comminution

Exclusion criteria	Medical contraindications, open fractures, concomitant injuries making outcomes difficult to evaluate, bilateral fractures, previous injuries, diseases in the fracture wrist, language problems, fractures older than 10 days, AO type B fractures
Recruitment/selection of patients	Patients recruited between November 2007 and June 2009
Age, gender and ethnicity	Age - Mean (range): 54 (20–84). Gender (M:F): 22/89. Ethnicity:
Further population details	1. Adults: Adults aged 16–50 (Adults aged 20–84). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular fractures). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: External fixation - Bridging ex-fix. Hoffman II external fixator (Stryker, Switzerland) used in 57 cases and an external distal radius fixator (Synthes, Switzerland) used in 2 cases. Two pins introduced into the second metacarpal by stab incision and 2 pins in the radius through a 2–4 cm incision. Three adjuvant Steinmann 1.8 mm pins used in all cases. Duration 6 weeks. Concurrent medication/care: not reported (n=54) Intervention 2: Internal fixation - Volar/palmar plating. Volar locking plate, three different plates used (Acumed Acu-Loc = 28, Syntehs 2.4 LCP Distal Radius System = 18, Hand Innovation DVR = 6). Duration remained in situ. Concurrent medication/care: Dorsal plaster cast used for 2 weeks
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRIDGING EX-FIX versus VOLAR/PALMAR PLATING Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Pain at rest at 1 year; Group 1: mean 0.1 mm (SD 0.81); n=54, Group 2: mean 0.3 mm (SD 0.81); n=50; Visual analogue scale 0–100 Top=High is poor outcome; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): MAYO score at 1 year; Group 1: mean 85 (SD 14.8); n=54, Group 2: mean 90 (SD 14.8); n=50; MAYO score 0–100 Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Complex regional pain syndrome at 1 year; Group 1: 4/59, Group 2: 2/52; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): Pin infection at 1 year; Group 1: 6/59, Group 2: 0/52; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post

	traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 111: Wong 2010[156]

Study	Wong 2010[156]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=60)
Countries and setting	Conducted in Hong Kong (China)
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 65 or over, unstable (dorsal angulation >20 degrees, radial shortening >5 mm) dorsally angulated extra-articular fracture of the distal radius
Exclusion criteria	Intra-articular fractures, open fractures, concomitant fractures elsewhere, palmar angulated fractures, minimally displaced fractures, fractures with dorsal tilting <20 degrees, fractures more than 2 weeks old, patients with dementia or psychiatric illness
Recruitment/selection of patients	Patients recruited between July 2006 and July 2007
Age, gender and ethnicity	Age - Mean (range): 71 (65–76). Gender (M:F): 11/49. Ethnicity: not reported
Further population details	1. Adults: Adults aged >70 (Adults aged >64). 2. Articular involvement: Extra-articular 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Conservative treatment - Plaster cast or splint. Fracture reduced under haematoma-block. No fluoroscopic guidance - pre and post reduction plain X-ray films obtained. Below-elbow plaster cast applied under haematoma block without fluoroscopic guidance. Duration 6 weeks. Concurrent medication/care: Fracture reduced under haematoma-block. No fluoroscopic guidance - pre and post reduction plain X-ray films obtained (n=30) Intervention 2: Percutaneous wiring - K-wires. Procedure performed under Bier's block. Prophylactic antibiotic (Cefazolin) delivered prior to procedure to prevent pin tract infection. Three percutaneous K-wires inserted under

	fluoroscopic guidance through three small stab incisions. One 1.5 mm wire inserted via the dorso-radial side of the distal radius through the radial styloid process, directed obliquely to fix the fracture and was anchored in the far cortex, the second 1.5 mm wire was inserted from the dorso-ulnar side of the distal radius directed obliquely to fix the fracture and was anchored in the palmar cortex, the third 1.5 mm wire was inserted from the palmar radial side of the distal radius and directed dorsally to anchor in the proximal dorsal cortex. Duration 6 weeks. Concurrent medication/care: not reported
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: K-WIRES versus PLASTER CAST OR SPLINT Protocol outcome 1: Quality of life - Actual outcome for Adults (16+ years): WHOQoL at 1 year; Group 1: mean 3.7 (SD 0.7); n=30, Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Mayo Score (0-100) at 1 year; Group 1: mean 82.2 (SD 6.2); n=30, Group 2: mean 80.5 (SD 7.5); n=30; Mayo scale 0-100 Top=--; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): complex regional pain syndrome at 1 year; Group 1: 0/30, Group 2: 1/30; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 1 year; Group 1: 1/30, Group 2: 0/30; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 112: Xu 2009[158]

Study	**Xu 2009[158]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=35)
Countries and setting	Conducted in Singapore

Line of therapy	2nd line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 16 to 60 years, AO type C fractures initially managed with closed reduction, either failing to achieve adequate reduction on first manipulation or de-displacing within 2 weeks
Exclusion criteria	Premature menopause, drug/alcohol abuse, skeletal immaturity, sever open or delayed open fracture where ORIF is contraindicated, Isolated radial styloid or volar baron's fracture
Recruitment/selection of patients	Recruited between December 2003 and September 2005
Age, gender and ethnicity	Age - Mean (range): 43.43 (21–56). Gender (M:F): 18/12. Ethnicity:
Further population details	1. Adults: Not applicable/Not stated/Unclear 2. Articular involvement: Intra-articular 3. Children: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Internal fixation - Mixed methods of internal fixation. Plates used 3.5 mm AO T or oblique plates and a volar, dorsal or volar/dorsal approach used. Duration 3–24 months. Concurrent medication/care: Bone grafting, open reduction, k-wiring and use of fluoroscopy used at the surgeons discretion (n=14) Intervention 2: External fixation - Mixed methods of external fixation. External fixator (no other details). Duration 3-24 months. Concurrent medication/care: Bone grafting, open reduction, k-wiring and use of fluoroscopy used at the surgeons discretion
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MIXED METHODS OF INTERNAL FIXATION versus MIXED METHODS OF EXTERNAL FIXATION

Protocol outcome 1: Hand and wrist function
- Actual outcome for Adults (16+ years): Gartland and Werley Score at 1 year; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for Adults (16+ years): Green & O'Brien Score at 1 year; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 2: AE - post traumatic osteoarthritis
- Actual outcome for Adults (16+ years): Knirk and Jupiter post-traumatic OA grade 1 (radiological) at 2 years; Group 1: 4/16, Group 2: 4/14; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 3: AE - complex regional pain syndrome - Actual outcome for Adults (16+ years): Reflex sympathetic dystrophy at 1 year; Group 1: 0/16, Group 2: 0/14; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: AE - pin site infection - Actual outcome for Adults (16+ years): pin site infection at 1 year; Group 1: 0/16, Group 2: 0/14; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - Pain; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

Table 113: Young 2003[159]

Study	**Young 2003[159]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=125)
Countries and setting	Conducted in United Kingdom
Line of therapy	1st line
Duration of study	Intervention and follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults (16+ years)
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 16–75 years, dorsally angulated fracture of the distal radius which required manipulative reduction (greater than 10 degrees dorsal angulation or greater than 2 mm radial shortening)
Exclusion criteria	Bilateral fractures, ipsilateral limb injuries, die punch fractures
Age, gender and ethnicity	Age - Median (range): conservative treatment 60 (24–75) external fixator 54 (21–73). Gender (M:F): 28/97. Ethnicity:
Further population details	1. Adults: Adults aged 16–50 (Adults aged 16–75). 2. Articular involvement: Not applicable/Not stated/Unclear (Both intra and extra-articular). 3. Children: Not applicable/Not stated/Unclear (Adults only)
Indirectness of population	No indirectness
Interventions	(n=66) Intervention 1: Conservative treatment - Plaster cast or splint. Dorsal plaster slab converted to a complete below-elbow cast at 1 week if fracture position still satisfactory. Duration 6 weeks. Concurrent medication/care: Reduction under general or regional anaesthesia (use of fluoroscopy not specified)

	(n=59) Intervention 2: External fixation - Bridging ex-fix. Primary bridging external fixator (Penning fixator, Orthofix, Maidenhead, UK). Duration 6 weeks. Concurrent medication/care: Reduction under general anaesthetic (use of fluoroscopy not specified)
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PLASTER CAST OR SPLINT versus BRIDGING EX-FIX Protocol outcome 1: Patient outcomes - Pain - Actual outcome for Adults (16+ years): Persistent pain at 7 years; Group 1: 10/49, Group 2: 6/36; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Hand and wrist function - Actual outcome for Adults (16+ years): Gartland and Werley score >9 (poor or fair) at 7 years; Group 1: 2/49, Group 2: 2/36; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient outcomes - return to normal activities; Patient outcomes - psychological wellbeing; AE - post traumatic osteoarthritis; AE - complex regional pain syndrome; AE - pin site infection; Need for further surgery; Need for further surgery; Number of hospital attendances/bed days

G.4.3 Definitive treatment - humerus facture

Table 114: Boons 2012[19]

Study	Boons 2012[19]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Netherlands; Setting: Orthopaedic Department, Rijnstate Hospital, Arnhem
Line of therapy	1st line
Duration of study	Intervention and follow up: 5 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients 65 years or older who had displaced proximal humeral four-part fractures. The diagnosis of a four-part

	humeral fracture was made from an AP view, a lateral shoulder view in the scapular plane, and an axillary radiograph according to Neer's criteria.
Exclusion criteria	We excluded patients with the following conditions: (1) pre-existing mental disorders or who were unable to provide informed consent or answer the questionnaires; (2) disabling disorder or additional trauma to the affected arm; (3) pathologic or open fractures; (4) associated neurovascular injury; (5) pre-existing impairment of the contralateral shoulder (we compared maximal function and strength with those of the unaffected shoulder; (6) unable to understand the Dutch language; (7) unable to participate in the rehabilitation protocol; and (8) contraindicated for surgery (American Society of Anaesthesiologists [ASA] Physical Status I–III).
Age, gender and ethnicity	Age - Mean (SD): 78.15 (6.6). Gender (M:F): 1:18. Ethnicity:
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Operative - Hemiarthroplasty. Deltopectoral approach was used in all patients, we used the Global1 FX shoulder fracture endoprosthesis (DePuy, Leeds, UK). Care was taken to restore stem height and retroversion with the medial calcar and bicipital groove as landmarks for correct tuberosity alignment. Three drill holes were made in the humeral shaft and loaded with three Number 5.0 Ethibond1 (Ethicon, Inc, Somerville, NJ, USA) no absorbable sutures. All endoprostheses were cemented after application of Biostop1 (DePuy) with Palamed1 G gentamicin cement (Heraeus Medical GmbH, Wehrheim, Germany) using a cement gun.. Duration 12 Months. Concurrent medication/care: A standard procedure was performed by two experienced shoulder surgeons from the institution. Patients received general anaesthesia and were placed in the beach chair position. A prophylactic antibiotics regimen of 2g systemic cefazolin was administered in all cases. Experienced shoulder physical therapists instructed the patients for 40-minute sessions three times a week up to 12 weeks. Every patient started with a shoulder immobilizer for 2 weeks postoperatively or post-trauma with light passive ROM movements. (n=25) Intervention 2: Conservative - Immobilisation in arm sling. Wore a shoulder immobilizer for 6 weeks. Duration 12 Months. Concurrent medication/care: Experienced shoulder physical therapists instructed the patients for 40-minute sessions three times a week up to 12 weeks. Every patient started with a shoulder immobilizer for 2 weeks postoperatively or post trauma with light passive ROM movements.
Funding	Other (Funded by Industry)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HEMIARTHROPLASTY versus IMMOBILISATION IN ARM SLING

Protocol outcome 1: Mortality
- Actual outcome: Mortality at 12 Months; Group 1: 1/24, Group 2: 0/24; Risk of bias: Low; Indirectness of outcome: No indirectness

Protocol outcome 2: Functional score (DASH/Constant)

- Actual outcome: Constant Score at 12 Months; Group 1: mean 64 (SD 15.8); n=23, Group 2: mean 60 (SD 17.6); n=24; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: Adverse effects - Infection - Actual outcome: Infection at 12 Months; Group 1: 0/25, Group 2: 0/25; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 4: Adverse effects - Need for further/operative treatment - Actual outcome: Need for further operation at 12 Months; Group 1: 1/25, Group 2: 1/25; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Quality of life; Adverse effects - Nerve damage; Adverse effects - Avascular necrosis; Return to normal activity

Table 115: Cai 2012[25]

Study	**Cai 2012[25]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=32)
Countries and setting	Conducted in China; Setting: Orthopaedic Hospital, China
Line of therapy	1st line
Duration of study	Intervention and follow up: 5 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	The fracture inclusion criteria, based on conventional radiographs and computed tomography, were displacement of the shaft of more than 10 mm and/or more than 45° of angulation in relation to the head fragment, combined with a displacement of the greater or lesser tubercle of more than 10 mm in relation to the head fragment.
Exclusion criteria	A minimally displaced or non-displaced fracture of the other tubercle that did not meet Neer criteria to be considered a separate fracture segment was not considered to be an exclusion criterion. Patients with a completely displaced shaft in relation to the head fragment, such as a fracture without bony contact, were considered to have an absolute indication for surgery and, therefore, were not included, nor were patients with a valgus impact fracture.
Age, gender and ethnicity	Age - Median (range): 71.9 (67–86). Gender (M:F): 1:4. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Operative - Hemiarthroplasty. The Hemiarthroplasty prosthesis (DePuy, Warsaw, Indiana) was

Study	Cai 2012[25]
	used in the shoulder Hemiarthroplasty group. Surgery was performed in the beach-chair position on the edge of the table, with the operated arm positioned over the edge. A deltopectoral approach was used in all patients without detaching the anterior deltoid and the upper third of the pectoralis major. Duration 2 Years. Concurrent medication/care: Postoperatively, the arm was placed in a sling, and all patients were referred to physiotherapy. The sling was used for 4 weeks, after which patients were allowed to use it at their own convenience. Pendulum exercises and passive elevation/ abduction up to 90° were started on postoperative day 1. After 4 weeks, the patients were allowed free active range of motion. (n=13) Intervention 2: Operative - Open reduction and plating. The Philos plate (Synthes, Stockholm, Sweden). The plate is anatomically shaped and is recommended to be placed at least 8 mm distal to the upper end of the greater tubercle (rotator cuff insertion) and slightly dorsal to the long head of the biceps. Duration 2 Years. Concurrent medication/care: Postoperatively, the arm was placed in a sling, and all patients were referred to physiotherapy. The sling was used for 4 weeks, after which patients were allowed to use it at their own convenience. Pendulum exercises and passive elevation/ abduction up to 90° were started on postoperative day 1. After 4 weeks, the patients were allowed free active range of motion.
Funding	Academic or government funding (National Science Foundation for Distinguished Young Scholars of China, The Research Fund for the Doctoral Programme of Higher Education and The Bureau of Public Health of Shanghai, China)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HEMIARTHROPLASTY versus OPEN REDUCTION AND PLATING Protocol outcome 1: Mortality - Actual outcome: Mortality at 2 Years; Group 1: 1/16, Group 2: 0/12; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Quality of life - Actual outcome: EQ-5D at 2 Years; Group 1: mean 0.81 (SD 0.17); n=15, Group 2: mean 0.74 (SD 0.26); n=12; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Adverse effects - Need for further/operative treatment - Actual outcome: Need for additional surgery at 2 Years; Group 1: 3/19, Group 2: 3/13; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Functional score (DASH/Constant); Adverse effects - Avascular necrosis; Adverse effects - Nerve damage; Adverse effects - Infection; Return to normal activity

Table 116: Fjalestad 2014a[41]; Fjalestad 2012[40]

Study	Fjalestad 2014a[41]; Fjalestad 2012[40]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Norway; Setting: University Hospital, Oslo
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 Years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients aged 60+ years with a displaced, unstable three or four-part proximal humerus fracture of OTA group 11-B2 or 11-C2 (displaced fracture of extra-articular or articular, bifocal type) were included in this study. The subgroups 1, 2, and 3 were included for both B2 and C2 groups if the fracture was severely displaced. Severe displacement was defined as malposition of at least 45 angular deviation in true frontal or transthoracic radiographic projections regardless of whether or not the fracture was impacted. The greater or lesser tuberosity had to be displaced at least 10 mm. Furthermore, the displacement between the head and metaphyseal main fragments could not exceed 50% of the diaphyseal diameter.
Exclusion criteria	Exclusion criteria were: 1) younger than 60 years old; 2) history of injury or illness of the injured or contralateral shoulder; 3) injuries of other parts of the humerus or the contralateral upper extremity; 4) alcohol or drug abuse; 5) dementia; 6) neurologic diseases; or 7) severe cardiovascular diseases that would contraindicate surgery. Patients of non- Scandinavian ethnicity were also excluded to reduce possible bias from differences in bone mineral content given the high incidence of osteoporosis in Scandinavians.
Age, gender and ethnicity	Age - Mean (range): 75.7 (60–86). Gender (M:F): 1:5. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Operative - Open reduction and plating. Surgery was performed using a 10-cm deltoid–pectoral approach with additional percutaneous techniques as needed. Osteosynthesis was performed with an angular stable locking plate device (a nonspecific LCT plate of the AO basic type; Synthes, Bettlach/Solothurn, Switzerland).Surgery was performed under general anaesthesia with the patient in a beachchair position. After surgery, patients were immobilized in a modified Velpeau bandage until self exercises and training instructed by a physical therapist were started on the third postoperative day. Duration 12 Months. Concurrent medication/care: Surgery was performed

	under general anaesthesia with the patient in a beach chair position. (n=25) Intervention 2: Conservative - Immobilisation in arm sling. On admission to the hospital, patients were immobilized in a modified Velpeau bandage. All patients allocated to conservative treatment stayed in the hospital for at least 1 day and received the same instructions from the physiotherapist as patients allocated to surgery.. Duration 12 Months. Concurrent medication/care: The arm was immobilized in the modified Velpeau bandage (a sling bandage immobilizing the arm to the chest and a pillow in theaxilla to apply ''ligamentotaxis'') and fracture alignment confirmed by radiographic examination.
Funding	No funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: OPEN REDUCTION AND PLATING versus IMMOBILISATION IN ARM SLING Protocol outcome 1: Mortality at 12 Months - Actual outcome: Death at 12 Months; Group 1: 2/25, Group 2: 0/25; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 2:Health related quality of life - Actual outcome: 15D at 24 Months; MD = 0.024, p-value = 0.436; Group 1: mean 0.849 no SD reported; n=23, Group 2: mean 0.825 no SD reported; n=25; Risk of bias: HIgh; Indirectness of outcome: No indirectness Protocol outcome 3: Functional score (DASH/Constant) - Actual outcome: Constant Score at 24 Months; Group 1: mean 75.1 (CI 65.5 to 84.7); n=23, Group 2: mean 77.1 (CI 67.9 to 84.7); n=25; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: Adverse effects - Avascular necrosis - Actual outcome: Avascular Necrosis at 24 Months; Group 1: 12/23, Group 2: 15/25; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 5: Adverse effects - Need for further/operative treatment - Actual outcome: Re-operation at 24 Months; Group 1: 4/23, Group 2: 1/25; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 6: Adverse effects - Nerve damage - Actual outcome: EMG Examination at 12 Months; Group 1: 4/20, Group 2: 3/24; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Quality of life; Adverse effects - Infection; Return to normal activity

Table 117: Gallinet 2009[46]

Study	Gallinet 2009[46]
Study type	Comparative cohort study
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in France
Line of therapy	1st line
Duration of study	Intervention time: 8 Years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients undergoing shoulder replacement for three or four part displacement fracture of the proximal humerus
Exclusion criteria	Not reported
Age, gender and ethnicity	Age - 74 (49–95): Gender (M:F): 1:4. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: Operative - Hemiarthroplasty. Patients were operated on by a deltopectoral approach, with the patient semi-seated on the shoulder. Standard cemented-stem Aequalis® (TORNIER) prostheses were implanted. Tuberosities were reinserted using Boileau's technique. Duration 16.5 Months. Concurrent medication/care: Postoperative rehabilitation followed Neer's program with immediate passive rehabilitation and active rehabilitation initiated around day 45. (n=19) Intervention 2: Operative - Reverse (geometry) shoulder replacement. Patients were operated on by a superolateral approach, with the patient semi-seated on the shoulder. Cemented-stem Delta III® (DEPUY) reverse prostheses were implanted (Fig. 3). The anterior deltoid was detached subperiosteally from the anterior edge of the acromion and reinserted by bone suture at the end of surgery. Duration 12.4 Months. Concurrent medication/care: Passive and active rehabilitation were initiated as of postoperative week 1.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: REVERSE (GEOMETRY) SHOULDER REPLACEMENT versus HEMIARTHROPLASTY	

Protocol outcome 1: Adverse effects - Infection - Actual outcome: Infection at 1 year - 16 months; Group 1: 2/16, Group 2: 1/17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Adverse effects - Need for further/operative treatment - Actual outcome: Need for further surgery at 1 year - 16 months; Group 1: 1/16, Group 2: 0/17; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Adverse effects - Nerve damage - Actual outcome: Nerve damage at 1 year - 16 months; Group 1: 1/16, Group 2: 3/17; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Mortality at 12 Months; Quality of life; Functional score (DASH/Constant); Adverse effects - Avascular necrosis; Return to normal activity

Table 118: Handoll 2015[54]; Rangan 2015[118]

Study	Handoll 2015[54]; Rangan 2015[118]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=250)
Countries and setting	Conducted in UK; Setting: Orthopaedic departments (fracture clinics or wards) at 32 NHS hospitals
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 Years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients were eligible for inclusion if they were aged 16 years or older and presented within 3 weeks after sustaining a displaced fracture of the proximal humerus that involved the surgical neck. The degree of displacement had to be sufficient for the treating surgeon to consider surgical intervention but did not have to meet Neer's displacement criteria (1cm or/and 45° angulation of displaced parts) for inclusion in the trial.
Exclusion criteria	Excluded were patients who had associated dislocation of the injured shoulder joint; open fracture; insufficient mental capacity to understand the trial or instructions for rehabilitation; co-morbidities precluding surgery or anaesthesia; clear indication for surgery such as severe soft-tissue compromise; multiple injuries (upper limb fractures); pathological fracture (other thanosteoporotic); terminal illness; or were not resident in the hospital catchment area.

Age, gender and ethnicity	Age - Mean (sd): 66.02 (11.9). Gender (M:F): 1:3. Ethnicity: 100% White
Indirectness of population	No indirectness
Interventions	(n=125) Intervention 1: Operative - Participants allocated to surgery received either internal fracture fixation, such as with plate and screws, that preserved the humeral head; or humeral head replacement (hemi-arthroplasty). (n=125) Intervention 2: Conservative - Participants allocated non-surgical treatment were given a sling for the injured arm for as long as the treating clinician deemed necessary (3 weeks was suggested), followed by active early rehabilitation.
Funding	HTA

Protocol outcome 1:Mortality at 24 Months
- Actual outcome: Mortality at 2 Years; Group 1: 9/125, Group 2: 5/125; Risk of bias: Low; Indirectness of outcome: No indirectness

Protocol outcome 2: Quality of life
- Actual outcome: EQ-5D at 2 Years; Group 1: mean 0.67 (SD 0.30); n=109, Group 2: mean 0.69 (SD 0.31); n=109; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Quality of life
- Actual outcome: SF-12 physical component at 2 Years; Group 1: mean 45.68 (CI = 43.28 to 48.08); n=111, Group 2: mean 44.20 (CI = 41.87 to 46.54); n=115; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 4: Quality of life
- Actual outcome: SF-12 mental component at 2 Years; Group 1: mean 49.30 (CI = 46.97 to 51.64); n=111, Group 2: mean 50.69 (48.40 to 52.97); n=115; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 5: Functional score (Oxford Shoulder Score)
- Group 1: mean 40.11 (SD 6.5); n=114, Group 2: mean 40.4 (SD 9.88); n= 117; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 6: Adverse effects - Need for further/operative treatment
- Actual outcome: Need for further Operation at 2 Years; Group 1: 11/125, Group 2: 11/125; Risk of bias: Low; Indirectness of outcome: No indirectness

Protocol outcome 7: Adverse effects – Infection
- Actual outcome: Surgical site infection at 2 years; Group 1: 2/125, Group 2: 0/125; Risk of bias: Low; Indirectness of outcome: No indirectness

Protocol outcome 8: Adverse effects – Nerve damage - Actual outcome: Nerve injury at 2 years; Group 1: 2/125, Group 2: 0/125; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 9: Adverse effects – Avascular necrosis - Actual outcome: Avascular necrosis at 2 years; Group 1: 4/125, Group 2: 1/125; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Return to normal activity

Table 119: Olerud 2011[108]

Study	**Olerud 2011[108]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=55)
Countries and setting	Conducted in Sweden; Setting: University Hospital
Line of therapy	1st line
Duration of study	Intervention + follow up: 2 Years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	The patient inclusion criteria were age 55 years or older, a fracture sustained after a low-energy trauma (ie, simple fall), no previous shoulder problems, independent living conditions (i.e. not institutionalized), and no severe cognitive dysfunction (i.e. 3 correct answers on a 10-item mental test, Short Portable Mental Status Questionnaire [SPMSQ]).
Exclusion criteria	Not defined
Age, gender and ethnicity	Age - Mean (range): 76.5 (58–90). Gender (M:F): 1:4. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=27) Intervention 1: Operative - Hemiarthroplasty. All patients were given 2 g cloxacillin (Ekvacillin ; AstraZeneca, Sweden) preoperatively, followed by 2 additional doses during the first 24 hours. The Global Fx prosthesis (DePuy, Sollentuna, Sweden) was used in all patients. Duration 6 Weeks. Concurrent medication/care: After surgery, the arm was placed in a sling and all patients were referred to a physiotherapist. The sling was used for 6 weeks; afterwards, the patients were allowed to use it at their own convenience.

	(n=28) Intervention 2: Conservative - Immobilisation in arm sling. Patients randomized to non-operative treatment had their arm immobilized in a sling for 2 weeks; afterwards, they were allowed to use it at their own convenience as long as they adhered to the rehabilitation regimen. Duration 6 Weeks. Concurrent medication/care: After 2 weeks, the patients were referred to a physiotherapist and pendulum exercises and passive elevation/ abduction up to 90 degrees were started. After 4 weeks, the patients were allowed a free active ROM.
Funding	Other (The study was supported by Trygg-Hansa Insurance Company and the Stockholm County Council)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HEMIARTHROPLASTY versus IMMOBILISATION IN ARM SLING Protocol outcome 1: Mortality at 12 Months - Actual outcome: Mortality at 2 Years; Group 1: 3/27, Group 2: 2/28; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 2: Quality of life - Actual outcome: EQ-5D at 2 Years; Group 1: mean 0.81 (SD 0.12); n=24, Group 2: mean 0.65 (SD 0.27); n=25; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: Functional score (DASH/Constant) - Actual outcome: Constant Score at 2 Years; Group 1: mean 48.3 (SD 16.4); n=24, Group 2: mean 49.6 (SD 20.5); n=24; Risk of bias: High; Indirectness of outcome: No indirectness - Actual outcome: DASH Score at 2 Years; Group 1: mean 30.2 (SD 18.3); n=24, Group 2: mean 36.9 (SD 21.3); n=24; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: Adverse effects - Infection - Actual outcome: Infection at 2 Years; Group 1: 0/24, Group 2: 0/25; Risk of bias: Low; Indirectness of outcome: No indirectness Protocol outcome 5: Adverse effects - Need for further/operative treatment - Actual outcome: Need for further Operation at 2 Years; Group 1: 3/27, Group 2: 1/28; Risk of bias: Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Adverse effects - Nerve damage; Adverse effects - Avascular necrosis; Return to normal activity

Table 120: Sebastia-Forcada 2014[129]

Study	**Sebastia-Forcada 2014[129]**

Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=62)
Countries and setting	Conducted in Spain
Line of therapy	1st line
Duration of study	Intervention + follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults aged >/= 70 years with an acute proximal humeral fracture who were candidates for shoulder arthroplasty. Indications for shoulder arthroplasty were complex fractures not amenable to reconstruction, including displaced 4-part fractures, fracture-dislocations with 3-part fractures, and head-splitting fractures with more than 40% articular surface involvement. Confirmation of diagnosis made using CT.
Exclusion criteria	Contra-indications to surgery, prior surgery in the shoulder, associated upper limb fracture, and neurologic disorder.
Recruitment/selection of patients	Consecutive patients
Age, gender and ethnicity	Age - Mean (range): 74 years (70 - 85). Gender (M:F): 9/61. Ethnicity: not reported
Further population details	1. Age: >50 Years (70 years and over). 2. Severity: Not applicable / Not stated / Unclear (Not stated).
Extra comments	All patients injured due to a fall on the upper extremity
Indirectness of population	No indirectness
Interventions	(n=31) Intervention 1: Operative - Hemiarthroplasty. An SMR trauma prosthesis was implanted. The proximal humeral body had holes to allow suture of the tuberosities to the stem, and the modular head was in titanium alloy. Surgical technique involved preservation of the origin and insertion of the deltoid muscle, biceps tenodesis, restoration of humeral length by proper stem height, and approximately 30 degrees of retroversion as measured with respect to the forearm with the elbow flexed at 90 degrees. Tuberosities were reattached with horizontal and vertical nonabsorbable sutures to fix the tuberosities to each other, to the prosthesis and to the shaft. Duration 2 years. Concurrent medication/care: All shoulders were immobilised after surgery with a sling, which was gradually discontinued around 3 weeks. Passive mobilisation and pendulum exercises were allowed immediately. At week 2, passive and active-assisted

	exercises were allowed in a rehabilitation center and forward elevation and abduction limited to 100 degrees and external rotation limited to 30 degrees. When consolidation of tuberosities was observed on the radiographs (approx 6-weeks), active and resisted exercises were started.A suction drain was placed post-operatively. Standard antibiotic and antithrombotic prophylaxis was given. Further details: 1. Additions: Not applicable / Not stated / Unclear (Not stated). (n=31) Intervention 2: Operative - Reverse (geometry) shoulder replacement. The SMR reverse prosthesis was implanted. The proximal humeral body was in titanium alloy with a hole to allow suture of the tuberosities. The reverse liner of polyethylene had a chamfer in its inferior portion designed to decrease the risk of impingement and the consequent scapular notching. The glenosphere was a convex titanium alloy with a titanium baseplate with a hydroxyapatite coating, a central peg, and initial stability provided by 2 screws. The glenoid baseplate was placed according to the manufacturer's recommendations. It was placed inferiorly on the glenoid such that the baseplate was flush with the inferior border of the glenoid, with inferior inclination of approximately 10 degrees and neutral version. A basic principle was to restore the humeral length to obtain proper conjoined and deltoid tension. The stem was implanted in 20 degrees of retroversion. Adjustment of the version nd of the length of the humerus was carried out after a trial reduction to test the laxity and stability of the joint. When necessary, an epiphyseal augment was placed on the stem to optimise deltoid tension.. Duration 2 years. Concurrent medication/care: Shoulder were immobilised post-operatively in sling for 2 weeks. Patients then continued with physiotherapy in a rehabilitation centre for at least 4 weeks to perform deltoid activation exercises and activities as tolerated. A suction drain was placed post-operatively. Standard antibiotic and antithrombotic prophylaxis was given. Further details: 1. Additions: Not applicable / Not stated / Unclear (Not stated).
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HEMIARTHROPLASTY versus REVERSE (GEOMETRY) SHOULDER REPLACEMENT

Protocol outcome 1: Mortality at 12 Months
- Actual outcome: Death at 2 years; Group 1: 1/31, Group 2: 0/31; Risk of bias: high; Indirectness of outcome: No indirectness

Protocol outcome 2: Functional score (DASH/Constant)
- Actual outcome: Constant score at 2 years; Group 1: mean 40 (SD 18.15); n=30, Group 2: mean 56.1 (SD 18.15); n=31; Risk of bias: high; Indirectness of outcome: No indirectness
- Actual outcome: Quick DASH score at 2 years; Group 1: mean 24.4 (SD 7.78); n=30, Group 2: mean 17.5 (SD 7.78); n=31; Risk of bias: high; Indirectness of outcome: No indirectness

Protocol outcome 3: Adverse effects - Infection - Actual outcome: Infection at 2 years; Group 1: 1/30, Group 2: 1/31; Risk of bias: high; Indirectness of outcome: No indirectness Protocol outcome 4: Adverse effects - Need for further/operative treatment - Actual outcome: Need for further surgery at 2 years; Group 1: 6/30, Group 2: 1/31; Risk of bias: low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Quality of life; Adverse effects - Nerve damage; Adverse effects - Avascular necrosis; Return to normal activity

Table 121: Young 2010[160]

Study	Young 2010[160]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=20)
Countries and setting	Conducted in New Zealand
Line of therapy	1st line
Duration of study	Intervention and follow up: 44 Months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients who underwent hemiarthroplasty for acute fracture of the proximal humerus
Exclusion criteria	Not defined
Age, gender and ethnicity	Age (Mean) 76.35: Gender (M:F): 1:9 Define. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=10) Intervention 1: Operative - Hemiarthroplasty. Tuberosities were reduced and secured using transosseus cerclage sutures and/or suture tension bands. The prosthesis used was the Bigliani–Flatlow (Zimmer,Warsaw, Indiana, USA) in three patients and the Aequalis Prosthetic System (Tornier Company, St. Ismier Cedex, France) in the remaining patients. Duration 44 months. Concurrent medication/care: Patients were allowed passive range of motion exercises only for 6 weeks.

	(n=10) Intervention 2: Operative - Reverse (geometry) shoulder replacement. Both tuberosities were reattached using transosseus cerclage sutures in five patients, the greater tuberosity only in four patients, and both tuberosities were excised in one patient. The SMR reverse shoulder prosthesis was used in all patients, with the humeral component inserted in 10° of retroversion. Six of the implants were uncemented. We used the fracture prosthesis in nine humeral implants, which has a lateral fin with small openings to allow suture fixation of the greater tuberosity. The glenosphere implant was standard in five patients and in five patients' 36-mm eccentric. Duration 22 months. Concurrent medication/care: Passive range of motion was permitted for the first 6 weeks, except the patient in whom both tuberosities were excised who began immediate active range of motion post-operatively.
Funding	Funding not stated (Not reported)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: REVERSE (GEOMETRY) SHOULDER REPLACEMENT versus HEMIARTHROPLASTY Protocol outcome 1: Adverse effects - Infection - Actual outcome: Infection at Up to 44 months; Group 1: 0/10, Group 2: 1/10; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Adverse effects - Need for further/operative treatment - Actual outcome: Need for further operation at 6 months; Group 1: 0/10, Group 2: 2/10; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Mortality at 12 Months; Quality of life; Functional score (DASH/Constant); Adverse effects - Nerve damage; Adverse effects - Avascular necrosis; Return to normal activity.

Table 122: Zyto 1997[161]

Study	**Zyto 1997[161]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=38)
Countries and setting	Conducted in Sweden; Setting: Huddinge University Hospital in Stockholm, Sweden
Line of therapy	1st line
Duration of study	Intervention and follow up: 3 Years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall

Subgroup analysis within study	Not applicable
Inclusion criteria	A displaced three- or four-part fracture of the humerus not caused by high-energy trauma and not pathological; at least 30% contact between the humeral head and the humeral shaft.
Exclusion criteria	No other fractures elsewhere in the upper limbs; no concomitant disease likely to influence the end result; and ability of the patient to co-operate.
Age, gender and ethnicity	Age - Mean (SD): 74 (7.1). Gender (M:F): 1:4. Ethnicity: Not reported
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Operative - Open reduction and plating. Tension-band surgery was performed within 48 hours under general anaesthesia through deltopectoral incision, the cephalic deltoid was retracted laterally but was not released from the clavicle. Duration 50 months. Concurrent medication/care: The patients received prophylactic cephalosporin perioperative. The same physiotherapy regime was used for the patients in the conservative group. (n=20) Intervention 2: Conservative - Immobilisation in arm sling. In the conservative group the injured arm was supported in a sling for seven to ten days, followed by physiotherapy according to a standard regimen. No attempt was made to manipulate the fracture. Duration 50 Months. Concurrent medication/care: The same physiotherapy regime was used for the patients in the surgical group.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: OPEN REDUCTION AND PLATING versus IMMOBILISATION IN ARM SLING Protocol outcome 1: Functional score (DASH/Constant) - Actual outcome: Constant Score at 50 Months; Group 1: mean 60 (SD 19); n=14, Group 2: mean 65 (SD 19); n=15; Constant Scale 0–100 Top=High is good outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Adverse effects - Infection - Actual outcome: Infection at 50 Months; Group 1: 2/14, Group 2: 0/15; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality at 1 Month; Mortality at 12 Months; Quality of life; Adverse effects - Need for further/operative treatment; Adverse effects - Nerve damage; Adverse effects - Avascular necrosis; Return to normal activity

G.4.4 Definitive treatment - paediatric femoral fractures

Table 123: Bar-on 1997[14]

Study	Bar-on 1997[14]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=19); NB the analysis has used n=20, on the basis of 20 fractures being observed in 19 people. Since it was unclear which group contained the person with 2 fractures, it was not possible to correct this unit of analysis error, and so the reported data has been used.
Countries and setting	Conducted in Israel; Setting: Children's medical centre
Line of therapy	1st line
Duration of study	Follow up (post intervention): 14 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: No X-rays reported
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	5–15 years; fractures of shaft of femur at least 3cm distal to the lesser trochanter and 3cm proximal to the distal physis with less than 50% of the width in a butterfly fragment or open I and II; parents had made a fully informed choice of surgical treatment
Exclusion criteria	implicit in inclusion criteria
Recruitment/selection of patients	All eligible patients
Age, gender and ethnicity	Age - Range: 5.2–13.2. Gender (M:F): Unclear. Ethnicity: Unclear
Further population details	1. Age or weight: 7–15 years (21–50kg) (aged 5.2 to 13.2, but this seems to fit 7–15 subgroup best).
Indirectness of population	No indirectness
Interventions	(n=10) Intervention 1: Surgical - External fixation. EF performed with either an Orthofix or an AO external fixator. Duration NA. Concurrent medication/care: performed or supervised by surgeons with subspecialty training in either trauma or paediatric orthopaedics. Fluoroscopic control in all cases

	(n=10) Intervention 2: Surgical - elastic intramedullary nailing. Stainless steel or titanium nails used. Duration NA. Concurrent medication/care: performed or supervised by surgeons with subspecialty training in either trauma or paediatric orthopaedics
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EXTERNAL FIXATION versus ELASTIC INTERMEDULLARY NAILING

Protocol outcome 1: Quality of life at Define
- Actual outcome for >28 days old or >5kg: Parent satisfaction - would choose same treatment again at 14 months; External Fixation: 8/10, Elastic intramedullary nailing: 10/10; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Number of follow up revisions/surgeries at Define
- Actual outcome for >28 days old or >5kg: Removal of surgical implants at 14 months; External Fixation: 2/10, Elastic intramedullary nailing: 1/10; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 3: Pain or discomfort at Define
- Actual outcome for >28 days old or >5kg: Deep infections at 14 months; External Fixation: 2/10, Elastic intramedullary nailing: 0/10; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 4: Return to normal activities at Define
- Actual outcome for >28 days old or >5kg: Weeks to return to school; External Fixation: 13 weeks (range 3–32), Elastic intramedullary nailing: 5 weeks (range 2–12); Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 5: Neurovascular damage at Define
- Actual outcome for >28 days old or >5kg: foot drop at 14 months; External Fixation: 0/10, Elastic intramedullary nailing: 1/10; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 6: Deformity/limb length discrepancy at Define
- Actual outcome for >28 days old or >5kg: limb length discrepancy at 14 months; External Fixation: 2/10, Elastic intramedullary nailing: 0/10; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for >28 days old or >5kg: misalignment at 14 months; External Fixation: 4/10, Elastic intramedullary nailing: 0/10; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 7: Non-union/malunion at Define

- Actual outcome for >28 days old or >5kg: Rotatory malunion at 14 months; External Fixation: 1/10, Elastic intramedullary nailing: 0/10; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	PODCI-POSNA score at Define; Mortality at Define; Vascular compromise at Define; Avascular necrosis at Define; Length of hospital stay at Define

Table 124: Hsu 2009[63]

Study	**Hsu 2009[63]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=51)
Countries and setting	Conducted in Philippines; Setting: medical centre in Philippines
Line of therapy	1st line
Duration of study	Intervention and follow up: 12 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 5–12; femoral fracture
Exclusion criteria	Multiple fractures; type II or III open fractures; pathological fractures; neuromuscular disease; incomplete radiographic or clinical data
Recruitment/selection of patients	Consecutive
Age, gender and ethnicity	Age - Range of means: 7.3 to 8.7. Gender (M:F): 41:10. Ethnicity: Unclear
Further population details	1. age or weight: 7–15 years (21–50kg) (Ages 5–12 but this sub-group is the most applicable).
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Conservative - Dynamic hip spica casting. Patients placed in Buck's traction on admission and

	then immediately placed in a dynamic hip spica apparatus (DSTSC) using ketamine sedation. Under sterile conditions, a Kirschner wire placed through distal tibia anterior to fibula at a distance 5–7cm proximal to the tip of the lateral malleolus for skeletal traction. Xerofoam gauze applied followed by a felt pad to prevent lateral pin migration. Kirschner wire then attached to a traction bow and placed under tension. While maintaining manual traction, the patient was placed in a half hip spica cast with the fractured side and normal leg both casted above the knee. Femurs were positioned according to fracture level and abducted 35–45 deg, externally rotated 10–15 deg and flexed 20–30 deg (or up to 45 deg for proximal fractures). Traction force was between 3.5–5.5 kg of traction applied for optimal fracture site overlap. Traction maintained for 3-4 weeks. Crutches used after this for a period of approx. 1 month. Duration approx. 8 weeks. Concurrent medication/care: Injured leg supported by a cloth hammock and a few drops of alcohol were placed at the pin sites. (n=26) Intervention 2: Surgical - elastic intramedullary nailing. EIN procedure performed in retrograde fashion through the distal aspect of the femur. lateral and anteromedial incision sites were chosen 2-2.5 com proximal to the distal femoral physis or the superior border of the patella.. Duration unclear. Concurrent medication/care: Nail length was based on X-rays to allow the medial nail to extend into the femoral neck and the lateral nail to the greater trochanteric apophysis.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DYNAMIC HIP SPICA CASTING versus ELASTIC INTERMEDULLARY NAILING Protocol outcome 1: Length of hospital stay at Define - Actual outcome for >28 days old or >5kg: Total hospital stay; Dynamic hip spica casting: mean 6 days (SD 2.5); n=25, Elastic intramedullary nailing: mean 17 days (SD 8.5); n=26; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Pain or discomfort at Define - Actual outcome for >28 days old or >5kg: skin irritation; Dynamic hip spica casting: 0/25, Elastic intramedullary nailing: 2/26; Risk of bias: High; Indirectness of outcome: Serious indirectness - Actual outcome for >28 days old or >5kg: pin infection; Dynamic hip spica casting: 2/25, Elastic intramedullary nailing: 0/26; Risk of bias: High; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Quality of life at Define; PODCI-POSNA score at Define; Return to normal activities at Define; Mortality at Define; Neurovascular damage at Define; Deformity/limb length discrepancy at Define; Non-union/malunion at Define; Vascular compromise at Define; Avascular necrosis at Define; Number of follow up revisions/surgeries at Define

Table 125: Ruhullah 2014A[125]

Study	Ruhullah 2014A[125]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Nepal; Setting: Teaching hospital in Nepal
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Method of assessment /diagnosis not stated
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 3–13; presenting with diaphyseal femoral fracture
Exclusion criteria	Not reported
Recruitment/selection of patients	Unclear
Age, gender and ethnicity	Age - Mean (SD): 6.4(3.46). Gender (M:F): 38:12. Ethnicity: Unclear
Further population details	1. Age or weight: 7–15 years (21-50kg) (3–13 but this appeared to be the most applicable sub-group).
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Conservative - Hip spica casting. Fracture reduced on same day or next day of presentation to hospital with fluoroscopy control under GA and 1 1/2 spica casting applied. Children admitted until parents learned how to take care of the spica. X-ray evaluation conducted at week 6. if bridging callus seen at 3 or more cortices then child allowed to weight bear. If callus not evident a long leg cast was applied for 4 more weeks. Duration Unclear. Concurrent medication/care: None reported (n=25) Intervention 2: Surgical - elastic intramedullary nailing. Rush pins. Under GA, 2 small skin incisions made on either side of the distal metaphysis and 2 holes made obliquely facing towards medullary cavity one inch proximal to growth plate. 2 pre-contoured C shaped Rush pins passed retrogradely with flouroscoopy control until both tips reached just distal to the fracture site. Fracture reduced with manual traction and Rush pins are pushed into medullary

	cavity of proximal fragment under flouroscopy control. Tips of the pins were targeted up to the level of the neck and base of the greater trochanter. As soon as pain was tolerable, the hip and knee were mobilised and non-weight bearing ambulation was begun. Weight bearing allowed once bridging callus was evident on X-ray. Rush pins were removed at one year. Duration Unclear. Concurrent medication/care: None
Funding	Academic or government funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HIP SPICA CASTING versus ELASTIC INTERMEDULLARY NAILING

Protocol outcome 1: Length of hospital stay at Define
- Actual outcome for >28 days old or >5kg: length of hospital stay; Hip spica casting: mean 3.32 days (SD 1.4); n=24, Elastic intramedullary nailing: mean 6.56 days (SD 2.75); n=25; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Number of follow up revisions/surgeries at Define
- Actual outcome for >28 days old or >5kg: Further treatment; Hip spica casting: 1/24, Elastic intramedullary nailing: 3/25; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 3: PODCI-POSNA score at Define
- Actual outcome for >28 days old or >5kg: Flynn's grading - number with 'excellent' outcome; Hip spica casting: 4/24, Elastic intramedullary nailing: 19/25; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 4: Pain or discomfort at Define
- Actual outcome for >28 days old or >5kg: Pain (due to infection, bursitis, plaster sores etc); Hip spica casting: 3/24, Elastic intramedullary nailing: 2/25; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 5: Return to normal activities at Define
- Actual outcome for >28 days old or >5kg: return to independent ambulation; Hip spica casting: mean 74.69 days (SD 30.24); n=24, Elastic intramedullary nailing: mean 46.2 days (SD 9.03); n=25; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for >28 days old or >5kg: return to school; Hip spica casting: mean 15.6 weeks (SD 2.98); n=24, Elastic intramedullary nailing: mean 8.82 weeks (SD 1.7); n=25; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for >28 days old or >5kg: return to normal activities; Hip spica casting: mean 12.08 weeks (SD 4.51); n=24, Elastic intramedullary nailing: mean 8.76 weeks (SD 2.27); n=25; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 6: Non union/malunion at Define
- Actual outcome for >28 days old or >5kg: malunion (any angular deformity); Hip spica casting: 4/24, Elastic intramedullary nailing: 1/25; Risk of bias: Very high;

Indirectness of outcome: Serious indirectness Protocol outcome 7: Avascular necrosis at Define - Actual outcome for >28 days old or >5kg: avascular necrosis; Hip spica casting: 0/24, Elastic intramedullary nailing: 1/25; Risk of bias: Very high; Indirectness of outcome: Serious indirectness	
Protocol outcomes not reported by the study	Quality of life at Define; Neurovascular damage at Define; Deformity/limb length discrepancy at Define; Vascular compromise at Define; Mortality at Define

Table 126: Shemshaki 2011[131]

Study	**Shemshaki 2011[131]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in Iran; Setting: Two university hospitals in Iran
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	Simple femoral shaft fractures; aged 6–12
Exclusion criteria	segmental Winquist types III and IV comminuted fractures; previously diagnosed neuromuscular disease; metabolic bone diseases; pathological fractures.
Recruitment/selection of patients	Consecutive
Age, gender and ethnicity	Age - Range of means: 6.5–7.1. Gender (M:F): 31:15. Ethnicity: Unclear
Further population details	1. Age or weight: 7–15 years (21–50kg) (6–12 years, but this sub-group is the most applicable).

Extra comments	Children with fractures from Isfahan, Iran
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Conservative - Hip spica casting. Skeletal traction for 3 weeks and then with a spica cast. The traction pin was inserted in the distal part of the femur on the OR under GA. Pin removed after sufficient callus formation seen on X-ray and a 1 1/2 hip spica was applied (with hips at 20–30 deg of flexion and the limb in 10–15 deg external rotation) under GA. Cast maintained for 1 month. After cast removal patients referred for PT if needed. Duration Unclear but appears to be 7 weeks. Concurrent medication/care: Hip-supported long-limb casting splints without skeletal traction applied to all patients in study initially to relieve pain (n=23) Intervention 2: Surgical - elastic intramedullary nailing. Titanium elastic nailing, applied according to the Flynn method. Surgery done under GA. Linear incision, hole drilled in femur and enlarged, and each titanium elastic nail retrogradely placed through the distal part of the femur. each nail was 40% of the canal diameter at the narrowest site of the femoral shaft. reduction and fixation was done under C-arm image intensifier. Antibiotic prophylaxis started 12 hours pre-surgery and continued up to 48 hours post-surgery. Duration Unclear. Concurrent medication/care: Hip-supported long-limb casting splints without skeletal traction applied to all patients in study initially to relieve pain
Funding	Academic or government funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HIP SPICA CASTING versus ELASTIC INTERMEDULLARY NAILING

Protocol outcome 1: Quality of life
- Actual outcome for >28 days old or >5kg: parental satisfaction - good or excellent; Hip spica casting: 17/23, Elastic intramedullary nailing: 23/23; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Length of hospital stay
- Actual outcome for >28 days old or >5kg: length of hospital stay; Hip spica casting: mean 20.5 days (SD 5.8); n=23, Elastic intramedullary nailing: mean 6.9 days (SD 2.9); n=23; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Pain or discomfort
- Actual outcome for >28 days old or >5kg: infection; Hip spica casting: 0/23, Elastic intramedullary nailing: 3/23; Risk of bias: Very high; Indirectness of outcome: Serious indirectness

Protocol outcome 4: Return to normal activities
- Actual outcome for >28 days old or >5kg: Time to return to school; Hip spica casting: mean 64.3 days (SD 19.6); n=23, Elastic intramedullary nailing: mean 31.5 days (SD

13.4); n=23; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for >28 days old or >5kg: Time to start walking independently; Hip spica casting: mean 80 days (SD 10.1); n=23, Elastic intramedullary nailing: mean 35.2 days (SD 13.2); n=23; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: Neurovascular damage - Actual outcome for >28 days old or >5kg: Nerve injury; Hip spica casting: 0/23, Elastic intramedullary nailing: 1/23; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 6: Non union/malunion - Actual outcome for >28 days old or >5kg: Malunion; Hip spica casting: 0/23, Elastic intramedullary nailing: 3/23; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	PODCI-POSNA score; Mortality; Deformity/limb length discrepancy; Vascular compromise; Avascular necrosis; Number of follow up revisions/surgeries

Table 127: Wang 2014[147]

Study	**Wang 2014[147]**
Study type	Retrospective cohort study
Number of studies (number of participants)	1 (n=38)
Countries and setting	Conducted in China; Setting: University Hospital in China
Line of therapy	1st line
Duration of study	Intervention time:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: X-ray
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	all infants with isolated femoral diaphyseal fractures who had been managed with one of the two interventions at the hospital

Exclusion criteria	Any fractures with >2cm of shortening; open fractures; multiple long bone fractures of lower extremity; pathological fractures; metabolic bone disease; pathologic failure; underlying neuromuscular disease
Recruitment/selection of patients	Retrospective study of clinical records
Age, gender and ethnicity	Age - Mean (range): 6.1 (1–12) months. Gender (M:F): 26:12. Ethnicity: Chinese
Further population details	1. Age or weight: 28 days to 1 year (5–10 kg)
Extra comments	63% of fractures were mid shaft, 32% proximal and 5% distal
Indirectness of population	No indirectness
Interventions	(n=17) Intervention 1: Conservative - Bryant's traction. Supine with hips flexed 90 degrees. Weight applied was enough to allow surgeon to slip hand under nappy; bone protrusion was protected by pad cotton. Duration 2–4 weeks. Concurrent medication/care: Skin of legs examined everyday (n=21) Intervention 2: Conservative - Pavlik harness (fabric splint). Modified Pavlik harnesses applied in combination with intravenous pain medication. Affected hip flexed 80-90 deg and abducted to 50 deg. Duration 4 weeks, but unclear. Concurrent medication/care: X-ray confirmation of fracture site. patient spent 24 hours in hospital for observation and then discharged, being folowed up at 1, 2 and 4 weeks post fixation, whereapon AP and lateral X-rays were taken.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: BRYANT'S TRACTION versus PAVLIK HARNESS (FABRIC SPLINT)

Protocol outcome 1: Length of hospital stay at Define
- Actual outcome for >28 days old or >5kg: length of hospital stay; BRYANT'S TRACTION: mean 17.8 days (SD 11.5); n=17, PAVLIK HARNESS (FABRIC SPLINT): mean 1.4days (SD11.5); n=21; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Deformity/limb length discrepancy at Define
- Actual outcome for >28 days old or >5kg: leg length discrepancy at 4 weeks; BRYANT'S TRACTION: mean 8 mm (SD 12.12); n=17, PAVLIK HARNESS (FABRIC SPLINT): mean 7.6mm (SD12.12); n=21; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Non union/malunion at Define
- Actual outcome for >28 days old or >5kg: number with malunion at 1 year; BRYANT'S TRACTION: 0/17, PAVLIK HARNESS (FABRIC SPLINT): 0/21; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Quality of life at Define; PODCI-POSNA score at Define; Pain or discomfort at Define; Return to normal activities at Define; Mortality at Define; Neurovascular damage at Define; Vascular compromise at Define; Avascular necrosis at Define; Number of follow up revisions/surgeries at Define

Table 128: Wright 2005[157]

Study	**Wright 2005[157]**
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	1 (n=108)
Countries and setting	Conducted in Australia, Canada, New Zealand, USA; Setting: Multi-national study, with centres at Children's hospitals in Canada, Australia, new Zealand and USA
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: Not reported
Stratum	>28 days old or >5kg: Aged 6.4
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	4–10 years; midshaft femoral fractures
Exclusion criteria	hip fracture; distal femoral fracture; GCS<11; pathological fractures; open fractures
Recruitment/selection of patients	Block randomisation (variable sizes) for hospital, surgeon and age
Age, gender and ethnicity	Age - Range of means: 6.3–6.5. Gender (M:F): 76:32. Ethnicity: Not reported
Further population details	1. Age or weight: 1 year to 6 years (11–20 kg) (4–10 but closest subgroup would be 1–6).
Extra comments	All had diaphyseal fractures (spiral, oblique or transverse). Most were due to falls and pedestrian/MV collisions.
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Conservative - Hip spica casting. Given a GA. Cast incorporated the affected limb not including

	foot with hip and knee flexed to about 70 degrees. Adequate closed reduction defined as 1–2 cm of shortening; no posterior angulation; <20 deg anterior angulation; no varus angulation; and <15 deg valgus angulation. Duration 3 weeks. Concurrent medication/care: Walking with crutches allowed and discharged from hospital and reviewed weekly as outpatients. (n=48) Intervention 2: Surgical - External fixation. Given GA for closed reduction of the fracture and application of a dynamised Orthofix external fixator. satisfactory reduction defined as up to 1cm of overlap; <15 deg of varus or valgus angulation; <20 deg of ant or posterior angulation. Duration 3 weeks. Concurrent medication/care: Children encouraged to walk with crutches and discharged from hospital in 1–2 days and reviewed weekly
Funding	Academic or government funding (MRC of Canada; Canadian OREA)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HIP SPICA CASTING versus EXTERNAL FIXATION Protocol outcome 1: Quality of life at Define - Actual outcome for >28 days old or >5kg: RAND child health status scale (higher worse) at 2 years; Hip spica casting: mean 68 points (SD 7.38); n=56, External fixation: mean 69 points (SD 7.38); n=45; RAND child health status scale 0-135 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Pain or discomfort at Define - Actual outcome for >28 days old or >5kg: Adverse events requiring other treatment - pin site infections at unclear; Hip spica casting: 0/56, External fixation: 20/45; Risk of bias: Very high; Indirectness of outcome: Serious indirectness Protocol outcome 3: Non-union/malunion at Define - Actual outcome for >28 days old or >5kg: Fracture malunion (defined as limb length discrepancy >2cm or >15 deg ant/post ang or >10 deg var/valg ang) at 2 years; Hip spica casting: 25/56, External fixation: 7/45; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Number of follow up revisions/surgeries at Define; PODCI-POSNA score at Define; Return to normal activities at Define; Mortality at Define; Neurovascular damage at Define; Deformity/limb length discrepancy at Define; Vascular compromise at Define; Avascular necrosis at Define; Length of hospital stay at Define

Table 129: Park 2012[110]

Study	**Park 2012[110]**
Study type	Non-randomised comparative study

Number of studies (number of participants)	1 (n=55)
Countries and setting	Conducted in South Korea
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: X-ray
Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	>10 years old; fracture 3cm distal to lesser trochnater and 5cm proximal to the distal femoral physis; closed or grade I/II open fracture
Exclusion criteria	Pathological fractures; refractures; Grade II open fractures; closed physes; follow up shorter than 1 year
Recruitment/selection of patients	As there were <10% open fractures in this study, it has been retained in the review
Age, gender and ethnicity	Age - Mean (range): 13.6–14.2. Gender (M:F): 34:9. Ethnicity: Korean
Further population details	1. age or weight: 7–15 years (21–50kg) (Up to 17 years but this is the most appropriate sub-group category).
Indirectness of population	No indirectness
Interventions	(n=21) Intervention 1: Surgical - standard intramedullary nailing. Nail of adequate size was passed through the fracture sit from the proximal fragment to the distal fragment without reaming. Duration NA. Concurrent medication/care: Nails were either unreamed tibial nail or the Sirius femoral nail. All nails were locked at proximal and distal sites of fractures. (n=22) Intervention 2: Surgical - Traditional open plate fixation. Narrow or broad locking compression plate used. A plate was pre-bent to the contour of the contralateral femur. Sum-muscular tunnels for plate insertion made at proximal and distal femoral sides. At least three screws were achieved on each side of the fracture. Duration NA. Concurrent medication/care: As above
Funding	Academic or government funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: STANDARD INTERMEDULLARY NAILING versus TRADITIONAL OPEN PLATE FIXATION	

Protocol outcome 1: Quality of life at Define - Actual outcome for >28 days old or >5kg: Flynn grading - excellent at NA; Group 1: 13/22, Group 2: 12/23; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Number of follow up revisions/surgeries at Define - Actual outcome for >28 days old or >5kg: need for re-operation at NA; Group 1: 2/21, Group 2: 0/22; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Return to normal activities at Define - Actual outcome for >28 days old or >5kg: Ambulation without limping at 2 years at NA; Group 1: 21/21, Group 2: 22/22; Risk of bias: ; Indirectness of outcome: No indirectness Protocol outcome 4: Deformity/limb length discrepancy at Define - Actual outcome for >28 days old or >5kg: leg length discrepancy > 1cm at NA; Group 1: 0/21, Group 2: 0/22; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 5: Non union/malunion at Define - Actual outcome for >28 days old or >5kg: Non-union at NA; Group 1: 1/21, Group 2: 0/22; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	PODCI-POSNA score at Define; Pain or discomfort at Define; Mortality at Define; Neurovascular damage at Define; Vascular compromise at Define; Avascular necrosis at Define; Length of hospital stay at Define

Table 130: Ramseier 2010[117]

Study	**Ramseier 2010[117]**
Study type	Non-randomised comparative study
Number of studies (number of participants)	1 (n=194)
Countries and setting	Conducted in Canada
Line of therapy	1st line
Duration of study	Follow up (post intervention):
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: X-ray

Stratum	>28 days old or >5kg
Subgroup analysis within study	Not applicable
Inclusion criteria	11–18 years old; diaphyseal femoral fracture
Exclusion criteria	Pathological fractures;
Recruitment/selection of patients	
Age, gender and ethnicity	Age - Mean (range): 13.2 (11–17.6). Gender (M:F): 145:44. Ethnicity: unclear
Further population details	1. Age or weight: 7–15 years (21–50kg) (Up to 17 years but this is the most appropriate sub-group category).
Indirectness of population	No indirectness
Interventions	(n=105) Intervention 1: Surgical - Elastic intramedullary nailing. (n=33) Intervention 2: Surgical – External fixation. (n=105) Intervention 3: Surgical - Rigid intramedullary nailing. (n=33) Intervention 4: Surgical – Plating.
Funding	None

RESULTS

Ramseier 2010 compared SIN, EIN, External fixation and plating. There were serious group discrepancies at baseline for key confounders such as fracture type and age, and so only outcomes analysed via a multivariable analysis were extracted. Relationships between EIN and external fixation were not extracted as these data had previously been gathered from RCTs.

It was found that after adjustment for age, sex, bodyweight, high energy trauma, polytrauma, increased comminution, fracture level and pattern, and open/closed fracture status rigid nail and plate fixation were not significantly different from elastic nail fixation with regard to **malunion** (p=0.99). Measures of effect such as ORs were not provided.

A major complication was defined as one or more of the following; loss of reduction, malunion or shortening and/or a re-operation for any reason other than routine

hardware removal. After multivariable analysis, the risk of a major complication did not differ significantly among the elastic nail, rigid nail and plate fixation groups.	
Protocol outcomes not reported by the study	PODCI-POSNA score at Define; Pain or discomfort at Define; Mortality at Define; Neurovascular damage at Define; Vascular compromise at Define; Avascular necrosis at Define; Length of hospital stay at Define

G.4.5 Post operative mobilisation – ankle fractures

Table 131: Ahl 1986[4]

Study	Ahl 1986[4]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: Not detailed
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with dislocated fractures of the fibula with pre-operatively verified ruptures of the anterior tibiofibular ligament who underwent internal fixation
Exclusion criteria	People <18 years, those presumed to be unable to cooperate (e.g. alcoholics, drug addicts, senile people), those with concomitant injuries interfering with the post-operative program
Recruitment/selection of patients	Not detailed
Age, gender and ethnicity	Age - Mean (SD): 44. Gender (M:F): 22/24. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Non-removable splint/cast (Below knee cast)
Indirectness of population	No indirectness
Interventions	(n=24) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. From 1st post-operative day. Duration 6 months. Concurrent medication/care: Below knee cast for 7 weeks

	Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (1 day) (n=22) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. Restricted weight bearing for 4 weeks postoperatively. Duration 6 months. Concurrent medication/care: Below knee cast for 7 weeks Further details: 1. Delay until unrestricted weight bearing: 3–6 weeks (4 weeks)
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING Protocol outcome 1: Displacement. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Redislocation of lateral malleolus at 6 months; Group 1: 0/22, Group 2: 2/22; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-operation at 6 months; Group 1: 0/22, Group 2: 0/22; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 3: Wound infection. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Infection at 6 months; Group 1: 0/22, Group 2: 0/22; Risk of bias: High; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes (OMAS, AAOFAS, DRI); Return to normal activities; Non-union/malunion; DVT/PE at 3 months; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

Table 132: Ahl 1987[5]

Study	Ahl 1987[5]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=53)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis

Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with displaced bimalleolar or trimalleolar ankle fractures who underwent internal fixation
Exclusion criteria	Children, patients with open fractures, injuries interfering with the rehabilitation programme, those unable to cooperate (e.g. alcoholics, drug addicts)
Recruitment/selection of patients	No details of recruitment
Age, gender and ethnicity	Age - Mean (SD): 57. Gender (M:F): 16/37. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Non-removable splint/cast (Below-the-knee cast)
Extra comments	Classification - Weber B: 27, Weber C: 26. Fracture of the posterior tibial margin in 43/53 cases
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. From the first postoperative day (in below-the-knee cast). Duration 6 months. Concurrent medication/care: No background treatment detailed Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (1 day) (n=28) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. From 4th week after operation. Duration 6 months. Concurrent medication/care: No background treatment detailed Further details: 1. Delay until unrestricted weight bearing: 3–6 weeks (4 weeks)
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING

Protocol outcome 1: Patient reported outcomes (OMAS, AAOFAS, DRI)
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Ankle function score at 3 months; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Ankle function score at 6 months; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Displacement
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-dislocation at 6 months; Group 1: 1/25, Group 2: 0/26; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 3: Need for re-operation

- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-operation at 6 months; Group 1: 0/25, Group 2: 0/26; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: Wound infection - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Superficial wound infection or skin irritation at 6 months; Group 1: 6/25, Group 2: 2/26; Risk of bias: High; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Deep infection at 6 months; Group 1: 0/25, Group 2: 0/26; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 5: Length of hospital stay or return to normal residence/step down - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Time spent in hospital at 6 months; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Return to normal activities; DVT/PE at 3 months; Non-union/malunion; Number of hospital/outpatient attendances

Table 133: Ahl 1988[7]

Study	Ahl 1988[7]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=51)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with displaced lateral malleolar fractures with a rupture of the anterior tibiofibular ligament who underwent internal fixation
Exclusion criteria	Children, open fractures, people with other injuries interfering with rehabilitation process, those unable to cooperate (e.g. alcoholics, drug addicts, people who were senile)
Recruitment/selection of patients	Not detailed

Age, gender and ethnicity	Age - Mean (range): 43 (18–74). Gender (M:F): 25/26. Ethnicity:
Further population details	1. Age: Not applicable/Not stated /Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear
Indirectness of population	--
Interventions	(n=25) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. after 1 week. Duration 6 months. Concurrent medication/care: Ankle immobilised in plaster cast during first post-operative week. An orthosis was fitted after the first week and people were encouraged to perform active unloaded plantar/dorsal ankle movements at least 5 times daily Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (1 week) (n=26) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. Unrestricted weight bearing delayed until after 7 weeks. Duration 6 months. Concurrent medication/care: Ankle immobilised in plaster cast during first post-operative week. A dorsal splint was attached and people were encouraged to perform active unloaded plantar/dorsal ankle movements at least 5 times daily Further details: 1. Delay until unrestricted weight bearing: Not applicable/Not stated/Unclear (7 weeks)
Funding	Other (Financial support from Skandia)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING Protocol outcome 1: Displacement - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-dislocation at 6 months; Group 1: 0/25, Group 2: 0/26; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Need for re-operation - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-operation at 6 months; Group 1: 0/25, Group 2: 0/26; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Wound infection - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Infection at 6 months; Group 1: 0/25, Group 2: 0/26; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes (OMAS, AAOFAS, DRI); Return to normal activities; Non-union/malunion; DVT/PE at 3 months; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

Table 134: Ahl 1989[8]

Study	Ahl 1989[8]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=99)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 18 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with dislocated lateral malleolar or bimalleolar fractures with a rupture of the anterior tibiofibular ligament who underwent internal fixation
Exclusion criteria	Children, open fractures, people with other injuries interfering with rehabilitation process, those unable to cooperate (e.g. alcoholics, drug addicts, people who were senile)
Recruitment/selection of patients	Not detailed
Age, gender and ethnicity	Age - Mean (range): 51 (17–86). Gender (M:F): 38/61. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear (Differing interventions between groups).
Indirectness of population	No indirectness
Interventions	(n=49) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. From the 1st postoperative day. Duration 18 months. Concurrent medication/care: None detailed Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (1st postoperative day). (n=50) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. From 4th/5th postoperative week. Duration 18 months. Concurrent medication/care: None detailed Further details: 1. Delay until unrestricted weight bearing: 3–6 weeks (4th/5th postoperative week).
Funding	Other (Grants from Karolinska Institute and the Skandia Insurance Company Research Fund)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING Protocol outcome 1: Displacement. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-dislocation at 18 months; Group 1: 1/47, Group 2: 2/46; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Patient reported outcomes (OMAS, AAOFAS, DRI); Return to normal activities; Need for re-operation; Non-union/malunion; DVT/PE at 3 months; Wound infection; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down.

Table 135: Ahl 1993[6]

Study	**Ahl 1993[6]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=43)
Countries and setting	Conducted in Sweden; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 18 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with displaced bimalleolar or trimalleolar ankle fractures who underwent internal fixation
Exclusion criteria	Children, open fractures, injuries interfering with the rehabilitation programme
Recruitment/selection of patients	No recruitment details
Age, gender and ethnicity	Age - Mean (range): Dorsal splint group: 22 (22–77), Orthosis group: 55 (20–76). Gender (M:F): 7/33. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear (Not stated whether removable or not)
Extra comments	People with displaced bimalleolar or trimalleolar ankle fractures who underwent internal fixation
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. Plaster cast and no weight bearing for

	one week postoperatively. Fitted with an orthosis and instructed to weight bear from 2nd postoperative week Duration 7 weeks. Concurrent medication/care: People were instructed to perform active unloaded plantar/dorsal ankle movements at least 5 times daily Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (2nd postoperative week) (n=23) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. Plaster cast and no weight bearing for one week postoperatively. Dorsal splint and no/restricted weight bearing for 7 weeks. Duration 7 weeks. Concurrent medication/care: People were instructed to perform active unloaded plantar/dorsal ankle movements at least 5 times daily Further details: 1. Delay until unrestricted weight bearing: Not applicable/Not stated/Unclear (7 weeks)
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING Protocol outcome 1: Patient reported outcomes (OMAS, AAOFAS, DRI). - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Ankle function score at 3 months; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Ankle function score at 6 months; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 2: Displacement. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-displacement at 18 months; Group 1: 0/19, Group 2: 0/21; Risk of bias: Very high; Indirectness of outcome: No indirectness Protocol outcome 3: Need for re-operation. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Re-operation at 18 months; Group 1: 0/19, Group 2: 0/21; Risk of bias: High; Indirectness of outcome: No indirectness Protocol outcome 4: Wound infection. - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Deep infection at 18 months; Group 1: 0/19, Group 2: 0/21; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: Superficial wound infection at 18 months; Group 1: 3/19, Group 2: 0/21; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Return to normal activities; Non-union/malunion; DVT/PE at 3 months; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

Table 136: Finsen 1989[39]

Study	Finsen 1989[39]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=56)
Countries and setting	Conducted in Norway; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 2 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People with an ankle fracture who underwent rigid internal fixation
Exclusion criteria	Did not give consent
Recruitment/selection of patients	All patients between November 1983 and June 1985
Age, gender and ethnicity	Age - Mean (SD): 42. Gender (M:F): 13/25. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear
Extra comments	No fracture had obvious displacement of fragments on post-operative radiograph, except posterior tibia fractures. In those patients, the fracture involved under a third of the tibial articular surface
Indirectness of population	No indirectness
Interventions	(n=19) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. from 1st postoperative day. Duration 24 months. Concurrent medication/care: Below knee cast with rubber walker (removed after 6 weeks) Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (1st postoperative day) (n=19) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. Restricted weight bearing until 6 weeks postoperatively. Duration 24 months. Concurrent medication/care: Wore plaster of Paris splint, removed after 6 weeks. Further details: 1. Delay until unrestricted weight bearing: 3–6 weeks (6 weeks)
Funding	Academic or government funding (Trondheim University and Trondheim University Hospital)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING Protocol outcome 1: Patient reported outcomes (OMAS, AAOFAS, DRI). - Actual outcome: Functional score at 9 weeks; Group 1: mean 8.8 (SD 5.9); n=19, Group 2: mean 11.6 (SD 4.6); n=19; Modified Weber demerit scale 0–24 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Functional score at 18 weeks; Group 1: mean 5.4 (SD 4.3); n=19, Group 2: mean 5.3 (SD 4.3); n=19; Modified Weber demerit scale 0–24 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Functional score at 36 weeks; Group 1: mean 3.3 (SD 3.5); n=19, Group 2: mean 2.2 (SD 1.9); n=19; Modified Weber demerit scale 0–24 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Functional score at 52 weeks; Group 1: mean 1.9 (SD 2.6); n=19, Group 2: mean 1.8 (SD 2.7); n=19; Modified Weber demerit scale 0–24 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness - Actual outcome: Functional score at 104 weeks; Group 1: mean 1.1 (SD 1.6); n=19, Group 2: mean 0.5 (SD 1.2); n=19; Modified Weber demerit scale 0–24 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Return to normal activities; Displacement; Need for re-operation; Non-union/malunion; DVT/PE at 3 months; Wound infection; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

Table 137: Honigmann 2007[61]

Study	Honigmann 2007[61]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in Switzerland; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Skeletally mature [young people and adults 16 years and over]
Subgroup analysis within study	Not applicable
Inclusion criteria	People between 16 and 65 years, with a body mass index (BMI) <35, who had sustained a displaced malleolar fracture type Weber A or B (AO 44 A1, 2, 3 and AO 44 B1, 2) because of a single trauma
Exclusion criteria	None detailed

Recruitment/selection of patients	Not detailed
Age, gender and ethnicity	Age - Median (range): Immediate weight bearing: 42.5 (17–62), Delayed weight bearing: 38.1 (19–66). Gender (M:F): 23/22. Ethnicity:
Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. From 14 days postoperatively. Duration 10 weeks. Concurrent medication/care: Orthesis was applied between the second and the fourth day postoperatively. Partial weight bearing of 15 kg and free ankle movements were then established. Patients were allowed to take the orthesis off for the actively assisted physiotherapy (pain depending free movement of the ankle) and during night rest Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (2 weeks) (n=22) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. From the 6 weeks postoperatively Duration 10 weeks. Concurrent medication/care: A bandage was applied around the ankle postoperatively Mobilization with partial weight bearing of 15 kg on crutches with free movement of the ankle joint started between the third and fifth postoperative day. It was continued until the end of the sixth postoperative week Further details: 1. Delay until unrestricted weight bearing: 3–6 weeks (6 weeks).
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING

Protocol outcome 1: Patient reported outcomes (OMAS, AAOFAS, DRI).
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Olerud and Molander score at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Olerud and Molander score at 10 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Pain at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Pain at 10 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Comfort at 10 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Comfort at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Walking confidence at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for Skeletally mature [young people and adults 16 years and over]: Walking confidence at 10 weeks; Risk of bias: --; Indirectness of outcome: No

indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: SF12 physical score at 10 weeks; Risk of bias: --; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: SF12 physical score at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: SF12 mental score at 6 weeks; Risk of bias: --; Indirectness of outcome: No indirectness - Actual outcome for Skeletally mature [young people and adults 16 years and over]: SF12 mental score at 10 weeks; Risk of bias: --; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Return to normal activities; Displacement; Need for re-operation; Non-union/malunion; DVT/PE at 3 months; Wound infection; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

Table 138: Van laarhoven 1996[145]

Study	**Van laarhoven 1996[145]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=81)
Countries and setting	Conducted in Netherlands; Setting: Hospital
Line of therapy	1st line
Duration of study	Intervention and follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Ankle fractures treated by internal fixation
Exclusion criteria	Fractures assessed as unstable for early mobilisation after operation (e.g. insufficient fixation in severely osteoporotic bone), Grade II and III open fractures, pilon fractures of the tibia, open injuries to the physeal plate of the distal tibia, those unable to cope with either of the post-treatment schemes
Recruitment/selection of patients	Consecutive patients
Age, gender and ethnicity	Age - Median (range): Immediate weight bearing: 35.5 (17–77), Delayed weight bearing: 37 (15–77). Gender (M:F): 45/36. Ethnicity:

Further population details	1. Age: Not applicable/Not stated/Unclear 2. DVT prophylaxis (only for DVT/PE outcome): Not applicable/Not stated/Unclear 3. Intervention for fracture: Not applicable/Not stated/Unclear
Indirectness of population	No indirectness
Interventions	(n=41) Intervention 1: Weight bearing - Immediate unrestricted weight bearing. From 2 to 5 postoperative days. Duration 12 months. Concurrent medication/care: Patients were treated in a plaster cast for two to five days and exercises to prevent equinus. They were then given below-knee walking plasters. Nine received physiotherapy in the period between six weeks and one year after the operation Further details: 1. Delay until unrestricted weight bearing: 0–3 weeks (2 to 5 days) (n=40) Intervention 2: Weight bearing - Delayed unrestricted weight bearing. Delay until unrestricted weight bearing not detailed. Duration 12 months. Concurrent medication/care: Patients were treated in a plaster cast for two to five days and exercises to prevent equinus. They were then given crutches. 14 received physiotherapy in the period between six weeks and one year after the operation Further details: 1. Delay until unrestricted weight bearing: Not applicable/Not stated/Unclear
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: IMMEDIATE UNRESTRICTED WEIGHT BEARING versus DELAYED UNRESTRICTED WEIGHT BEARING

Protocol outcome 1: Patient reported outcomes (OMAS, AAOFAS, DRI).
- Actual outcome: Linear outcome score at 10 days; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Linear outcome score at 6 weeks; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Linear outcome score at 3 months; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Linear outcome score at 12 months; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Subjective ankle score at 10 days; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Subjective ankle score at 6 weeks; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Subjective ankle score at 3 months; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Subjective ankle score at 12 months; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 2: Return to normal activities.
- Actual outcome: Return to full time work at 12 months; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome: Return to part time work at 12 months; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 3: Displacement.
- Actual outcome: Redislocation at 12 months; Group 1: 0/41, Group 2: 0/40; Risk of bias: Very high; Indirectness of outcome: No indirectness

Protocol outcome 4: Wound infection - Actual outcome: Superficial wound infection at 12 months; Group 1: 4/41, Group 2: 2/40; Risk of bias: Very high; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Need for re-operation; Non-union/malunion; DVT/PE at 3 months; Number of hospital/outpatient attendances; Length of hospital stay or return to normal residence/step down

G.5 Documentation, information and support

G.5.1 Information and support

Table 139: Forsberg 2014[43]

Study	Forsberg 2014[43]
Aim	To describe people's experiences of suffering a lower limb fracture and undergoing surgery.
Population	People with a lower limb fracture who had surgery and spent time in a hospital in Northern Sweden. Five women and four men; aged 24–72 years; 6 employed and 3 pensioners; 6 with children; causes: a car accident and different fall traumas relating to work or leisure; femur fractures (n=2), tibia/fibula fractures (n=4), ankle fractures (n=4); 7 had surgery with regional anaesthesia, 2 had general anaesthesia.
Methods	Purposive sampling: 9/30 agreed to participate. Personal semi-structured interviews, held between 1 month and 1 year after surgery. Held at home (n=6), the university (n=2) or workplace (n=1). Interviews lasted 30–60 minutes, transcribed verbatim by the paper author, and analysed using qualitative content analysis. There was no mention of triangulation, member checking or any other methods to measure trustworthiness of findings. Very high risks of bias due to lack of methods to ensure trustworthiness and long duration after surgery for some.
Themes with findings	<u>Information desired whilst waiting for surgery</u> Worry while waiting for surgery 'depended on what they did not know would happen'. Most participants 'lacked information about time intervals, routines in the ward and the medical care of a fracture'. Participants agreed that 'an approximate time schedule would have been desirable'. Some 'participants wished that they could have gotten written information: "I lacked information/what is the plan…wanted a document to read…an ordinary fracture...then this and this will happened..." <u>Information desired during surgery</u> During surgery, those with regional anaesthesia reported 'feelings of curiosity and desired to know what was occurring…they appreciated when the staff narrated what they were doing and why: "I heard them banging and I felt when I was…I said what are you doing and they said [orthopaedic] now we are spiking the long nail in". When 'staff promised to give sedative drugs if the sense of being awake became unbearable, participants could see a possible way out of a situation they had not chosen'. <u>Information desired post-surgery</u> Awake patients 'said it was a comfortable feeling to arrive at the PACU, often having already been informed about the outcome of the surgery. Patients who had had a GA 'expressed great need for orientation in time and space and a desire to know the outcome of the surgery'.

Study	Forsberg 2014[43]
	Patients felt it was professional when staff behaviours included 'explaining which kind of drug was being administered when giving pain relief, why an apparatus was sounding or how long the stay would be'. Some 'participants stated that laying there not knowing how long they would stay in the PACU was a real strain'. Participants wished to know about the metalwork inserted into their body. Being shown 'a similar material or an X-ray ….was described ….as helpful for understanding what had been done and remembering the information they had been given. Participants described the importance of being treated as a person and not as 'the fracture'. They wanted staff members to speak directly to them and not about them and their diagnosis'. When staff offered 'suggestions of solutions like repositioning the fractured limb to relieve the pain, or informing participants that they could decide when they wanted pain relief, this contributed to a sense of involvement.'
	<u>Information prior to discharge</u> Patients were insecure about being able to do post-discharge tasks, such as using their mobility device or blood thinners, after discharge. 'Participants remembered learning best when staff in the ward gradually explained things while participants were doing them
	<u>Information post-discharge</u> Patients felt that it 'was difficult to assess for themselves what was normal during recovery, although they received much verbal information from various professionals. Some participants received conflicting information, but stated that it also was difficult to remember. They emphasised the importance of getting individual coherent written information in connection with discharge from the hospital'.

Table 140: Sleney 2014[135]

Study	Sleney 2014[135]
Aim	To explore experiences of patients after injury and identify implications for clinical care and support within the hospital setting and primary care
Population	This was an indirect population as not all had fractures; however, although there was no detailed breakdown on the injury types, the results section appeared to be mainly consisting of themes relating to people with fractures. The population was: people aged >5 years attending an emergency department or admitted to hospital following a wide range of injuries.
Methods	Purposive sampling: 89 included out of 140. The study aimed to get participants from 3 centres in Bristol, Surrey and Swansea, with quotas in each centre and within the following age ranges: 5–24,25–59 and 60+. There were also attempts to ensure an equal gender ratio and a cross-section of injury types. Individual semi-structured interviews with thematic qualitative analysis. The topic guide in the interviews was guided by the research aims and also 5 pilot interviews. For children aged <12 (n=8) a parent or carer was interviewed. Interviews were transcribed verbatim and imported into the computer-assisted qualitative data analysis software NVivo7 to allow in-depth

Study	Sleney 2014[135]
	thematic content analysis. One researcher carried out all data analysis. Triangulation of researcher interpretations was used.
Themes with findings	<u>General</u> Information 'they had been given about treatment or aftercare' was viewed positively by inpatients. What was very valued were the efforts of particular members of staff who 'had taken time to explain the treatment that they were to receive or had received and to answer questions and this was much valued'. Some patients 'received conflicting information from different hospital departments over whether or not they should receive physiotherapy. This was confusing for patients and unsettling in what was already a stressful situation'. For many participants, the information that they received in relation to their injury met their needs. Information from consultants and other health professionals about procedures and likely outcomes inspired confidence for many of the participants: ''…the consultant he was... absolutely on the ball and that's one thing I have to say, he instilled confidence..., you know he kept me fully informed and made sure that I knew what was going on'' In one or two cases, the language used by healthcare professionals was reported to be too technical for the participant to fully understand although this was not necessarily regarded as problematic: ''I had a letter sent to the doctor with everything stating on it and a copy given to me so I could read it as well. Not that I could fully understand all the terms, but I got the gist of it.'' More significantly many participants had received some information but would have welcomed more. In the majority of cases, this related to treatment or aftercare. Participants wanted answers to questions such as when improvements would be noticeable, when they could or should use an injured limb as normal and whether mobility and strength would improve with time. Such questions may be complex to answer from a clinical perspective but are central to the patient's desire to return to normal life and their ability to manage their injury in the interim: ''The hardest thing I thought was not any feedback because there was no one there saying like now you can start lifting light weights, now you can do this. Just after they straightened my arm out they just left me. I was ringing them up and they were just saying 'Just take your time it is a big injury (...) back on track. The only thing that has got me back on track is my ambition not so much push myself but made sure I was doing things and made sure my arm was all right and trained it up really. Some guidance might have...If I had some feedback from the doctors I might have been recovered quicker maybe, I don't know.'' With regard to surgery, some participants reported that whilst information was provided beforehand to gain consent if an operation was required, they were not necessarily in a fit state to take this in. Some participants would have liked to have also seen a member of the surgical team after the operation: ''...I must admit maybe it is just norm but the follow up from the operation was pretty non-existent, in other words I don't know what do you expect? Do you expect the surgeon to come round, sit down and have a long chat with you? I guess he's rather busy. But I must admit he was conspicuous by his absence". Some participants had been given written information, for example about caring for plaster casts or danger signs to look for in the case of a head injury, and this was felt to be useful. More verbal information would also have been welcomed by some, whilst a few participants said that written information was useful to take home because they had found it difficult to take in verbal information from staff while they were in the hospital. <u>Social support after discharge</u> In the vast majority of cases, participants did have at least one person to support them on discharge from hospital. This was usually a family

Study	Sleney 2014[135]
	member, friend or neighbour. In one particular case, however, a participant with a dislocated knee had no family and no friends that lived close by. She had moved into her flat a week previously, did not know anyone in the area and her telephone was not yet connected. The discharge process took no account of these circumstances: ''I had nothing, no particular food or anything, my car was left at [name of hospital] Hospital, so and I live four miles from a local shop, I live in a very rural area on my own. There was no questions about that aspect; you know it's all very well discharging people but what are you discharging them to particularly with a massive injury, which it was. In fact it was so debilitating that it – an arm is quite different, you can walk around with your arm – but with a leg, particularly as I had steps to negotiate to my flat as well. I was totally bed bound, absolutely bed bound, massive pain. [...] I had really minimal support and I think that what is worrying is that the patient is not really looked at as a whole but only, in my respect, I was 'a knee' but you know that knee inhabits a person and that person needs to have some sort of support, whether it's food, just being kept in touch with.'' In some cases where participants were older and their children had left home, it was mainly their partner who helped them and this could be problematic if the partner was unwell at the time or in hospital themselves. The quote below is an extreme but not isolated example of the lengths people might have to go to in order to cope: ''So then I had my leg in plaster and my wife had a severe chest infection and was in bed so I then had to, we are in a ground floor flat, so I had to then take food into her on my crutches [...] In one pocket I had a mug and in the other pocket I had a thermos flask and in my mouth I was holding a bag with things like boiled eggs, bread and butter and so on and then at one point we noticed that the bag had on it ''Help the Aged''. (laughing) We are quite versatile you know in our family.''
	<u>Rehabilitation</u> Participants who had received no physiotherapy said that they were unsure what to do to improve the strength and mobility of their injured limb or what to expect in terms of the likely completeness or speed of recovery. They were also unsure how much they should use the injured limb or when they would be able to put pressure on it, for example start playing sport again or resume a physically demanding job: ''You don't really know how much you know you have to push it yourself, how much you can bend things and force things to get it going. It was only my daughter mainly because she's got a sports science degree and has been involved with injuries herself and it was only from that experience and her experience that we knew basically what we needed to do anyway.'' A number of participants reported that it was a physiotherapist that had helped them most in their recovery and provided the most useful information or advice. These participants all had fractures.

Table 141: Okonta 2011[107]

Study	Okonta 2011[107]
Aim	To explore the experience of patients with traumatic fractures treated for more than 6 months at a Doctors On Call for Service (DOCS) hospital in The Republic of Congo.
Population	Patients with fractures treated for more than 6 months at a Doctors On Call for Service (DOCS) hospital in The Republic of Congo.

Study	Okonta 2011[107]
Methods	Purposive sampling: details not given. 'Free-attitude' interviews transcribed verbatim in French and evaluated using content analysis. Interviews lasted 50-90 minutes. Data saturation reached after the 6th interview. For each interview a separate relative, who was the main caregiver, was interviewed to 'validate' the information given by the patient. However this failed to validate researcher's analytical interpretations. Another researcher independently listened to all the tapes and transcribed the texts for agreement on the categories used in identification of themes. It is unclear if this person triangulated the data or was the sole person analysing the data.
Themes with findings	'Most of the participants were not informed about their condition and the management plan and were therefore not part of decision making: "they did not inform me how long the nail will stay in my bone"; "if I was informed about the duration of my hospital stay I would manage my financial resources accordingly".' 'Most patients disclosed their needs and their expectations of caregivers: "we need to get information about the steps of treatment"; …"we need reassurance by doctors".

Table 142: O'Brien 2010[105]

Study	O'Brien 2010[105]
Aim	To describe patients' experience of distraction splinting and to identify key issues in patient adherence to their splint wear and exercise programme.
Population	People who had sustained an intra-articular finger fracture within the previous eight years that was treated with distraction splinting at the research hospital, and who were on the database of a previous quantitative study. 18 were identified as eligible and 12 agreed to participate. 6 were women; age 24–50; 11 PIP#, 1DIP#;0.2–7.8 years post-injury; 5 ball sport, 3 fall, 2 bicycle accident, 1 crush, 1 stub.
Methods	Personal semi-structured interview conducted by first author of study; interviews completed in hand department (n=10), home (n=1) or by phone (n=1). Interviews transcribed verbatim. Two parallel analytical strategies were used for all analysis of interview transcripts. The first author conducted a manual analysis and developed preliminary findings. Transcripts were also entered into a computer data management program (nVIVO Version 2.0; QSR International, Melbourne, VIC, Australia) and were independently analysed by the second author. For the phenomenological component of this study, a systematic process for coding data was used in which specific statements were analysed and categorized into clusters of meaning that represented a phenomenon of interest. To develop an explanatory framework for predicting treatment adherence, grounded theory's method of comparison using three stages of coding was used. The first stage involved open coding: examining and comparing data, then developing coding categories that reflected the content of the data collected. The data were then reassembled into groupings based on patterns and relationships between the categories and patient report of adherence to treatment (axial coding). Finally, the central or core category was identified and described. The themes, patterns, categories, descriptive examples, and quotations identified through the analysis formed the basis of the interpretation of the findings.

Study	O'Brien 2010[105]
	For both analyses, the authors compared emergent themes and categories to review thematic and conceptual consistency, and any disagreements were resolved by consensus moderation. To ensure trustworthiness of the results, the researchers also ''member checked'' the emerging themes and categories with two of the interviewees to ensure that the interpretation of the findings were an accurate representation of the participants' accounts of their experience.
Themes with findings	One participant was relieved to find that her splint was not as big as the ''banjo'' style splint that she was expecting: I was told that I would have a distraction splint. I didn't really understand what that involved so I looked it up online and the picture was some huge enormous thing and my big concern was how on earth would I manage with that, and when I learned that the splint I was going to have was a lot more compact I was relieved. Although most found the explanation of the treatment and its rationale clear and logical at the time it was given, it is worth noting how easily the individual's belief in the legitimacy of the treatment approach could be undermined by the contrary opinions of others. There were also some patients who believed that their treatment was ''experimental'' and that they were not given any other option. This appeared to be underpinned by the belief that they should have received a much simpler treatment, such as an operation to pin the fracture. "I was expecting that firstly they would put some plaster on it… They didn't explain anything [in the Emergency Department]. They were experimenting, I believe, on that day... It seemed like quite a new thing that they were going through, and I didn't really know what the reason was and why they were doing it and all that. That said, obviously they explained to an extent, but I didn't really know the technicalities of this and what other options are available and that sort of thing.

Appendix H: Economic evidence tables

H.1 Acute stage assessment and diagnostic imaging

H.1.1 Selecting patients for imaging – clinical prediction rules for knee fractures

Study	Nichol 1999[104]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CC **Study design:** Probabilistic decision analytic model based on a non-randomised implementation trial[137,138] **Approach to analysis:** Decision tree model using diagnostic accuracy data from Stiell 1997. **Perspectives:** US Medicare and Canada. **Time horizon:** Until fracture healed. **Treatment effect**	**Population:** People with acute blunt knee trauma. **Cohort settings:** N: 3907 Mean age: 39 years Male: 54.1% **Intervention 1:** No rule **Intervention 2:** Ottawa knee rule	**Total costs (mean per patient):** **US Medicare perspective:** Intervention 1: £270 Intervention 2: £248 Incremental (2−1): £22 (95% CI £15–£30; p=NR) **Canadian perspective:** Intervention 1: £205 Intervention 2: £185 Incremental (2−1): £20 (95% CI £14–£28; p=NR) **Currency & cost year:** 1996 US dollars (presented here as 1996 UK pounds[(a)])	**QALYs (mean per patient):** Intervention 1: n/a Intervention 2: n/a Incremental (2−1): n/a (95% CI NR; p=NR)	**ICER (Intervention 2 versus Intervention 1):** n/a 95% CI: n/a Probability Intervention 2 cost-effective (£20K/30K threshold): NR%/NR% **Analysis of uncertainty:** One-way sensitivity analyses were performed for each variable using the 95% CIs from the implementation trial and cost data sources. Threshold analyses identified the value of each parameter at which the cost of the two strategies became equal. Most variables did not affect the results. Sensitivity and specificity did and the thresholds are presented below as the values at which Ottawa Knee rules are cost saving and are in the format: **Basecase/US Medicare threshold/Canada threshold.** • Sensitivity: 99.5%/≥98.5%/≥96.9% • Specificity: 46%/≥0%/≥24%

duration: Until fracture healed. **Discounting:** Costs: n/a; Outcomes: n/a		**Cost components incorporated (US Medicare/Canada/Fee-for-service):** • Physician visit (£30/£10/NR) • Radiograph examination (£14/£17/£84) • Hourly wage (£8/£7/NR)		• A fee-for-service sensitivity analysis was performed where the cost of a knee radiograph was taken from the average charges of a convenience sample of American hospitals. The cost saving for the Ottawa Knee rule was £35 (95% CI £22–£58) • Two structural sensitivity analyses were also performed to assess physician apprehension of using the tool and also incorrect application of the tool. The results were robust to these changes.
Data sources				
Health outcomes: n/a **Quality-of-life weights:** n/a **Cost sources:** American Medical Association, American College of Radiology, Ontario provincial fee schedules, US Department of Labor, Physicians Insurance Association of America, Canadian Medical Protective Association.				
Comments				
Source of funding: Supported in part by a grant (11095N) from the Emergency Health Services Branch of the Ontario Ministry of Health. **Limitations:** Costs are from a US Medicare perspective and also include the societal cost of missed work days in relation to missed fractures. No health benefits are included as this is a cost minimisation study.				
Overall applicability[(b)]**:** Partially applicable **Overall quality**[(c)]**:** Potentially serious limitations				

Abbreviations: CC: comparative cost analysis; NR: not reported; QALYs: quality-adjusted life years; n/a: not applicable
(a) Converted using 1996 purchasing power parities[109]
(b) Directly applicable/Partially applicable/Not applicable
(c) Minor limitations/Potentially serious limitations/Very serious limitations
(d) The fee-for-service cost is used in a sensitivity analysis

Study	**Tigges 2001**[143]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CC **Study design:** Deterministic decision	**Population:** People with acute blunt knee trauma. **Cohort settings:**	**Total costs (mean per patient):** Intervention 1: NR Intervention 2: NR Incremental (2−1): Saves £2	**QALYs (mean per patient):** Intervention 1: n/a Intervention 2: n/a Incremental (2−1):	**ICER (Intervention 2 versus Intervention 1):** n/a 95% CI: n/a Probability Intervention 2 cost-effective (£20K/30K threshold): NR%/NR%

analytic model based on previous validation study[143]. **Approach to analysis:** Decision tree model using diagnostic accuracy from external validation study of Ottawa knee rules[143]. **Perspective:** US Medicare **Time horizon:** 1 week **Treatment effect duration:** 1 week **Discounting:** Costs: n/a; Outcomes: n/a	N: 384 Mean age: 38 years Male: 58.3% **Intervention 1:** No rule **Intervention 2:** Ottawa knee rule	(95% CI NR; p=NR) **Currency & cost year:** 1999 US dollars (presented here as 1999 UK pounds[(a)]) **Cost components incorporated:** – Plain radiograph knee series (£19) – Patient waiting time (£9 per hour)[(a)] – Re-evaluation of patient with missed fracture (£135) – Patient workdays missed due to delayed diagnosis of missed fracture (£351 per week)[(c)]	n/a (95% CI NR; p=NR)	**Analysis of uncertainty:** One-way sensitivity analyses were performed on all parameters. Only one of the analyses favoured the 'no rule' strategy and that was when the sensitivity of the Ottawa rule was reduced from 0.98 to 0.87. This resulted in a saving of £4 per person for the 'no rule' strategy. The Ottawa rule was the least costly strategy when the sensitivity of the Ottawa rule was at least 0.94. A best-case and worst-case analysis was also performed to combine the effect of uncertainty in all parameters. Best case: £24 saving per person for Ottawa rule. Worst case: £17 saving per person for 'no rule'. An additional analysis was performed where the worst-case scenario was adjusted by using the baseline sensitivity of the Ottawa rule. This resulted in a saving of £1 per person for the 'no rule' strategy.
Data sources				
Health outcomes: n/a **Quality-of-life weights:** n/a **Cost sources:** Medicare, Bureau of Labor Statistics 1999.				
Comments				
Source of funding: NR **Limitations:** Costs are from a US Medicare perspective and also include the societal cost of missed work days. No health benefits are included as this is a cost minimisation study. It is based on an observational study. Minimal time horizon.				
Overall applicability[(d)]: Partially applicable **Overall quality[(e)]:** Potentially serious limitations				

Abbreviations: CC: comparative cost analysis; NR: not reported; QALYs: quality-adjusted life year; n/a: not applicable

(a) Converted using 1999 purchasing power parities[109]

(b) Hourly industrial wage rate for production and nonsupervisory workers on private nonfarm payrolls.

(c) Average weekly wage rate for full-time wage and salary workers.

(d) Directly applicable/Partially applicable/Not applicable
(e) Minor limitations/Potentially serious limitations/Very serious limitations
(e)

H.1.2 Imaging of scaphoid

Study	Patel 2013[111]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CCA **Study design:** Within-trial analysis (RCT) **Approach to analysis:** Analysis of individual level resource use with unit costs applied. Self-reported pain scores and satisfaction scores were also analysed. **Perspective:** UK NHS **Follow-up:** 14 days and 42 days. **Treatment effect duration:** n/a **Discounting:** Costs: n/a; Outcomes: n/a	**Population:** People presenting to the ED in a DGH with clinical but not radiographic evidence of a scaphoid fracture. **Cohort settings:** Intervention 1: N=39 Male = 33.3% Mean age = 35.7 years Intervention 2: n=45 Male = 53.3% Mean age = 36.2 years **Intervention 1:** Re-assessment at clinic **Intervention 2:** Early MRI	**Total costs (mean per patient):** Intervention 1: £533 Intervention 2: £504 Incremental (2−1): -£29 (95% CI NR; p=NR) **Currency & cost year:** 2006 UK pounds **Cost components incorporated (cost per unit of resource):** • ED attendance (£101) • Removable plaster cast (£21) • Radiographic examination - 4 views (£21) • MRI examination (£140) • Radiologist report for MRI (£26) • Initial fracture clinic consultation (£157) • Follow-up fracture clinic consultation (£87) • Physiotherapy consultation (£40)	**Pain[(a)] – Incremental (2 – 1)** Day 0: 0 (p=0.65) Day 14: -0.6 (p=0.46) Day 42: -0.9 (p=0.22) **Satisfaction[(b)] – Incremental (2 – 1)** Day 0: 0.3 (p=0.85) Day 14: 0.9 (p=0.27) Day 42: 0.9 (p=0.35) **Hindrance[(c)] – Incremental (2 – 1)** 1.4 (p= 0.03) **Perceived effect on activities[(d)] – Incremental (2 – 1)** <u>Work effect</u> Day 14: 0.4 (p=0.27) Day 42: -0.6 (p=0.35) <u>Carer effect</u> Day 14: 0.2 (p=0.27) Day 42: 0.4 (p=0.35) <u>Sport effect</u> Day 14: 0.5 (p=0.27)	**ICER (Intervention 2 versus Intervention 1):** n/a **Analysis of uncertainty:** No analysis of uncertainty.

		• Definitive scaphoid fibreglass cast (£36)	Day 42: -0.4 (p=0.35)	

Data sources
Health outcomes: Patient reported scores from RCT. **Quality-of-life weights:** n/a **Cost sources:** All management costs were calculated from the total expenditure figures provided by the Costings and Service Agreement Accountant in the Finance Department at West Middlesex University Hospital. These were based on annual reference costs reported to the Department of Health in 2005/2006.
Comments
Source of funding: NR. **Limitations:** This trial is unblinded which could lead to bias. No quality of life outcomes. Costs taken from one particular hospital rather than the national average. Not all relevant outcomes are reported, e.g. malunion, non-union and functional outcomes. **Other:** The two treatment groups had a difference in the proportion of patients whose injury was in their dominant hand (57.8% for the MRI group and 35.9% for the control group).
Overall applicability[(e)]: Partially applicable **Overall quality[(f)]:** Potentially serious limitations

Abbreviations: CCA: cost–consequence analysis; 95% CI: 95% confidence interval; DGH: district general hospital; ED: emergency department; ICER: incremental cost-effectiveness ratio; NR: not reported.

(a) No pain=0; Worst pain ever=10

(b) Disgusted = 0; Blissfully happy=10

(c) Defined as the overall difficulty with daily life on a scale of 0–10, where 0=no effect and 10=total hindrance

(d) No effect=0; inability to participate=4

(e) Directly applicable/Partially applicable/Not applicable

(f) Minor limitations/Potentially serious limitations/Very serious limitations

H.1.3 Hot reporting

Study	**Hardy 2013[56]**			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA **Study design:** Within-trial analysis (RCT) Hardy 2013A[55] **Approach to analysis:** Analysis of individual	**Population:** Patients attending ED with a musculoskeletal injury experienced in the preceding 48 hours. **Cohort settings:** N: 1502	**Total costs (mean per patient):** Intervention 1: £108 Intervention 2: £85 Incremental (2−1): -£23 (95% CI NR; p=NR) **Currency & cost year:** 2010 UK pounds	**EQ-5D (mean change from baseline):** Intervention 1: 0.345 Intervention 2: 0.340 Incremental (2−1): -0.005 (95% CI NR; p=NR) **Missed fractures:**	**ICER (Intervention 2 versus Intervention 1):** Intervention 1 was dominated as there was no clinical difference in EQ5D. **Analysis of uncertainty:** No analysis of uncertainty undertaken.

level data, with EQ-5D questionnaires completed for 763 (50.8%) people, and unit costs applied. **Perspective:** UK NHS **Follow-up:** 8 weeks **Treatment effect duration:** n/a **Discounting:** Costs: n/a ; Outcomes: n/a	Age: (0-17) = 26.8% (18-64) = 64.3% (65+) = 8.9% Male: 55.1% **Intervention 1:** Delayed (cold) reporting **Intervention 2:** Immediate (hot) reporting	**Cost components incorporated (cost per unit of resource):** • Hospital in-patient days (£255) • ED clinic referral (£100) • Outpatient clinic referral (£100)	Intervention 1: 12 Intervention 2: 1 Incremental (2−1): 11 fewer (95% CI NR; p=NR) **Patients recalled:** Intervention 1: 7 Intervention 2: 0 Incremental (2−1): 7 fewer (95% CI NR; p=NR)	
Data sources				
Health outcomes: RCT (Hardy 2013A)[55] **Quality-of-life weights:** EQ-5D UK tariff. **Cost sources:** NHS Reference Cost 2009–2010.				
Comments				
Source of funding: National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) programme (PB-PG-0407-13033) **Limitations:** The costs of implementing the hot reporting service are not formally included in the analysis. **Other:** The study estimated the annual savings to a typical NHS hospital trust with 20,000 ED MSK radiography referrals would save £468,000. The study also reported that they estimated a minimum of 5–6 whole time equivalent reporting radiographers would be needed to implement the service. Assuming an advanced practitioner salary at midpoint Agenda for Change Band 7 (point 30 - £35,184) and 20% on-costs (£7037), the annual staff cost was estimated to be £253,326.				
Overall applicability[(a)]: Directly applicable **Overall quality[(b)]:** Potentially serious limitations				

Abbreviations: CCA: cost–consequence analysis; 95% CI: 95% confidence interval; ED: emergency department; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years

(a) Directly applicable/Partially applicable/Not applicable

(b) Minor limitations/Potentially serious limitations/Very serious limitations

H.2 Management and treatment plan in the emergency department

H.2.1 Treatment of torus fractures

Study	Davidson 2001 [35]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CCA **Study design:** Within trial analysis (RCT) **Approach to analysis:** Radiographic assessment of fracture position and union, with unit costs of resources used. **Perspective:** UK hospital.(a) **Follow-up:** Three weeks. **Treatment effect duration:** n/a **Discounting:** Costs: n/a ; Outcomes: n/a	**Population:** Children with torus fractures **Cohort settings:** N = 201 Mean age = 8.9 years (Range: 2–15) Male = 53.2% **Intervention 1:** Plaster-of-Paris cast. **Intervention 2:** Removable splint	**Total costs (mean per patient):** Intervention 1: £116.98 Intervention 2: £65.75 Incremental (2−1): -£51.23 (95% CI NR; p=NR) **Currency & cost year:** UK pounds(b) **Cost components incorporated (cost per unit of resource):** • Radiograph (£16) • Clinic attendance (£47) • Full plaster-of-Paris cast (£5.42) • Plaster-of-Paris backslab (£2.03) • Futura splint (£2.75) • Temporary splint (£1.56)	All fractures united clinically and radiologically with no loss of position.	**ICER (Intervention 2 versus Intervention 1):** n/a Probability Intervention 2 cost-effective (£20K/30K threshold): NR%/NR% **Analysis of uncertainty:** None
Data sources				
Health outcomes: From within the RCT **Quality-of-life weights:** n/a **Cost sources:** Contracts department of Alder Hey Children's Hospital				
Comments				
Source of funding: NR. **Limitations:** Although this is a UK study, it may not represent the UK as a whole as it is based on the costs from a particular hospital. No quality of life outcomes are reported – only the success of fracture union.				
Overall applicability(a): Partially applicable **Overall quality(b):** Potentially serious limitations				

Abbreviations: CCA: cost–consequence analysis; CEA: cost-effectiveness analysis; 95% CI: 95% confidence interval; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; pa: probabilistic analysis; QALYs: quality-adjusted life years.

(a) Alder Hey Children's hospital, Liverpool, England.

(b) No year reported.
(c) Directly applicable/Partially applicable/Not applicable
(d) Minor limitations/Potentially serious limitations/Very serious limitations

H.3 On-going management

H.3.1 Timing of surgery – ankle fractures

Study	**Manoukian 2013[90]**			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CC **Study design:** Retrospective within-group analysis of hospital stay costs. **Approach to analysis:** Unit costs of hospital stay attached to the number of days in the study. **Perspective:** UK NHS **Time horizon:** Until discharge. **Treatment effect duration:** n/a **Discounting:** Costs: n/a;	**Population:** Patients with ankle fractures requiring operative fixation. **Cohort settings:** N = 98 Male = 52% Mean age = 47.8 years **Analysis 1** **Intervention 1:** Surgery <24 hours **Intervention 2:** Surgery >24 hours **Analysis 2** **Intervention 1:** Surgery <48 hours **Intervention 2:**	**Total costs (mean per patient):** **Analysis 1** Intervention 1: £1040 Intervention 2: £1838 Incremental (2−1): £798 (95% CI NR; p=NR) **Analysis 2** Intervention 1: £1040 Intervention 2: £2528 Incremental (2−1): £1488 (95% CI NR; p=NR) **Currency & cost year:** 2007 UK pounds **Cost components incorporated:**	n/a	**ICER (Intervention 2 versus Intervention 1):** n/a **Analysis of uncertainty:** No analysis of uncertainty.

Outcomes: n/a	Surgery >48 hours	Hospital stay: £227		
Data sources				
Health outcomes: n/a **Quality-of-life weights:** n/a **Cost sources:** NHS Reference Costs 2006–2007				
Comments				
Source of funding: NR. **Limitations:** This is a retrospective within-group analysis that could be prone to bias. No health outcomes are included. Not all relevant costs are included, for example, physiotherapy visits.				
Overall applicability[(a)]**:** Partially Applicable **Overall quality**[(b)]**:** Potentially serious limitations				

Abbreviations: CC: comparative cost analysis; 95% CI: 95% confidence interval; ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years
(f) Directly applicable/Partially applicable/Not applicable
(g) Minor limitations/Potentially serious limitations/Very serious limitations

H.3.2 Definitive treatment of distal radial fractures

Study	**Costa 2015** [30,31]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA **Study design:** Within-trial analysis conducted alongside the DRAFFT trial. **Approach to analysis:** Intention-to-treat analysis; incremental analysis using a full trial dataset where missing data was dealt with using two different methods. Firstly, the last number carried forward was used for imputation and then the multiple imputation method was	**Population:** Patients 18 years and over with a dorsally displaced fracture of the distal radius that was believed to benefit from operative fixation by the treating consultant surgeon. **Cohort settings:** N=461 Mean age: 58.8 Male: 17% **Intervention 1:** Kirschner wires	**Total costs (mean per patient):** Intervention 1: 3,440 Intervention 2: 4,145 Incremental (2−1): 705 Incremental (2−1) based on bootstrapped estimates: 726 (95% CI: 588 to 864; p=NR) **Currency & cost year:** 2012 UK pounds **Cost components incorporated:**	**QALYs (mean per patient):** Intervention 1: 0.734 Intervention 2: 0.742 Incremental (2−1): 0.008 Incremental (2−1) based on bootstrapped estimates: 0.008 (95% CI: -0.001 to 0.018; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £89,322 per QALY gained (pa) 95% CI: NR Probability Intervention 2 cost-effective (£20K/30K threshold): 0%/3% **Analysis of uncertainty:** Overall results did not change in the following analyses: • Complete case analysis: only complete data were used. • Societal perspective • Analysis adjusting for baseline age, gender and EQ5D score. • Subgroup analysis by age (<50 versus ≥50). K-wires dominated in the <50 age group.

used. **Perspective:** UK NHS **Time horizon/Follow-up** 12 months **Treatment effect duration:** 12 months **Discounting:** Costs: 3.5%; Outcomes: 3.5%	**Intervention 2:** Volar locking plates	Surgical intervention (including the costs of the surgical team, implants, consumables and unexpected surgical procedures and inpatient stay), costs of visits to both primary and secondary health-care professionals (e.g. hospital outpatient visits, hospitalisation, physiotherapy appointments). Medication, aids and adaptation equipment were also included.		
Data sources				
Health outcomes: DRAFFT trial. **Quality-of-life weights:** EQ-5D UK tariff. **Cost sources:** published national averaged tariffs: Unit Costs of Health and Social Care [Personal Social Services Research Unit (PSSRU)], NHS Reference Costs and the British National Formulary (BNF). Costs that could not be obtained from these sources were provided by University Hospital Coventry and Warwickshire.				
Comments				
Source of funding: HTA **Limitations:** No major limitations were observed. **Other:** This study was also included in the clinical review.				
Overall applicability[(a)]: Directly applicable **Overall quality[(b)]:** Minor limitations				

Abbreviations: 95% CI: 95% confidence interval; CUA: cost–utility analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years

(c) Directly applicable / Partially applicable / Not applicable

(d) Minor limitations / Potentially serious limitations / Very serious limitations

H.3.3 Definitive treatment of humerus facture

Study	**Handoll 2015[54]**			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA	**Population:** Patients aged 16 years or	**Total costs (mean per patient):**	**QALYs (mean per patient):** Intervention 1 – based on	**ICER (Intervention 2 versus Intervention 1):**

Study design: economic analysis conducted alongside the ProFHER trial **Approach to analysis:** Intention-to-treat analysis; the incremental analysis was conducted using the multiple imputed data set and a sensitivity analysis of complete cases was carried out to test the impact of excluding patients with missing data on the final results. The incremental mean utility and the incremental mean cost between the two treatments were estimated through regression equations using the bivariate method. The covariates used to adjust for in the model were age, gender, treatment group and tuberosity involvement (yes/no) at baseline. EQ5D was estimated at baseline, then 3, 6, 12 and 24 months. **Perspective:** UK NHS **Follow-up:** 2 years **Discounting:** Costs: 3.5%; Outcomes: 3.5%	older who presented within 3 weeks after sustaining a displaced fracture of the proximal humerus that involved the surgical neck. **Cohort settings:** N =250 Start age: 66.02 Male:Female: 1:3 **Intervention 1:** N =125 Surgery: Participants allocated to surgery received either internal fracture fixation, such as with plate and screws, that preserved the humeral head; or humeral head replacement (hemi-arthroplasty). **Intervention 2:** N =125 Conservative: Participants allocated non-surgical treatment were given a sling for the injured arm for as long as the treating clinician deemed necessary (3 weeks was suggested), followed by active early rehabilitation.	Intervention 1 – based on complete case: £3,346 Intervention 2 – based on complete case: £1,462 Incremental (2−1): saves £1,758 (95% CI: £2,389 - £1,126; p=NR) Estimated using multiple imputation and OLS regression. **Currency & cost year:** 2012 UK pounds **Cost components incorporated:** Surgical intervention (including the costs of the surgical team, implants, consumables and unexpected surgical procedures and inpatient stay), costs of visits to both primary and secondary health-care professionals (e.g. hospital outpatient visits, hospitalisation, physiotherapy appointments).	complete case: 1.34 Intervention 2 – based on complete case: 1.38 Incremental (2−1): 0.0101 (95% CI: -0.11 – 0.13; p=NR) Estimated using multiple imputation and OLS regression.	Surgery is dominated Probability Intervention 2 cost-effective (£20k/30k threshold): 94%/85% **Analysis of uncertainty:** Overall results did not change in the following analyses: • Complete case analysis: only complete cases data were used. • Analysis using both shoulder- and non-shoulder-related resource use • Analysis using patient questionnaires (rather than hospital forms) as the main source for hospital data
Data sources				
Health outcomes: patient questionnaires from ProFHER trial**. Quality-of-life weights:** EQ-5D UK tariff. **Cost sources:** published national averaged tariffs: Unit Costs of				

Health and Social Care [Personal Social Services Research Unit (PSSRU)], NHS Reference Costs, and the British National Formulary (BNF). Costs of surgical implants were provided by the hospitals participating in the ProFHER trial and represent the actual costs paid by the hospital including any discount.	
Comments	
Source of funding: HTA **Limitations:** No major limitations were observed. **Other:** This study was included also in the clinical review.	
Overall applicability[(a)]: Directly Applicable	**Overall quality[(b)]:** Minor Limitations

Abbreviations: 95% CI: 95% confidence interval; CUA: cost–utility analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years

(a) Directly applicable / Partially applicable / Not applicable

(b) Minor limitations / Potentially serious limitations / Very serious limitations

Appendix I: GRADE Tables

I.1 Initial pain management and immobilisation

I.1.1 Initial pharmacological pain management

Table 143: Clinical evidence profile: Intranasal Opioid versus Intravenous Opioid (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intra-nasal	Intravenous Opioid	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	-
Pain (Final Score) (follow-up mean 30 minutes; measured with: Pain; range of scores: 0–100; Better indicated by lower values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious imprecision[(a)]	none	33	34	-	MD 4.0 higher (-15.99 lower to 7.99 higher)	LOW	CRITICAL
Pain (Final Score) (follow-up mean 30 minutes; measured with: Pain; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	35	37	-	MD 0.52 lower (-0.57 lower to 1.61higher)	LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting												
2	RCT	very serious[(b)]	serious[(c)]	no serious indirectness	very serious[(a)]	none	1/67 (1.5%)	1/70 (1.4%)	RR 1.04 (0.15 to 7.29)	1 more per 1000 (from 12 fewer to 90 more)	VERY LOW	CRITICAL
Need for further analgesia												
2	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(a)]	none	2/68 (2.9%)	1/71 (1.4%)	RR 1.74 (0.23 to 12.77)	10 more per 1000 (from 11 fewer to 166 more)	LOW	IMPORTANT

[(a)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*
[(b)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*
[(c)] *Downgraded by one increment because the point estimate varies widely across studies, unexplained by subgroup analysis.*

Table 144: Clinical evidence profile: Oral Codeine (Codeine) versus Oral Codeine (Oxycodone) (Children)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Oral Codeine**	**Codeine (Children)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Pain												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	51	56	-	MD 0.4 lower (0.69 to 0.11 lower)	VERY LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/51 (2%)	1.8%	RR 1.1 (0.07 to 17.1)	2 more per 1000 (from 17 fewer to 290 more)	VERY LOW	CRITICAL

[a] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*
[b] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 145: Clinical evidence profile: Oral NSAIDs versus Oral Codeine (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral NSAIDs	Oral Codeine (Children)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain Score (Change Score) (follow-up mean 60 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	58	50	-	MD 22 lower (28.58 to 15.42 lower)	HIGH	CRITICAL
Nausea/Vomiting												
1	RCT					none	0/22 (0%)	0/22 (0%)	not pooled	not pooled		CRITICAL
Need for further analgesia												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious imprecision[(a)]	none	1/22 (4.5%)	0/22 (0%)	not pooled	50 more per 1000 (from 0 more to 160 more)	LOW	IMPORTANT
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 146: Clinical evidence profile: Oral NSAIDs versus Oral Paracetamol (Children)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Oral NSAIDs**	**Oral Paracetamol (Children)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain Score (Change Score) (follow-up mean 60 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[(a)]	none	58	51	-	MD 15 lower (23.2 to 6.8 lower)	MODERATE	CRITICAL
Nausea/Vomiting												

1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	2/29 (6.9%)	0%	OR 12.41 (0.72 to 213.59)	70 more per 1000 (from 0 more to 170 more)	VERY LOW	CRITICAL
Delayed Union												
1	RCT					none	0/29 (0%)	0/43 (0%)	not pooled	not pooled		CRITICAL
Need for further analgesia (follow-up mean 2 hours)												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	4/29 (13.8%)	7%	RR 1.98 (0.48 to 8.19)	69 more per 1000 (from 36 fewer to 503 more)	VERY LOW	IMPORTANT
Need for further analgesia (follow-up mean 48 hours)												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	2/29 (6.9%)	4.7%	RR 1.48 (0.22 to 9.94)	23 more per 1000 (from 37 fewer to 420 more)	VERY LOW	IMPORTANT
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*
[(b)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*

Table 147: Clinical evidence profile: Oral Codeine versus Oral Paracetamol (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral Codeine	Oral Paracetamol (Children)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain Score (Change Score) (follow-up mean 60 minutes; range of scores: 0-100; Better indicated by lower values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[(a)]	none	50	51	-	MD 7 higher (1.9 to 12.1 higher)	MODERATE	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 148: Clinical evidence profile: Oral Opioid versus Intravenous Opioid (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral Opioid	Intravenous Opioid (Children)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain (Final Score) (follow-up mean 30 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	47	40	-	MD 10.9 lower (20.58 to 1.22 lower)	LOW	CRITICAL
Pain (Final Score) (follow-up mean 60 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	47	40	-	MD 14.4 lower (24.2 to 4.6 lower)	LOW	CRITICAL
Nausea/Vomiting												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/47 (8.5%)	5%	RR 1.7 (0.33 to 8.81)	35 more per 1000 (from 34 fewer to 391 more)	VERY LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*
[(b)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 149: Oral NSAIDs versus Oral Tramadol (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral NSAIDs	Oral Tramadol (Children)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting												
1	RCT	very serious[a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	0/60 (0%)	4.6%	OR 0.14 (0.01 to 2.23)	26 fewer per 1000 (from 30 fewer to 11 more)	VERY LOW	CRITICAL
Need for further analgesia												
1	RCT	serious[a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	2/60 (3.3%)	12.3%	RR 0.27 (0.06 to 1.23)	90 fewer per 1000 (from 116 fewer to 28 more)	LOW	IMPORTANT
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*
[(b)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 150: Oral NSAIDs versus Oral Paracetamol-Codeine combination (Children)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral NSAIDs	Oral Paracetamol-Codeine Combination (Children)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain Score (Change Score) (follow-up mean 20 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very serious[(a)]	no serious inconsistency	serious[(b)]	serious[(c)]	none	34	32	-	MD 0.6 higher (1.42 lower to 0.22 higher)	VERY LOW	CRITICAL
Pain Score (Change Score) (follow-up mean 60 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very serious[(a)]	no serious inconsistency	serious[(b)]	serious[(c)]	none	34	32	-	MD 0.2 higher (0.82 lower to 1.22 higher)	VERY LOW	CRITICAL
Nausea (follow-up mean 1 hour)												

1	RCT	very serious[a]	no serious inconsistency	serious[b]	very serious[c]	none	0/34 (0%)	3.1%	OR 0.13 (0 to 6.42)	27 fewer per 1000 (from 31 fewer to 139 more)	VERY LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[a] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*
[b] *The evidence included studies with a non-fracture population.*
[c] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.*

Table 151: Oral NSAIDs + Codeine combination versus Oral NSAIDs (Children)

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral NSAIDs + Codeine (Combination)	Oral NSAIDs + Codeine (Children)	Relative (95% CI)	Absolute		
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting (follow-up mean 2 hours)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	1/21 (4.8%)	0%	OR 7.75 (0.15 to 390.96)	50 more per 1000 (from 0 more to 170 more)	VERY LOW	CRITICAL
Need for further analgesia (follow-up mean 2 hours)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	0/21 (0%)	4.5%	OR 0.14 (0.00 to 7.15)	39 fewer per 1000 (from 45 fewer to 209 more)	VERY LOW	IMPORTANT
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.
(b) Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

Table 152: Oral NSAIDs + Codeine combination versus Oral Codeine (Children)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Oral NSAIDs + Codeine (Combination)**	**Oral NSAIDs + Codeine (Children)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting (follow-up mean 2 hours)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/21 (4.8%)	0%	OR 7.75 (0.15 to 390.96)	50 more per 1000 (from 0 more to 170 more)	VERY LOW	CRITICAL
Need for further analgesia (follow-up mean 2 hours)												
1	RCT						0/21 (0%)	0%	Not pooled	Not pooled		IMPORTANT
Missed diagnosis of compartment syndrome												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.
(b) Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

Table 153: Oral NSAID's versus Oral Morphine (Children)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Oral NSAIDs**	**Oral Morphine (Children)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain Score (Change Score) (follow-up mean 20 minutes; range of scores: 0–10; Better indicated by lower values)												

1	RCT	serious[a]	no serious inconsistency	none	none	none	68	66	-	MD 0.2 lower (0.57 lower to 0.17 higher)	MODERATE	CRITICAL
Nausea (follow-up mean 24 hour)												
1	RCT	none	none	none	serious[b]	none	2/68 (2.9%)	15.2%	RR 0.19 (0.04 to 0.85)	123 fewer per 1000 (from 23 fewer to 146 fewer)	VERY LOW	CRITICAL
Nausea (follow-up mean 1 hour)												
1	RCT	none	none	none	serious[b]	none	17/68 (25%)	14.7%	RR 1.7 (0.84 to 3.44)	103 more per per 1000 (from 24 fewer to 359 more)	VERY LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.
(b) Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

Table 154: Oral Opioid versus Intravenous Opioid (Adult)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral Opioid	Intravenous Opioid (Adults)	Relative (95% CI)	Absolute		
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain (Final Score) (follow-up mean 30 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	49	50	-	MD 0 higher (0.69 lower to 0.69 higher)	MODERATE	CRITICAL
Pain (Final Score) (follow-up mean 60 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44	45	-	MD 0 higher (0.29 lower to 0.29 higher)	MODERATE	CRITICAL
Nausea/Vomiting (follow-up mean 30 minutes)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	7/49 (14.3%)	12%	RR 1.19 (0.43 to 3.29)	23 more per 1000 (from 68 fewer to 275 more)	VERY LOW	CRITICAL
Nausea/Vomiting (follow-up mean 60 minutes)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	0/44 (0%)	2.2%	OR 0.14 (0 to 6.98)	19 fewer per 1000 (from 22 fewer to	VERY LOW	CRITICAL

										114 more)		
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.
(b) Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

Table 155: Oral Codeine versus Oral Codeine (Adult)

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral Codeine	Oral Codeine (Adults)	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Pain (Change Score) (follow-up mean 30 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious	no serious inconsistency	no serious indirectness	serious[(a)]	none	32	30	-	MD 1.2 lower (2.32 to 0.08 lower)	LOW	CRITICAL
Pain Score (Change Score) (follow-up mean 60 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	26	21	-	MD 1.4 lower (2.81 lower to 0.01 higher)	LOW	CRITICAL
Nausea/Vomiting (follow-up mean 48 hours)												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	1/16 (6.3%)	11.1%	RR 0.56 (0.06 to 5.63)	49 fewer per 1000 (from 104 fewer to 514 more)	VERY LOW	CRITICAL
Need for further analgesia												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	4/35 (11.4%)	21.9%	RR 0.52 (0.17 to 1.62)	105 fewer per 1000 (from 182 fewer to 136 more)	VERY LOW	IMPORTANT
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.
(b) Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

Table 156: IV Opioids versus IV Paracetamol (Adults)

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**IV Opiods**	**IV Paracetamol (Adults)**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain (Final Score) (follow-up mean 30 Minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	27	28	-	MD 8.5 lower (22.42 lower to 5.42 higher)	LOW	CRITICAL
Pain (Final Score) (follow-up mean 60 minutes; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	27	28	-	MD 8.9 lower (22.15 lower to 4.35 higher)	LOW	CRITICAL
Need for further analgesia (follow-up mean 24 hours)												
1	RCT	serious[c]	no serious inconsistency	no serious	very	none	8/27	28.6%	RR 1.04	12 more per 1000	VERY	IMPORTANT

				indirectness	serious[b]		(29.6%)		(0.45 to 2.37)	(from 163 fewer to 406 more)	LOW	
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[a] Risk of selection bias - continuous outcome not matched at baseline.
[b] Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.
[c] Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

Table 157: Entonox versus Intravenous Opioid (Adults)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Entonox	IV Opioid (Adult)	Relative (95% CI)	Absolute		
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	-
Pain (Final Score) (follow-up mean 60 minutes; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 0.1 higher (0.59 lower to 0.79 higher)	MODERATE	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*

Table 158: Intravenous NSAIDs versus Intravenous Opioid (Adults)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intravenous NSAIDs	Intravenous Opioid	Relative (95% CI)	Absolute		
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nausea/Vomiting (follow-up mean 2 hours)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/21 (4.8%)	37%	OR 0.09 (0.04 to 0.20)	320 fewer per 1000 (from 265 fewer to 347 fewer)	MODERATE	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve and vascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory depression												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Local anaesthetic toxicity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission solely for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.*

I.1.2 Paediatric nerve blocks femoral fractures

Table 159: Clinical evidence profile: Fascia iliaca compartment block versus IV morphine

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fascia iliaca compartment Block	Control	Relative (95% CI)	Absolute		
Pain Score (follow-up mean 5 Minutes; measured with: CHEOPS Pain Score; range of scores: 4-13; Better indicated by lower values)												
1	randomised trials	very serious[A]	no serious inconsistency	no serious indirectness	Serious[B]	none	26	29	-	MD 0.7 higher (0.28 to 1.12 higher)	⊕OOO VERY LOW	CRITICAL
Pain Score (follow-up mean 30 minutes; measured with: CHEOPS Pain Score; range of scores: 4-13; Better indicated by lower values)												
1	randomised trials	very serious[A]	no serious inconsistency	no serious indirectness	Serious[B]	none	26	29	-	MD 1.39 higher (0.58 to 2.2 higher)	⊕OOO VERY LOW	CRITICAL
Health related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Respiratory Depression (follow-up mean 12 hours)												
1	randomised trials	very serious[A]	no serious inconsistency	no serious indirectness	very serious[B]	none	1/26 (3.8%)	20.7%	RR 0.19 (0.02 to 1.44)	168 fewer per 1000 (from 203 fewer to 91 more)	⊕OOO VERY LOW	CRITICAL
Nerve and vascular damage (follow-up mean 12 hours)												
1	randomised trials	very serious[A]	no serious inconsistency	no serious indirectness	very serious[B]	none	0/26 (0%)	6.9%	Peto OR 0.14 (0.01 to 2.39)	59 fewer per 1000 (from 68 fewer to 81 more)	⊕OOO VERY LOW	CRITICAL
Nausea and vomiting (follow-up mean 12 hours)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	Serious[B]	none	0/26 (0%)	13.8%	Peto OR 0.13 (0.02 to 1.01)	118 fewer per 1000 (from 135 fewer to 1 more)	⊕OOO VERY LOW	CRITICAL
Missed diagnosis of compartment syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Femoral injury												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Delayed bone healing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Haematoma												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Local infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Admission soley for recovery from pharmacological agent												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Need for rescue analgesia												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.

[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

I.2 Acute stage assessment and diagnostic imaging

I.2.1 Selecting patients for imaging – clinical prediction rules for ankle fractures

Table 160: Clinical evidence profile: Ottawa versus usual care

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ottawa	clinical assessment	Relative (95% CI)	Absolute	Quality	Importance
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to healthcare provider												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number with X-rays												
1	RCT	no serious risk of bias	no serious inconsistency	serious indirectness[(a)]	no serious imprecision	none	58/62 (93.5%)	54/61 (88.5%)	RR 1.06 (0.95 to 1.18)	53 more per 1000 (from 44 fewer to 159 more)	MODERATE	CRITICAL
Length of stay in emergency department												
1	RCT	no serious risk of bias	no serious inconsistency	serious indirectness[(a)]	serious imprecision[(b)]	none	MD (SE): -6.7 (7.12)		-	6.7 lower (from 20.65 lower to 7.25	LOW	CRITICAL

										higher)		
Missed diagnosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Adverse events												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient satisfaction												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] *Intervention involved additional clinical examination*

[b] *Outcomes were downgraded by one increment for serious imprecision, as shown by the lower confidence interval crossing the lower MID, defined as half the standard deviation of the control group (0.5*39.7=19.85)*

I.2.2 Imaging of scaphoid

Table 161: Clinical evidence profile: MRI versus delayed X-ray

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Early MRI	Later follow-up	Relative (95% CI)	Absolute	Quality	Importance
Time spent in plaster cast (measured with: time spent unnecessarily immobilised; Better indicated by lower values)												
1	RCT	serious risk of bias[a]	no serious inconsistency[b]	serious[c,5]	no serious imprecision[d]	none	10	17	not estimated[d]	The median time spent immobilised unnecessarily in the control group was 7 days The median time spent	LOW	CRITICAL

										immobilised unnecessarily following early MRI was 0 days		
Mean fracture clinic appointments (follow-up unclear; Better indicated by lower values)												
1	RCT	serious risk of bias[j]	no serious inconsistency[b]	serious[e]	no serious imprecision	none	45	39	-	MD 1.2 lower (1.49 to 0.91 lower)	LOW	CRITICAL
Number of outpatient visits (measured as emergency department visits, general practitioner consultation, specialist (initial and subsequent consultation) physiotherapy, and diagnostic services (radiographs, skeletal scintigraphy, and MRI); follow-up 3 months)												
1	RCT	serious risk of bias[a]	no serious inconsistency[b]	serious[e]	no serious imprecision[d]	none	10	17	not estimated[d]	The median number of health care appointments in the control group was 5 appointments The median number of health care appointments in the MRI group was 3 appointments	LOW	CRITICAL
Health related quality of life												
0	-	-	-	-	-	-	-	-	-	-		CRITICAL
Self-reported pain (14 days) (measured with: author developed scale; range of scores: 0-10; Better indicated by lower values)												
1	RCT	serious[g,j]	no serious inconsistency[b]	serious[e]	serious[f]	none	45	39	-	MD 0.6 lower (1.92 lower to 0.72 higher)	VERY LOW	CRITICAL
Self-reported pain (42 days) (Better indicated by lower values)												
1	RCT	serious[g,j]	no serious inconsistency[b]	serious[e]	serious[f]	none	45	39	-	MD 0.9 lower (2.34 lower to 0.54 higher)	VERY LOW	CRITICAL
Pain (1 month) (measured with: Patient rated wrist evaluation; Better indicated by lower values)												
1	RCT	serious[h]	no serious inconsistency[b]	serious[e]	no serious imprecision[i]	none	10	17	-	not estimated[i]	LOW	CRITICAL
Pain (2-months) (measured with: Patient rated wrist evaluation; Better indicated by lower values)												
1	RCT	serious[h]	no serious inconsistency[b]	serious[e]	no serious imprecision[i]	none	10	17	-	not estimated[i]	LOW	CRITICAL

Pain (3-months) (measured with: Patient rated wrist evaluation; Better indicated by lower values)												
1	RCT	serious[h]	no serious inconsistency[b]	serious[e]	no serious imprecision[i]	none	10	17	-	not estimated[i]	LOW	CRITICAL
Return to normal activities												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Psychological wellbeing												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Missed injury												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Non-union/Malunion												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Avascular necrosis												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Post-traumatic arthritis												
0	no evidence available	-	-	-	-	-	-	-	-	-		CRITICAL
Mean number of X-rays after initial assessment (follow-up unclear; Better indicated by lower values)												
1	RCT	serious risk of bias[j]	no serious inconsistency[b]	serious[e]	no serious imprecision	none	45	39	-	MD 0.50 lower (0.92 to 0.08 lower)	LOW	CRITICAL
Grip strength												
0	no evidence available					none	-	-	-	-		IMPORTANT
Range of motion												

0	no evidence available					none	-	-	-	-		IMPORTANT

[a] *Study assessed as high risk of bias (no allocation concealment)*
[b] *Could not be assessed as single study only*
[c] *Indirect outcome (time spent immobilised unnecessarily)*
[d] *Effect could not be assessed as data was reported as median and interquartile range*
[e] *Indirect intervention in the control group (not all patients received X-ray at follow-up assessment)*
[f] *CI crosses one MID*
[g] *Pain was assessed using an unvalidated measure of pain*
[h] *Study assessed as high risk of bias (allocation concealment, incomplete outcome reporting)*
[i] *Effect could not be assessed as no raw data reported (effect described as "non-significant")*
[j] *Study assessed as high risk of bias (attrition bias)*

I.2.3 Hot reporting

Table 162: Clinical evidence profile: hot reporting versus cold reporting

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Hot reporting**	**Cold reporting**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Change in health related quality of life (follow-up 8 weeks; measured with: EQ-5D; Better indicated by higher values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	383	380	-	MD 0.01 lower (0.05 lower to 0.04 higher)	HIGH	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient recalled (follow-up mean 1.09 days; assessed with: Immediate recall to hospital)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/752 (0%)	0.9%	OR 0.13 (0.03 to 0.59)	9 fewer per 1000 (from 17 fewer to 2 fewer)	HIGH	CRITICAL
Missed fractures (follow-up mean 1.09 days; assessed with: False negative on day of injury)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	1/752 (0.1%)	1.6%	OR 0.18 (0.06 to 0.54)	13 fewer per 1000 (from 15 fewer to 7 fewer)	HIGH	CRITICAL
Change in management plan												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

I.3 Management and treatment plan in the emergency department

I.3.1 Reduction anaesthesia – distal radius fractures

I.3.1.1 Clinical effectiveness review

Table 163: Clinical evidence profile: haematoma block versus IV regional anaesthesia

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Haematoma block**	**IV regional anaesthesia**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**

Pain score (measured with: Visual Analogue Scale; range of scores: 0–10; Better indicated by lower values)												
2	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	119	122	-	MD 1.5 higher (0.8 to 2.2 higher)	VERY LOW	CRITICAL
Painful/very painful												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	16/37 (43.2%)	26.2%	RR 1.65 (0.88 to 3.09)	170 more per 1000 (from 31 fewer to 548 more)	VERY LOW	CRITICAL
Need for surgical fixation												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(c)]	none	4/49 (8.2%)	0%	OR 8.04 (1.1 to 58.85)	80 more per 1000 (from 0 more to 170 more)	VERY LOW	CRITICAL
Need for re-manipulation												
2	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	29/106 (27.4%)	8.5%	RR 3.3 (1.68 to 6.45)	196 more per 1000 (from 58 more to 463 more)	LOW	CRITICAL
Median nerve decompression												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(c)]	none	2/49 (4.1%)	4%	RR 1.02 (0.15 to 6.96)	1 more per 1000 (from 34 fewer to 238 more)	VERY LOW	CRITICAL
Health-related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient-reported function												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Other adverse events												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] *The majority of evidence was from studies at very high risk of bias*
[(b)] *Confidence interval crossed one MID*
[(c)] *Confidence interval crossed both MIDs*

Table 164: Clinical evidence profile: Entonox versus IV regional anaesthesia

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Entonox	IV regional anaesthesia	Relative (95% CI)	Absolute	Quality	Importance
Pain score (measured with: Visual Analogue Scale; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	35	32	-	MD 3.6 higher (2.38 to 4.82 higher)	VERY LOW	CRITICAL
Need for surgical fixation												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(c)]	none	3/35 (8.6%)	3.1%	RR 2.74 (0.3 to 25.05)	54 more per 1000 (from 22 fewer to 746 more)	VERY LOW	CRITICAL
Need for re-manipulation												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	8/35 (22.9%)	6.3%	RR 3.66 (0.84 to 15.96)	168 more per 1000 (from 10 fewer to 942 more)	VERY LOW	CRITICAL
Health-related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient-reported function												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Adverse events												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] *The majority of evidence was from studies at very high risk of bias*
[b] *Confidence interval crossed one MID*
[c] *Confidence interval crossed both MIDs*

Table 165: Clinical evidence profile: Entonox versus haematoma Block

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Entonox	IV regional anaesthesia	Relative (95% CI)	Absolute	Quality	Importance
Pain score (measured with: Visual Analogue Scale; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	34	-	MD 4.39 higher (3.19 to 5.59 higher)	LOW	CRITICAL
Need for surgical fixation												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Need for re-manipulation												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Health-related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient-reported function												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Adverse events												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] *The majority of evidence was from studies at very high risk of bias*

Table 166: Clinical evidence profile: haematoma block versus regional nerve block

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Haematoma block	Regional nerve block	Relative (95% CI)	Absolute	Quality	Importance
Pain score (measured with: Visual Analogue Scale; range of scores: 0–10; Better indicated by lower values)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 0.38 higher (0.09 to 0.67 higher)	HIGH	CRITICAL
Moderate/severe pain												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	6/19 (31.6%)	56.3%	RR 0.56 (0.25 to 1.24)	248 fewer per 1000 (from 422 fewer to 135 more)	VERY LOW	CRITICAL
Need for re-manipulation												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(c)]	none	1/50 (2%)	2%	RR 1 (0.06 to 15.55)	0 fewer per 1000 (from 19 fewer to 291 more)	LOW	CRITICAL
Bronchial spasm												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(c)]	none	0/50 (0%)	2%	RR 0.33 (0.01 to 7.99)	13 fewer per 1000 (from 20 fewer to 140 more)	LOW	CRITICAL

Infection (at block site)												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(c)]	none	1/50 (2%)	0%	OR 7.39 (0.15 to 372.38)	-	LOW	CRITICAL
Need for surgical fixation												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Health-related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient-reported function												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Other adverse events												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] *The majority of evidence was from studies at very high risk of bias*
[(b)] *Confidence interval crossed one MID*
[(c)] *Confidence interval crossed both MIDs*

I.3.1.2 Adverse events review

Table 167: Clinical evidence profile: intravenous regional anaesthesia

Quality assessment							Risk of adverse event			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Risk by study**	**Combined risk**	**Quality**	**Importance**
Death										

2	case series	very serious risk of bias[(a)]	no serious inconsistency	no serious indirectness	not applicable	none	0/416 (0%) 0/915 (0%)	0/1331 (0%)	Very low	CRITICAL
Major cardiac event										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	0/479 (0%)	0/479 (0%)	Very low	CRITICAL
Arrhythmia										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	no serious indirectness	not applicable	none	0/416 (0%)	0/416 (0%)	Very low	CRITICAL
Convulsions/seizure										
2	case series	very serious risk of bias[(a)]	no serious inconsistency	no serious indirectness	not applicable	Patient with seizure had epilepsy	0/416 (0%) 1/915 (0.1%)	1/1331 (0.08%) 8 per 10000	Very low	CRITICAL
Operations cancelled due to tourniquet related technical problems										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	4/479 (0.8%)	4/479 (0.8%) 83 per 10000	Very low	CRITICAL
Cuff failure (asymptomatic)										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	no serious indirectness	not applicable	none	1/416 (0.2%)	1/416 (0.2%) 24 per 10000	Very low	CRITICAL
Health-related quality of life										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Laryngospasm/respiratory depression										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve damage										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Aspiration of gastric contents										
0	-	-	-	-	-	-	-	-	-	CRITICAL

Compromised airway/respiration										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Methaemoglobinaemia										
0	-	-	-	-	-	-	-	-	-	CRITICAL

(a) Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitations across studies were two or more.
(b) The majority of the evidence included an indirect population

Table 168: Clinical evidence profile: conscious sedation

Quality assessment							Risk of adverse event			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Risk by study**	**Combined risk**	**Quality**	**Importance**
Death										
4	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	0/979 (0%) 0/6209 (0%) 0/1208 (0%) 0/457 (0%)	0/8853 (0%)	Very low	CRITICAL
Cardiac arrest										
3	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	0/1402 (0%) 0/6209 (0%) 0/457 (0%)	0/8068 (0%)	Very low	CRITICAL
Seizure										
3	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	1/6209 (0.02%) 0/1028 (0%) 2/2146 (0.09%)	3/9383 (0.03%) 3 per 10000	Very low	CRITICAL

Laryngospasm										
2	case series	very serious risk of bias[a]	no serious inconsistency	serious indirectness[b]	not applicable	None	3/1402 (0.2%) 2/2146 (0.09%)	5/3548 (0.1%) 14 per 10000	Very low	CRITICAL
Bronchospasm										
1	case series	very serious risk of bias[a]	no serious inconsistency	no serious indirectness	not applicable	None	3/1402 (0.2%)	3/1402 (0.2%) 21 per 10000	Very low	CRITICAL
Aspiration/pulmonary aspiration/aspiration of a foreign body										
4	case series	very serious risk of bias[a]	no serious inconsistency	serious indirectness[b]	not applicable	none	0/979 (0%) 0/1402 (0%) 0/6209 (0%) 1/2146 (0.05%)	1/10736 (0.009%) 1 per 10000	Very low	CRITICAL
Arrhythmia/dysrhythmia										
3	case series	very serious risk of bias[a]	no serious inconsistency	serious indirectness[b]	not applicable	none	1/728 (0.1%) 3/1402 (0.2%) 9/6209 (0.1%)	13/8336 (0.2%) 16 per 10000	Very low	CRITICAL
Endotracheal intubation										
3	case series	very serious risk of bias[a]	no serious inconsistency	no serious indirectness	not applicable	none	0/792 (0%) 0/979 (0%) 0/457 (0%)	0/2228 (0%)	Very low	CRITICAL
Bag valve mask ventilation										
5	case series	very serious risk of bias[a]	serious inconsistency[c]	serious indirectness[b]	not applicable	none	15/728 (2%) 31/792 (4%) 32/1008 (3%) 5/1028 (0.5%) 66/2146 (3%)	149/5702 (3%) 261 per 10000	Very low	CRITICAL
Reversal agent used										
4	case series	very serious risk of bias[a]	serious inconsistency[c]	serious indirectness[b]	not applicable	none	22/1402 (2%) 4/1028 (4%)	42/5033 (0.8%) 83 per 10000	Very low	CRITICAL

							15/2146 (0.7%) 1/457 (0.2%)			
Hypotension (intervention required)										
5	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	1/728 (0.5%) 11/1008 (1%) 1/1028 (0.1%) 27/2146 (1%) 2/457 (0.4%)	42/5367 (0.8%) 78 per 10000	Very low	CRITICAL
Hypertension (intervention required)										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	2/728 (0.3%)	2/728 (0.3%) 27 per 10000	Very low	CRITICAL
Over sedation										
1	case series	very serious risk of bias[(a)]	no serious inconsistency	serious indirectness[(b)]	not applicable	none	4/1402 (0.3%)	4/1402 (0.3%) 29 per 10000	Very low	CRITICAL
Health-related quality of life										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve damage										
0	-	-	-	-	-	-	-	-	-	CRITICAL
Methaemoglobinaemia										
0	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitations across studies were two or more.

[(b)] The majority of the evidence included an indirect population

[(c)] Outcomes were downgraded by one increment for serious inconsistency, as shown by the I squared value being between 50 and 74%. A double downgrade was applied for very serious inconsistency if I squared was >75%.I squared calculated using methods from Neyeloff 2012.[103,103]

I.3.2 Treatment of torus fractures

Table 169: Clinical evidence profile: Rigid cast versus removable splint for torus fractures

Quality assessment							Events		Effect			
No of Studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Rigid cast	Removable splint	Relative (95% CI)	Absolute	Quality	Importance
Mild to moderate pain on activity at 3 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious imprecision[(b)]	none	24/73 (32.9%)	28/64 (43.8%)	RR 0.75 (0.49 to 1.15)	109 fewer per 1000 (from 223 fewer to 66 more)	VERY LOW	CRITICAL
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Median (IQR) pain score (VAS) at 2 weeks for those with pain score of >50 at baseline (lower scores better)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	likely to be very serious[(d)]	none	40 (25–50) [n=19]	40 (20–60)[n=24]	P=0.68	-	VERY LOW	CRITICAL
Median (IQR) pain score (VAS) at 2 weeks for those with pain score of ≤50 at baseline (lower scores better)												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	likely to be very serious[(d)]	none	30 (10–30) [n=23]	20 (10–40) [n=18]	P=0.66	-	VERY LOW	CRITICAL
Median (IQR) pain score (VAS) at 4 weeks (lower scores better)												

1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	probably not serious[d]	none	0 (0–0.5) [n=23]	0 (0–0) [n=18]	P=0.096	-	LOW	CRITICAL
Proportion finding treatment convenient at 3 weeks												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	66/73 (90.4%)	58/64 (90.6%)	RR 1 (0.89 to 1.11)	0 fewer per 1000 (from 100 fewer to 100 more)	LOW	CRITICAL
Adverse events - skin problems												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/73 (0%)	11/64 (17.2%)	OR 0.1 (0.03 to 0.34)	152 fewer per 1000 (from 106 fewer to 166 fewer)	LOW	CRITICAL
Adverse events – oedema												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious imprecision[b]	none	5/73 (6.8%)	0/64 (0%)	OR 6.91 (1.16 to 41.13)	70 more per 1000 (from 10 more to 130 more)	VERY LOW	CRITICAL
Proportion at 2–4 weeks who would choose to continue with same form of immobilisation weeks												
1	RCT	serious[a]	very serious[c]	no serious indirectness	serious imprecision[b]	none	60/116 (51.7%)	87/106 (82.1%)	Random effects RR 0.56 (0.29 to 1.06)	361 fewer per 1000 (from 583 fewer to 49 more)	VERY LOW	CRITICAL
Proportion at 2 weeks resuming normal activities												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious imprecision[b]	none	40/42 (95.2%)	28/42 (66.7%)	RR 1.43 (1.14 to 1.79)	287 more per 1000 (from 93 more to 527 more)	LOW	CRITICAL
Proportion at 2 weeks requiring re-immobilisation												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	very serious imprecision[b]	none	3/42 (7.1%)	6/42 (14.3%)	RR 0.5 (0.13 to 1.87)	71 fewer per 1000 (from 124 fewer to 124 more)	VERY LOW	IMPORTANT
Adverse events - re-fractures												

1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/45 (0%)	0/42 (0%)	not pooled	not pooled	LOW	CRITICAL
Number of outpatient visits												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] *Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations comprised one or more of the following: unclear allocation concealment, the lack of blinding, or inadequate allowance for drop-outs in the analysis.*

[(b)] *Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25.*

[(c)] *Outcomes were downgraded by one increment for serious inconsistency, as shown by the I squared value being between 50 and 74%. A double downgrade was applied for very serious inconsistency if I squared was >75%. If serious or very serious inconsistency existed, and there were >2 studies, pre-defined sub-grouping (see review question protocol) was applied. If consistency within each sub-group was achieved, then the results for each sub-group were reported as separate outcomes. If this did not reduce inconsistency to acceptable levels within all sub-groups, or there were only 2 studies, then the entire group was re-analysed using a random effects model to allow for the fact that a homogeneous population was not present.*

[(d)] *Imprecision estimation based on the p value.*

Table 170: Clinical evidence profile: Rigid casts versus soft casts for torus fractures

Quality assessment							No of patients		Effect			
No of Studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Rigid casts versus soft casts**	**Control**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Parental problems with casts at 3 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious imprecision[(b)]	none	5/48 (10.4%)	1/69 (1.4%)	RR 7.19 (0.87 to 59.59)	90 more per 1000 (from 2 fewer to 849 more)	VERY LOW	CRITICAL
pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Health related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number of outpatient visits												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Proportion of parents at 3 weeks who would choose that treatment in future												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/48 (6.3%)	68/69 (98.6%)	RR 0.06 (0.02 to 0.19)	926 fewer per 1000 (from 798 fewer to 966 fewer)	LOW	CRITICAL
Cast complications at 3 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious imprecision[(b)]	none	5/48 (10.4%)	1/69 (1.4%)	RR 7.19 (0.87 to 59.59)	90 more per 1000 (from 2 fewer to 849 more)	VERY LOW	CRITICAL
Number of outpatient visits												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Cast changes												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

(a) Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations comprised one or more of the following: unclear allocation concealment, the lack of blinding, or inadequate allowance for drop-outs in the analysis.

(b) Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25.

Table 171: Clinical evidence profile: Rigid cast versus bandaging for torus fractures

Quality assessment	No of patients	Effect	Quality	Importance

No of Studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Rigid cast**	**Bandaging**	**Relative (95% CI)**	**Absolute**		
Existence of pain at 4 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/21 (71.4%)	4/18 (22.2%)	RR 3.21 (1.3 to 7.95)	491 more per 1000 (from 67 more to 1000 more)	LOW	CRITICAL
Existence of pain for 2 or more days at 4 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/21 (71.4%)	1/18 (5.6%)	RR 12.86 (1.88 to 88.04)	659 more per 1000 (from 49 more to 1000 more)	LOW	CRITICAL
Proportion of patients with discomfort during treatment period												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	12/21 (57.1%)	1/18 (5.6%)	RR 10.29 (1.48 to 71.61)	516 more per 1000 (from 27 more to 1000 more)	LOW	CRITICAL
Proportion of patients finding treatment convenient at 4 weeks												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/21 (14.3%)	17/18 (94.4%)	RR 0.15 (0.05 to 0.43)	803 fewer per 1000 (from 538 fewer to 897 fewer)	LOW	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Adverse effects												
0	-	-	-	-	-	-	-	-	-	-	-	-
Number of outpatient visits												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

Cast changes												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] *Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations comprised one or more of the following: unclear allocation concealment, the lack of blinding, or inadequate allowance for drop-outs in the analysis.*

I.3.3 Referral for on-going management from the emergency department

I.3.3.1 Referral pathway decision makers (MDT)

No intervention after first attendance at fracture clinic (unnecessary attendance)

Table 172: Clinical evidence profile: consultant versus SHO

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Consultant	SHO	Relative (95% CI)	Absolute		
No intervention after first attendance at fracture clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/6 (16.7%)	6.3%	RR 2.67 (0.2 to 36.2)	105 more per 1000 (from 50 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 173: Clinical evidence profile: consultant versus clinical nurse specialist

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/6 (16.7%)	40%	RR 0.42 (0.06 to 2.91)	232 fewer per 1000 (from 376 fewer to 764 more)	⊕OOO VERY LOW	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 174: Clinical evidence profile: consultant versus registrar

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/6 (16.7%)	17.9%	RR 0.93 (0.14 to 6.09)	13 fewer per 1000 (from 154 fewer to 911 more)	⊕OOO VERY LOW	CRITICAL

Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 175: Clinical evidence profile: SHO versus clinical nurse specialist

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												

1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	1/16 (6.3%)	40%	RR 0.16 (0.02 to 1.21)	336 fewer per 1000 (from 392 fewer to 84 more)	⊕OOO VERY LOW	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed one MID

Table 176: Clinical evidence profile: registrar versus SHO

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Consultant	SHO	Relative (95% CI)	Absolute		
No intervention after first attendance at fracture												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10/56 (17.9%)	6.3%	RR 2.86 (0.39 to 20.68)	117 more per 1000 (from 38 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 177: Clinical evidence profile: registrar versus clinical nurse specialist

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Consultant	SHO	Relative (95% CI)	Absolute		
No intervention after first attendance at fracture												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10/56 (17.9%)	40%	RR 0.45 (0.17 to 1.15)	220 fewer per 1000 (from 332 fewer to 60 more)	⊕OOO VERY LOW	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed one MID

Number of referrals to specialist clinics

Table 178: Clinical evidence profile: consultant versus senior doctor

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Consultant	SHO	Relative (95% CI)	Absolute		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	15/42 (35.7%)	36.5%	RR 0.98 (0.63 to 1.53)	7 fewer per 1000 (from 135 fewer to 193 more)	⊕OOO VERY LOW	CRITICAL
Indicator of patient satisfaction (including quality of life)												

0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 179: Clinical evidence profile: consultant versus junior doctor

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
1	observational	very	no serious	no serious	very	none	15/42	34.3%	RR 1.04 (0.62	14 more per 1000 (from	⊕OOO	CRITICAL

	studies	serious[1]	inconsistency	indirectness	serious[2]		(35.7%)		to 1.75)	130 fewer to 257 more)	VERY LOW	
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 180: Clinical evidence profile: consultant versus ENP

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Number of referrals to a specialist clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15/42 (35.7%)	44%	RR 0.81 (0.53 to 1.25)	84 fewer per 1000 (from 207 fewer to 110 more)	⊕OOO VERY LOW	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed one MID

Table 181: Clinical evidence profile: Senior doctor versus junior doctor

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	73/200 (36.5%)	34.3%	RR 1.06 (0.73 to 1.54)	21 more per 1000 (from 93 fewer to 185 more)	⊕OOO VERY LOW	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed both MIDs

Table 182: Clinical evidence profile: Senior doctor versus ENP

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	73/200 (36.5%)	44%	RR 0.83 (0.66 to 1.05)	75 fewer per 1000 (from 150 fewer to 22 more)	⊕OOO VERY LOW	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed one MID

Table 183: Clinical evidence profile: Junior doctor versus ENP

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Consultant**	**SHO**	**Relative (95% CI)**	**Absolute**		
No intervention after first attendance at fracture												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Patients recalled for change of management												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

Number of different types of attendances												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Unnecessary attendance at a clinic												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Time to definitive management plan												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Number of referrals to a specialist clinic												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	24/70 (34.3%)	44%	RR 0.78 (0.55 to 1.11)	97 fewer per 1000 (from 198 fewer to 48 more)	⊕OOO VERY LOW	CRITICAL
Indicator of patient satisfaction (including quality of life)												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL
Other measure of efficiency of management plan process												
0	-	-	-	-	-	-	-	-	-	-	–	CRITICAL

[1] The majority of evidence was from studies at very high risk of bias
[2] Confidence interval crossed one MID

I.4 On-going management

I.4.1 Timing of surgery – ankle fractures

Table 184: Clinical evidence profile: surgery <24 hours versus surgery at later time points

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgery <24 hours	Control	Relative (95% CI)	Absolute	Quality	Importance
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hospital length of stay: <24 hours versus 2–7 days (follow-up 1 months; Better indicated by lower values)												
4	observational studies	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	164	154	-	MD 3.86 lower (5.21 to 2.52 lower)	VERY LOW	CRITICAL
Hospital length of stay: <24 hours versus 8–13 days (Better indicated by lower values)												
1	observational studies	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	67	17	-	MD 12.4 lower (17.39 to 7.41 lower)	VERY LOW	CRITICAL
Health related quality of life												
0	No evidence available					none						
Infection: <24 hours versus 2–7 days												

2	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	3/94 (3.2%)	12.5%	OR 0.23 (0.06 to 0.9)	101 fewer per 1000 (from 195 fewer to 8 fewer)	VERY LOW	CRITICAL
Infection: <24 hours versus 8–13 days												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	2/67 (3%)	17.7%	OR 0.08 (0.01 to 0.7)	147 fewer per 1000 (from 332 fewer to 39 more)	VERY LOW	CRITICAL
Infection: <24 hours versus >24 hours												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/60 (0%)	11%	OR 0.22 (0.07 to 0.67)	110 fewer per 1000 (from 167 fewer to 54 fewer)	VERY LOW	CRITICAL
Wound breakdown: <24 hours versus 2–7 days												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	2/22 (9.1%)	0%	OR 17.55 (0.95 to 325.63)	91 more per 1000 (from 41 fewer to 223 more)	VERY LOW	CRITICAL
Wound breakdown: <24 hours versus 8–13 days												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	3/67 (4.5%)	23.5%	OR 0.09 (0.01 to 0.58)	191 fewer per 1000 (from 398 fewer to 17 more)	VERY LOW	CRITICAL
VTE: <24 hours versus 8–13 days												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[c]	none	0/67 (0%)	0%	-	0 fewer per 1000 (from 79 fewer to 79 more)	VERY LOW	CRITICAL
Physiotherapy appointments												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] *Downgraded twice as the majority of the evidence was from studies at very high risk of bias*
[b] *Downgraded once as the confidence interval crosses one MID*

[c] *Downgraded twice as the confidence interval crosses two MIDs*

Table 11: Clinical evidence profile: surgery 24–48 hours versus surgery at later time points

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgery within 24–48 hours	Control	Relative (95% CI)	Absolute	Quality	Importance
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hospital length of stay												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Health related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Skin breakdown												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Infection: 24–48 hours versus 8–13 days												
1	observational studies	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	2/56 (3.6%)	20.7%	RR 0.17 (0.04 to 0.8)	172 fewer per 1000 (from 41 fewer to 199 fewer)	VERY LOW	CRITICAL
Infection : 24–48 hours versus >14 days												
1	observational studies	very serious[a]	no serious inconsistency	Serious[c]	very serious[d]	none	5/105 (4.8%)	6.2%	RR 0.77 (0.24 to	14 fewer per 1000 (from 47	VERY LOW	CRITICAL

									2.44)	fewer to 89 more)		
VTE												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Physiotherapy appointments												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] *Downgraded twice as the majority of the evidence was from studies at very high risk of bias*
[b] *Downgraded once as the confidence interval crosses one MID*
[c] *The outcome measured assesses the presence of any wound complication; including infection and wound breakdown*
[d] *Downgraded twice as the confidence interval crosses two MIDs*

I.4.2 Definitive treatment - distal radial fractures

Table 185: Clinical evidence profile: External fixation versus internal fixation in adults

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	External fixation	Internal fixation	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain (follow-up range 1–2 years; measured with: VAS/SF-36/DASH pain subscale; Better indicated by lower values)												
5	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	183	166	-	MD 0.23 lower (0.52 lower to 0.06 higher)	MODERATE	CRITICAL
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Hand and wrist function (follow-up 1 year; measured with: DASH/PRWE/MAYO/Gartland Werley/Michigan; Better indicated by lower values)												
7	RCT	very serious[d]	serious[b]	no serious indirectness	Serious imprecision	none	256	245	-	SMD 0.17 higher (0.19 lower to 0.54 higher)	VERY LOW	CRITICAL
Hand and wrist function (poor or fair) (follow-up 6weeks – 2 years)												
4	RCT	very serious[d]	no serious inconsistency	no serious indirectness	Very serious[c]	none	44/168 (26.2%)	32%	RR 0.1.02 (0.73-1.43)	6 more per 1000 (from 86 fewer to 138 more)	VERY LOW	CRITICAL
Pin site infection												
11	RCT	very serious[d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	39/364 (10.79 %)	0.82%	OR 6.41 (3.42 to 12.02)	100 more per 1000 (from 60 more to 130 more)[f]	LOW	CRITICAL
Post traumatic osteoarthritis (follow-up 2–7 years)												
3	RCT	very serious[d]	no serious inconsistency	no serious indirectness	Serious[e]	none	48/87 (55.2%)	25%	RR 1.46 (1.11 to 1.93)	115 more per 1000 (from 28 more to 232 more)	VERY LOW	CRITICAL
Complex regional pain syndrome (follow-up median 1 year)												
11	RCT	very serious[d]	no serious inconsistency	no serious indirectness	Very serious[c]	none	28/397 (7.1%)	2.8%	RR 1.55 (0.90 to 2.66)	15 more per 1000 (from 3 fewer to 46 more)	VERY LOW	CRITICAL
Need for further surgery (follow-up 1–7 years)												
3	RCT	very serious[d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/92 (9.8%)	9.1%	RR 1.07 (0.44 to 2.58)	6 more per 1000 (from 51 fewer to 144 more)	LOW	IMPORTANT
Return to normal activity												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	Very serious[c]	none	21/39 (53.8%)	61.1%	RR 0.88 (0.60-1.30)	73 fewer per 1000 (from 244 fewer to 183 more)	VERY LOW	IMPORTANT

(a) Downgraded once as the majority of the evidence was from studies at high risk of bias
(b) Downgraded once as heterogeneity in the data unexplained by subgroup analyses. Analysis conducted using random effects model.
(c) Downgraded once as CI crosses one MID
(d) Downgraded twice as the majority of the evidence was from studies at very high risk of bias
(e) Downgraded twice as CI crossed two MIDs
(f) Absolute effect calculated as relative effect calculated using Peto OR

Table 186: Clinical evidence profile: External fixation versus plaster cast/splint in adults

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	External fixation	Plaster cast/splint	Relative (95% CI)	Absolute	Quality	Importance
Quality of life (follow-up 3 months; measured with: SF-36; range of scores: 0–100; Better indicated by higher values)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20	20	-	MD 0.90 lower (7.25 fewer to 9.05 higher)	LOW	CRITICAL
Pain (follow-up 2 years; measured with: SF-36; range of scores: 0–100; Better indicated by higher values)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	0.5	0.1	-	MD 0.4 higher (0.03 to 0.77 higher)	VERY LOW	CRITICAL
Pain (follow-up 3 months–7 years)												
3	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	25/81 (30.9%)	20.4%	RR 0.66 (0.47 to 0.93)	69 fewer per 1000 (from 14 fewer to 108 fewer)	VERY LOW	CRITICAL
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

Hand and wrist function (fair/poor) (follow-up 6 weeks–7 years; assessed with: Gartland & Werley/Green & O'Brian/Stewart/Lidstrom/Sarmiento)											
10	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	65/268 (24.3%)	31%	RR 0.78 (0.60 to 1.02)	70 fewer per 1000 (from 145 fewer to 5 more)	VERY LOW	CRITICAL
Pin site infection (follow-up 6 weeks–2 years)											
7	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24/194 (12.4%)	0%	OR 5.96 (2.68 to 13.25)	113 more per 1000 (from 65 fewer to 162 more)[c]	LOW	CRITICAL
Post traumatic osteoarthritis (follow-up 1 year)											
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	6/28 (21.4%)	25.8%	RR 0.83 (0.33 to 2.1)	44 fewer per 1000 (from 173 fewer to 284 more)	VERY LOW	CRITICAL
Complex regional pain syndrome (follow-up median 6 months)											
10	RCT	very serious[a]	serious[e]	no serious indirectness	serious[b]	none	16/270 (5.9%)	5.6%	RR 1.08 (0.57 to 2.06)	4 more per 1000 (from 24 fewer to 59 more)	VERY LOW	CRITICAL
Need for further surgery (follow-up 8 weeks–6 months)											
4	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/109 (1.8%)	22%	OR 0.11 (0.05 to 0.22)	300 fewer per 1000 (from 390 fewer to 211 fewer)[c]	LOW	IMPORTANT

[a] *Downgraded twice as the majority of evidence was at very high risk of bias*
[b] *Downgraded once as the CI crossed one MID*
[c] *Absolute effect calculated as relative effect was calculated using Peto OR*
[d] *Downgraded twice as CI crossed two MIDs*
[e] *Downgraded once as variation in point estimates, although heterogeneity statistics are normal*

Table 187: Clinical evidence profile: External fixation versus k-wires in adults

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	External fixation	K-wires	Relative (95% CI)	Absolute		
Quality of life (follow-up 1 year; measured with: SF-36; range of scores: 0–100; Better indicated by higher values)												
1	RCT	very serious[c]	no serious inconsistency	no serious indirectness	serious[b]	none	17	17	-	MD 3 lower (10.39 lower to 4.39 higher)	VERY LOW	CRITICAL
Pain (follow-up 2 years; measured with: VAS; range of scores: 0–10; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	46	45	-	MD 0.2 higher (0.4 lower to 0.8 higher)	MODERATE	CRITICAL
Hand and wrist function (follow-up 1–2 years; range of scores: 0–100; Better indicated by lower values)												
2	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	63	62	-	MD 4.17 higher (1.18 lower to 9.51 higher)	LOW	CRITICAL
Hand and wrist function (fair/poor) (follow-up 6 months–2 years)												
2	RCT	very serious[c]	serious[d]	no serious indirectness	very serious[e]	none	6/55 (10.9%)	10.3%	RR 1.05 (0.37 to 3.02)	5 more per 1000 (from 65 fewer to 208 more)	VERY LOW	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pin site infection (follow-up 1 year)												

2	RCT	very serious[(c)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/43 (34.9%)	9.7%	RR 3.75 (1.35 to 10.44)	267 more per 1000 (from 34 more to 916 more)	LOW	CRITICAL
Complex regional pain syndrome (follow-up 1 year)												
3	RCT	very serious[(c)]	serious[(d)]	no serious indirectness	very serious[5]	none	11/72 (15.3%)	3.2%	RR 1.55 (0.66 to 3.64)	18 more per 1000 (from 11 fewer to 84 more)	VERY LOW	CRITICAL
Post traumatic Osteo-arthritis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded once as the majority of evidence was at high risk of bias*
[(b)] *Downgraded once as the CI crossed one MID*
[(c)] *Downgraded twice as the majority of the evidence was at very high risk of bias*
[(d)] *Downgraded once as the point estimates varied widely across studies*
[(e)] *Downgraded twice as the CI crossed two MIDs*

Table 188: Clinical evidence profile: Internal fixation versus k-wires in adults

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Internal fixation**	**K-wires**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life (follow-up 1 year; measured with: EQ-5D/SF-36; range of scores: 0–100; Better indicated by higher values)												
3	RCT	very serious[(c)]	serious[(b)]	no serious indirectness	no serious imprecision	none	315	327	-	MD 6.73 higher (5.38 lower to 18.84 higher)	VERY LOW	CRITICAL
Pain (follow-up 1 year; measured with: SF-36 (pain subscale); range of scores: 0–100; Better indicated by higher values)												
1	RCT	very	no serious	no serious	no serious	none	57	57	-	MD 8.5 higher	LOW	CRITICAL

		serious[c]	inconsistency	indirectness	imprecision					(4.33 to 12.67 higher)		
Pain (follow-up 1 year)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	3/66 (4.5%)	4.7%	RR 0.97 (0.2 to 4.63)	1 fewer per 1000 (from 38 fewer to 171 more)	VERY LOW	CRITICAL
Return to normal activities (follow-up 1 year; measured with: mean time until return to work; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[e]	none	21	21	-	MD 9 lower (23.63 lower to 5.63 higher)	LOW	CRITICAL
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hand and wrist function (follow-up 6 months–1 year; measured with: DASH/QuickDASH/MAYO/PRWE; range of scores: 0–100; Better indicated by lower values)												
7	RCT	serious[a]	serious[f]	no serious indirectness	serious[e]	none	440	453	-	MD 6.49 lower (10.59 to 2.40 lower)	VERY LOW	CRITICAL
Pin site infection (follow-up median 1 year)												
5	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/187 (1.6%)	14.3%	OR 0.22 (0.09 to 0.55)	75 fewer per 1000 (from 121 fewer to 30 fewer)[g]	MODERATE	CRITICAL
Complex regional pain syndrome (follow-up 6 months)												
1	RCT	very serious[c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/27 (0%)	0%	See comment[h]	-	LOW	CRITICAL
Post traumatic OA												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Need for further surgery (follow-up median 1 year)												
4	RCT	serious[a]	Serious[b]	no serious	serious[e]	none	7/337	8.5%	RR 0.42	49 fewer per	VERY LOW	IMPORTANT

				indirectness			(2.1%)		(0.18 to 0.98)	1000 (from 2 fewer to 70 fewer)		

[a] Downgraded once as the majority of the evidence was at high risk of bias
[b] Downgraded once as the point estimates varied widely across studies
[c] Downgraded twice as the majority of the evidence was at very high risk of bias
[d] Downgraded twice as the CI crossed two MIDs
[e] Downgraded once as the CI crossed one MID
[f] Downgraded once as heterogeneity in data unexplained by subgroup analyses. Analysis conducted using random effects model.
[g] Absolute effect calculated as relative effect was calculated using Peto OR
[h] Relative effect could not be calculated as zero events in both arms

Table 189: Clinical evidence profile: Internal fixation versus plaster cast/splint in adults

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Internal fixation	Plaster cast/splint	Relative (95% CI)	Absolute	Quality	Importance
Quality of life – EQ5D utility at 12 months												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	No serious imprecision[)	none	68	81	-	MD 0 higher (0.06 lower to 0.06 higher)	LOW	CRITICAL
Quality of life – SF36 physical at 12 months												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious[b	none	68	81	-	MD 3.3 higher (0.91 lower to 6.79 higher)	VERY LOW	CRITICAL
Quality of life – SF36 mental at 12 months												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	No serious imprecision[)	none	68	81	-	MD 0.2 higher (2.48 lower to 2.88 higher)	LOW	CRITICAL
Pain (follow-up 12 weeks; measured with: VAS; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very	no serious	no serious	serious[b]	none	36	37	-	MD 0.1 lower	VERY	CRITICAL

		serious[a]	inconsistency	indirectness						(0.44 lower to 0.24 higher)	LOW	
Psychological wellbeing												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hand and wrist function (follow-up 12 months; measured with: PRWE/DASH; range of scores: 0-100; Better indicated by lower values)												
2	RCT	very serious[a]	no serious inconsistency	no serious indirectness	No serious imprecision[)	none	104	118	-	SMD 0.2 lower (0.46 lower to 0.06 higher)	LOW	CRITICAL
Hand and wrist function (fair/poor) (follow-up 6–7 weeks)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	7/19 (36.84%)	56.5%	RR 0.65 (0.33 to 1.30)	198 fewer per 1000 (from 379 fewer to 169 more)	VERY LOW	CRITICAL
Post traumatic OA												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pin site infection (follow-up 6 weeks–1 year)												
2	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	2/59 (3.4%)	0%	OR 7.92 (0.49 to 126.92)	34 more per 1000 (from 21 fewer to 89 more)[d]	VERY LOW	CRITICAL
Complex regional pain syndrome (follow-up median 1 year)												
3	RCT	very serious[a]	serious[e]	no serious indirectness	very serious[c]	none	3/95 (3.2%)	3.3%	RR 0.51 (0.13 to 1.95)	16 fewer per 1000 (from 29 fewer to 31 more)	VERY LOW	CRITICAL

[a] *Downgraded twice as the majority of the evidence was at very high risk of bias*
[b] *Downgraded once as the CI crossed one MID*
[c] *Downgraded twice as the CI crossed two MIDs*

[d] *Absolute effect calculated as relative effect calculated using Peto OR*
[e] *Downgraded once as the point estimates varied widely across studies*

Table 190: Clinical evidence profile: K-wires versus plaster cast/splint in adults

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	K-wires	Plaster cast/splint	Relative (95% CI)	Absolute	Quality	Importance
Quality of life (follow-up 1 year; measured with WHOQOL and SF-36 (physical component); Better indicated by higher values)												
2	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	57	57	-	SMD 0.35 higher (0.02 lower to 0.72 higher)	LOW	CRITICAL
Pain (follow-up 1 year; measured with: VAS; range of scores: 0–10; Better indicated by lower values)												
1	RCT	very serious[b]	no serious inconsistency	no serious indirectness	serious[c]	none	27	27	-	MD 0.5 lower (1.28 lower to 0.28 higher)	VERY LOW	CRITICAL
Return to normal activities (follow-up 1 year; measured with: Activities of daily living (ADL); range of scores: 0–12; Better indicated by higher values)												
1	RCT	very serious[b]	no serious inconsistency	no serious indirectness	serious[c]	none	27	27	-	MD 0.3 higher (0.96 lower to 1.56 higher)	VERY LOW	CRITICAL
Hand and wrist function (follow-up 1 year; measured with: Cooney modification of Green & O'Brian; range of scores: 0–100; Better indicated by higher values)												
1	RCT	very serious[b]	no serious inconsistency	no serious indirectness	serious[c]	none	48	50	-	MD 15 lower (29.81 to 0.19 lower)	VERY LOW	CRITICAL
Hand and wrist function (follow-up 1 year; measured with: MAYO; range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[c]	none	30	30	-	MD 1.7 lower (5.18 lower to	LOW	CRITICAL

										1.78 higher)		
Hand and wrist function (fair/poor) (follow-up 7 weeks–6 months; assessed with: Sarmiento/McBride/Horne *et al*)												
3	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	8/68 (11.8%)	45%	RR 0.31 (0.15 to 0.64)	310 fewer per 1000 (from 162 fewer to 382 fewer)	LOW	CRITICAL
Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pin site infection (follow-up 7 weeks–1 year)												
5	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20/199 (10.1%)	0%	OR 8.3 (3.37 to 20.45)	146 more per 1000 (from 96 more to 195 more)[(d)]	LOW	CRITICAL
Complex regional pain syndrome (follow-up 7 weeks–1 year)												
3	RCT	very serious[(b)]	serious[(e)]	no serious indirectness	very serious[(f)]	none	1/73 (1.4%)	4.6%	OR 0.36 (0.05 to 2.58)	28 fewer per 1000 (from 81 fewer to 25 more)[(d)]	VERY LOW	CRITICAL
Post traumatic OA												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Need for further surgery (follow-up 1 week–1 year)												
3	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/146 (0%)	6.1%	OR 0.07 (0.03 to 0.18)	151 fewer per 1000 (from 210 fewer to 92 fewer)[(d)]	LOW	IMPORTANT

[(a)] *Downgraded once as the majority of the evidence was at high risk of bias*
[(b)] *Downgraded twice as the majority of the evidence was at very high risk of bias*
[(c)] *Downgraded once as the CI crossed one MID*
[(d)] *Absolute effect calculated as relative effect calculated using Peto OR*
[(e)] *Downgraded once as the point estimates varied widely across studies*
[(f)] *Downgraded twice as the CI crossed two MIDs*

Table 191: Clinical evidence profile: K-wires versus plaster cast/splint in children

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	K-wires	Plaster cast/splint	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hand and wrist function (follow-up 6 months; measured with: ABILHAND; range of scores: 0–42; Better indicated by higher values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	60	63	-	MD 0.4 higher (0.01 lower to 0.81 higher)	MODERATE	CRITICAL
Pin site infection (follow-up 1–6 months)												
2	RCT	serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/76 (5.3%)	0%	OR 8.4 (1.16 to 60.92)	53 more per 1000 (from 2 fewer to 108 more)[c]	VERY LOW	CRITICAL
Need for further surgery (follow-up 1–3 months)												
2	RCT	very serious[d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/51 (0%)	30.1%	OR 0.1 (0.03 to 0.31)	275 fewer per 1000 (from 399 fewer to 150 fewer)[c]	LOW	IMPORTANT

Pin site infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Post traumatic OA												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Complex regional pain syndrome												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded twice as the majority of evidence is at high risk of bias*
[(b)] *Downgraded twice as the CI crossed two MIDs*
[(c)] *Absolute effect calculated as relative effect was calculated using Peto OR*
[(d)] *Downgraded once as the majority of the evidence is at very high risk of bias*

I.4.3 Definitive treatment - humerus facture

Table 192: Clinical evidence profile: Hemiarthroplasty versus conservative

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Hemiarthroplasty**	**Conservative**	**Relative (95% CI)**	**Absolute**		
Mortality												
2	RCT	no serious risk of bias	serious[(a)]	no serious indirectness	very serious[(b)]	none	3/52 (5.8%)	5.4%	RR 1.10 (0.24 to 4.93)	5 more per 1000 (from 41 fewer to 212 more)	VERY LOW	CRITICAL
Health Related Quality of Life (EQ-5D) (range of scores: 0–1; Better indicated by higher values)												
1	RCT	serious[(c)]	no serious inconsistency	no serious indirectness	serious[(b)]	none	24	25	-	MD 0.16 higher (0.04 to 0.28 higher)	LOW	CRITICAL

Constant Score (range of scores: 0–100; Better indicated by higher values)												
2	RCT	serious[c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	47	48	-	MD 1.6 higher (5.47 lower to 8.67 higher)	MODERATE	CRITICAL
DASH Score (range of scores: 0–100; Better indicated by lower values)												
1	RCT	serious[c]	no serious inconsistency	no serious indirectness	serious[b]	none	24	24	-	MD 6.7 lower (17.93 lower to 4.53 higher)	LOW	
Need for further operative treatment												
2	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[b]	none	4/52 (7.7%)	2/53 (3.8%)	RR 2.05 (0.39 to 10.66)	40 more per 1000 (from 23 fewer to 365 more)	LOW	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Infection												
2	RCT					none	0/50 (0%)	0/52 (0%)	not pooled	not pooled		CRITICAL

[a] *The point estimate varies widely across studies, unexplained by subgroup analysis*
[b] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs*
[c] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias*

Table 193: Clinical evidence profile: Hemiarthroplasty versus open reduction

Quality assessment						No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hemiarthroplasty	Open reduction	Relative (95% CI)	Absolute		
Mortality												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	1/16 (6.3%)	0/12 (0%)	OR 5.75 (0.11 to 302.04)	60 more per 1000 (from 0 more to 230 more)	VERY LOW	CRITICAL
Health Related Quality of Life (EQ-5D) (range of scores: 0–1; Better indicated by higher values)												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	15	12	-	MD 0.07 higher (0.1 lower to 0.24 higher)	VERY LOW	CRITICAL
Functional score												
0	-	-	-	-	-	-	-	-	-	-	-	-
Need for further operative treatment												
1	RCT	serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	3/19 (15.8%)	3/13 (23.1%)	RR 0.68 (0.16 to 2.88)	74 fewer per 1000 (from 194 fewer to 434 more)	VERY LOW	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Infection												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

[(a)] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs*
[(b)] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias*

Table 194: Clinical evidence profile: Open reduction versus conservative

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Open reduction	Conservative	Relative (95% CI)	Absolute		
Mortality												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(a)]	none	2/25 (8%)	0/25 (0%)	OR 7.7 (0.47 to 126.75)	80 more per 1000 (from 0 more to 210 more)	LOW	CRITICAL
Health related quality of life at 2 years (range of scores: 0-1; Better indicated by higher values)												
1	RCT	serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	23	25	-	MD 0.02 higher (0.04 lower to 0.08 higher)	LOW	CRITICAL
Constant score (range of scores: 0–100; Better indicated by higher values)												
2	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	serious[(a)]	none	37	40	-	MD 3.37 lower lower (12.71 lower to 5.97 higher)	VERY LOW	CRITICAL
Infection												
1	RCT	very serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	2/14 (14.3%)	0/15 (0%)	OR 8.57 (0.51 to 144.39)	140 more per 1000 (from 0 more to 350 more)	VERY LOW	CRITICAL
Avascular necrosis												
1	RCT	serious[(b)]	no serious inconsistency	no serious indirectness	very serious[(a)]	none	12/23 (52.2%)	15/25 (60%)	OR 0.87 (0.52 to 1.44)	78 fewer per 1000 (from 288 fewer to 264 more)	VERY LOW	CRITICAL

Need for further operative treatment												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(a)]	none	4/23 (17.4%)	1/25 (4%)	RR 4.35 (0.52 to 36.11)	134 more per 1000 (from 19 fewer to 1000 more)	LOW	CRITICAL
Nerve damage												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[(a)]	none	4/20 (20%)	3/24 (12.5%)	RR 1.60 (0.40 to 6.32)	75 more per 1000 (from 75 fewer to 665 more)	LOW	CRITICAL

[(a)] Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs
[(b)] Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias

Table 195: Clinical evidence profile: Hemiarthroplasty versus reverse shoulder replacement

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Reverse Shoulder Arthoplasty**	**Hemiarthroplasty**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Mortality at 1 year												
1	RCT	serious[(a)]	no serious inconsistency	no serious indirectness	very serious[(b)]	none	1/31 (3.2%)	0/31 (0%)	OR 7.39 (0.15 to 372.38)	32 more per 1000 (from 53 fewer to 117	VERY LOW	CRITICAL

										more)[c]		
Constant score at 2 years (range of scores: 0-100; Better indicated by higher values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	30	31	-	MD 16.1 lower (25.21 to 6.99 lower)	LOW	CRITICAL
QuickDASH at 2 years (range of scores: 0-55; Better indicated by lower values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	30	31	-	MD 6.9 higher (2.99 to 10.81 higher)	LOW	CRITICAL
Infection at 2 years												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/30 (3.3%)	1/31 (3.2%)	RR 1.03 (0.07 to 15.78)	1 more per 1000 (from 30 fewer to 473 more)	VERY LOW	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Nerve damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Need for further operative treatment at 2 years												
1	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[b]	none	6/30 (20%)	1/31 (3.2%)	RR 6.2 (0.79 to 48.48)	166 more per 1000 (from 7 fewer to 1000 more)	MODERATE	CRITICAL

[a] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias*
[b] *Downgraded by two increments if the confidence interval crossed both MIDs*
[c] *Absolute effect calculated as analysis conducted using Peto OR*

Table 196: Clinical evidence profile: Surgical versus conservative

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgical	Conservative	Relative (95% CI)	Absolute		
Mortality (follow-up mean 2 years)												
4	RCT	serious[a]	serious[b]	no serious indirectness	serious	none	14/201 (7%)	8/202 (4%)	RR 1.68 (0.75 to 3.75)	27 more per 1000 (from 10 fewer to 109 more)	VERY LOW	CRITICAL
Health Related Quality of Life (follow-up mean 2 years; measured with: EQ-5D; range of scores: 0–1; Better indicated by higher values)												
3	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	156	159	-	MD 0.03 higher (0.01 to 0.07 higher)	MODERATE	CRITICAL
Health Related Quality of Life (follow-up mean 2 years; measured with: SF-12 physical component; range of scores: 0–100; Better indicated by higher values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	111	115	-	MD 1.48 higher (1.83 lower to 4.79 higher)	MODERATE	CRITICAL
Health Related Quality of Life (follow-up mean 2 years; measured with: SF-12 mental component; range of scores: 0–100; Better indicated by higher values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	111	115	-	MD 1.39 lower (4.62 lower to 1.84 higher)	MODERATE	CRITICAL
Oxford Shoulder Score (follow-up 2 years; range of scores: 0–48; Better indicated by higher values)												
1	RCT	serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	114	117	-	MD 0.29 lower (2.44 lower to 1.86 higher)	MODERATE	CRITICAL
Constant Score (follow-up 1–2 years; range of scores: 0–100; Better indicated by higher values)												

4	RCT	serious[a]	serious[c]	no serious indirectness	no serious imprecision	none	84	88	-	MD 0.21 higher (5.84 lower to 5.43 higher)	LOW	CRITICAL
Infection (follow-up 2 years)												
4	RCT	very serious[a]	serious[c]	no serious indirectness	serious[b]	none	4/189 (2.1%)	0/192 (0%)	OR 7.98 (1.1 to 57.81)	21 more per 1000 (from 2 fewer to 44 more)[c]	VERY LOW	CRITICAL
Avascular necrosis at 1–2 Years												
2	RCT	serious[a]	serious[c]	no serious indirectness	very serious[b]	none	16/148 (10.8%)	16/150 (10.7%)	RR 1.07 (0.65 to 1.78)	7 more per 1000 (from 37 fewer to 83 more)	VERY LOW	CRITICAL
Nerve damage at 2 years												
2	RCT	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[b]	none	6/145 (4.1%)	3/149 (2%)	OR 2.49 (0.62 to 9.99)	21 more per 1000 (from 18 fewer to 61 more)[c]	LOW	CRITICAL
Need for further operative treatment (follow-up 2 years)												
4	RCT	serious[a]	serious[c]	no serious indirectness	very serious[b]	none	18/204 (8.8%)	14/206 (6.8%)	RR 1.3 (0.66 to 2.53)	20 more per 1000 (from 23 fewer to 104 more)	VERY LOW	CRITICAL

[a] *Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias*
[b] *Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs*
[c] *Absolute effect calculated as analysis conducted using Peto OR*

I.4.4 Definitive treatment - paediatric femoral fractures

Table 197: Clinical evidence profile: Spica versus EIN

Quality assessment							Proportion (%) with events		Effect	Quality	Importance

							OR Mean(sd)[n]					
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Spica**	**EIN**	**Relative (95% CI)**	**Absolute**		
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number of follow up surgeries												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
PODCI-POSNA score												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Mortality												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Length of hospital stay (days) (Better indicated by lower values)												
3	RCT	very serious[(a)]	very serious[(b)]	no serious indirectness	very serious [(c)]	none	72	74	-	Random effects MD 0.19 lower (12.32 lower to 11.94 higher)	VERY LOW	IMPORTANT
Return to school (weeks) (Better indicated by lower values)												
2	RCT	very serious[(a)]	very serious[(b)]	no serious indirectness	no serious imprecision	none	47	48	-	Random effects MD 5.73 higher (3.68 to 7.79 higher)	VERY LOW	IMPORTANT
Return to (independent) ambulation (days) (Better indicated by lower values)												
2	RCT	very serious[(a)]	very serious[(b)]	no serious indirectness	no serious imprecision	none	47	48	-	Random effects MD 36.41 higher	VERY LOW	IMPORTANT

										(20.44 to 52.37 higher)		
Return to normal activities (weeks) (Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	25	-	MD 3.32 higher (1.31 to 5.33 higher)	LOW	IMPORTANT
Further treatment												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious [c]	none	1/24 (4.2%)	3/25 (12%)	RR 0.35 (0.04 to 3.11)	78 fewer per 1000 (from 115 fewer to 253 more)	VERY LOW	CRITICAL
Flynn grading 'excellent'												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	4/24 (16.7%)	19/25 (76%)	RR 0.22 (0.09 to 0.55)	593 fewer per 1000 (from 342 fewer to 692 fewer)	LOW	CRITICAL
Malunion												
2	RCT	very serious[a]	serious[b]	no serious indirectness	very serious [c]	none	4/47 (8.5%)	4/48 (8.3%)	Random effects RR 0.9 (0.03 to 24.99)	9 fewer per 1000 (from 82 fewer to 1000 more)	VERY LOW	CRITICAL
Avascular necrosis												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious [c]	none	0/24 (0%)	1/25 (4%)	Peto OR 0.14 (0 to 7.1)	34 fewer per 1000 (from 40 fewer to 188 more)	VERY LOW	CRITICAL
Parental satisfaction 'good or excellent'												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious [c]	none	17/23 (73.9%)	23/23 (100%)	RR 0.74 (0.58 to	260 fewer per 1000	VERY LOW	CRITICAL

									0.96)	(from 40 fewer to 420 fewer)		
Nerve injury												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious [c]	none	0/23 (0%)	1/23 (4.3%)	Peto OR 0.14 (0 to 6.82)	37 fewer per 1000 (from 43 fewer to 193 more)	VERY LOW	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations in these randomised studies were likely selection bias, performance bias, and detection bias.

[b] Outcomes were downgraded by one increment for serious inconsistency, as shown by the I squared value being between 50 and 74%. A double downgrade was applied for very serious inconsistency if I squared was >75%. If serious or very serious inconsistency existed, and there were >2 studies, pre-defined sub-grouping (see review question protocol) was applied. If consistency within each sub-group was achieved, then the results for each sub-group were reported as separate outcomes. If this did not reduce inconsistency to acceptable levels within all sub-groups, or there were only 2 studies, then the entire group was re-analysed using a random effects model to allow for the fact that a homogeneous population was not present.

[c] Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25.

Table 198: Clinical evidence profile: Spica versus Ext fixation

Quality assessment							Proportion (%) with events OR Mean(sd)[n]		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Spica**	**External fixation**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Quality of life												

0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number of follow up surgeries												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
PODCI-POSNA score												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Neurovascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Deformity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Vascular compromise												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Malunion												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	25/56 (44.6%)	7/45 (15.6%)	RR 2.87 (1.37 to 6.02)	291 more per 1000 (from 58 more to 781 more)	LOW	CRITICAL
Rand child health status (higher worse) (Better indicated by lower values)												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	serious [(b)]	none	68(7.38) [56]	69(7.38)[45]	-	MD 1 lower (3.9 lower to 1.9 higher)	VERY LOW	CRITICAL
Adverse events requiring other treatment												
1	RCT	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/56 (0%)	20/45 (44.4%)	OR 0.06 (0.02 to 0.17)	399 fewer per 1000 (from 325 fewer to 429 fewer)	LOW	CRITICAL

Pain													
0	-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Return to normal activities													
0	-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Duration of hospital stay													
0	-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Psychological well-being													
0	-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations in this randomised study were likely selection bias, performance bias, and detection bias.

[(b)] Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25

Table 199: Clinical evidence profile: Ext fixation versus EIN

Quality assessment							Proportion (%) with events OR Mean(sd)[n]		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ext fixation	EIN	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number of follow up surgeries												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
PODCI-POSNA score												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Mortality												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Neurovascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Non union/malunion												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Vascular compromise												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Parental satisfaction - would choose same treatment again												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious [b]	none	8/10 (80%)	10/10 (100%)	RR 0.81 (0.57 to 1.14)	190 fewer per 1000 (from 430 fewer to 140	VERY LOW	CRITICAL

										more)		
Number of follow up revisions												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/10 (20%)	1/10 (10%)	RR 2 (0.21 to 18.69)	100 more per 1000 (from 79 fewer to 1000 more)	VERY LOW	CRITICAL
Foot drop												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/10 (0%)	1/10 (10%)	Peto OR 0.14 (0 to 6.82)	85 fewer per 1000 (from 100 fewer to 331 more)	VERY LOW	CRITICAL
limb length discrepancy												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious [b]	none	2/10 (20%)	0/10 (0%)	Peto OR 8.26 (0.48 to 142.43)	200 more per 1000 (from 80 lower to 480 more)	VERY LOW	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Duration hospital stay												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Psychological well-being												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations in this randomised study were likely selection bias, performance bias, and detection bias.

[b] Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25.

Table 200: Clinical evidence profile: Bryant's traction versus Pavlik's harness

Quality assessment							Proportion (%) with events OR Mean(sd)[n]		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bryants	Pavlik	Relative (95% CI)	Absolute	Quality	Importance
Quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Number of follow up surgeries												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
PODCI-POSNA score												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Mortality												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Neurovascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Vascular compromise												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Malunion												
1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/17 (0%)	0/21 (0%)	not pooled	not pooled	VERY LOW	CRITICAL
Length of hospital stay (days) (Better indicated by lower values)												
1	Retrospective	very	no serious	no serious	no serious	none	17.8(11.5)	1.4(11.5)[21]	-	MD 16.4	VERY	CRITICAL

	cohort	serious[a]	inconsistency	indirectness	imprecision		[17]			higher (9.05 to 23.75 higher)	LOW	
Leg length discrepancy (mm) (Better indicated by lower values)												
1	Retrospective cohort	very serious[a]	no serious inconsistency	no serious indirectness	very serious imprecision[b]	none	8(12.12) [17]	7.6(12.12)[21]	-	MD 0.4 higher (7.35 lower to 8.15 higher)	VERY LOW	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Duration of hospital stay												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Psychological well being												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations in this non-randomised study were likely selection bias, performance bias, and detection bias.

[b] Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25.

Table 201: Clinical evidence profile: Standard IN versus submuscular plating

Quality assessment							Proportion (%) with events		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Standard IN	submuscular plating	Relative (95% CI)	Absolute	Quality	Importance
Health related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	-
Number of follow up surgeries												
0	-	-	-	-	-	-	-	-	-	-	-	-
PODCI-POSNA score												
0	-	-	-	-	-	-	-	-	-	-	-	-
Mortality												
0	-	-	-	-	-	-	-	-	-	-	-	-
Neurovascular damage												
0	-	-	-	-	-	-	-	-	-	-	-	-
Vascular compromise												
0	-	-	-	-	-	-	-	-	-	-	-	-
Avascular necrosis												
0	-	-	-	-	-	-	-	-	-	-	-	-
pain												
0	-	-	-	-	-	-	-	-	-	-	-	-
Flynn grading of 'excellent'												
1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious imprecision[(b)]	none	13/22 (59.1%)	12/23 (52.2%)	RR 1.13 (0.67 to 1.91)	68 more per 1000 (from 172 fewer to 475 more)	VERY LOW	CRITICAL
Return to ambulation without limping												

1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	21/21 (100%)	22/22 (100%)	RR 1 (0.92 to 1.09)	0 fewer per 1000 (from 80 fewer to 90 more)	VERY LOW	CRITICAL
Need for reoperation												
1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious imprecision[(b)]	none	2/21 (9.5%)	0/22 (0%)	OR 8.15 (0.49 to 134.79)	100 more per 1000 (from 50 fewer to 240 more)	VERY LOW	CRITICAL
Leg length discrepancy >1cm												
1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/21 (0%)	0/22 (0%)	not pooled	not pooled	VERY LOW	CRITICAL
Non union												
1	Retrospective cohort	very serious[(a)]	no serious inconsistency	no serious indirectness	very serious imprecision[(b)]	none	1/21 (4.8%)	0/22 (0%)	OR 7.75 (0.15 to 390.96)	50 more per 1000 (from 70 fewer to 170 more)	VERY LOW	CRITICAL
Pain												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Return to normal activities												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Duration of hospital stay												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
Psychological well being												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[(a)] Outcomes were downgraded by one increment if the weighted average number of serious methodological limitations across studies was one, and downgraded by two increments if the weighted average number of serious methodological limitation across studies were two or more. Methodological limitations in this non-randomised study were likely selection bias, performance bias, and detection bias.

[(b)] Outcomes were downgraded by one increment if the upper or lower 95% CI crossed the lower MID or the upper or lower 95% CI crossed the upper MID. Outcomes were downgraded by two increments if both MIDs were crossed by one or both of the 95% CIs. Default MIDs were set at RRs of 0.75 and 1.25

I.4.5 Post operative mobilisation – ankle fractures

Table 202: Immediate unrestricted weight bearing versus delayed unrestricted weight bearing

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Immediate WB	Delayed WB	Relative (95% CI)	Absolute	Quality	Importance
Ankle score @ 9 weeks (measured with: modified Weber demerit scale; range of scores: 0–24; Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	20	19	-	MD 2.8 lower (6.11 lower to 0.51 higher)	VERY LOW	CRITICAL
Ankle score @ 18 weeks (measured with: modified Weber demerit scale; range of scores: 0–24; Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	20	19	-	MD 0.1 higher (2.6 lower to 2.8 higher)	VERY LOW	CRITICAL
Ankle score @ 36 weeks (measured with: modified Weber demerit scale; range of scores: 0–24; Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	20	19	-	MD 1.1 higher (0.66 lower to 2.86 higher)	VERY LOW	CRITICAL
Ankle score @ 52 weeks (measured with: modified Weber demerit scale; range of scores: 0–24; Better indicated by lower values)												
1	RCT	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	20	19	-	MD 0.1 higher (1.57 lower to 1.77 higher)	VERY LOW	CRITICAL
Displacement/re-dislocation (follow-up mean 11 months)												
6	RCTs	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	2/180 (1.1%)	2.2%	RR 0.6 (0.15 to 2.45)	9 fewer per 1000 (from 19 fewer to 32 more)	VERY LOW	CRITICAL

Wound infection (follow-up mean 10 months)												
5	RCTs	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	13/133 (9.8%)	3%	RR 3.08 (1.11 to 8.51)	62 more per 1000 (from 3 more to 225 more)	VERY LOW	CRITICAL
Mortality												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Health-related quality of life												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Return to pre-injury mobility status/normal activity												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Other adverse effects												
0	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Hospital bed days												
0	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

[a] The majority of evidence was from studies at very high risk of bias
[b] Confidence interval crossed one MID
[c] Confidence interval crossed both MIDs

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