

## Fractures (non-complex): assessment and management

Fractures: diagnosis, management and follow-up of fractures

*NICE Guideline NG38*

*Appendices J - Q*

*February 2016*

*Final*

*Commissioned by the National Institute for  
Health and Care Excellence*



**Disclaimer**

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and, where appropriate, their guardian or carer.

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**Funding**

National Institute for Health and Care Excellence

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# Appendices

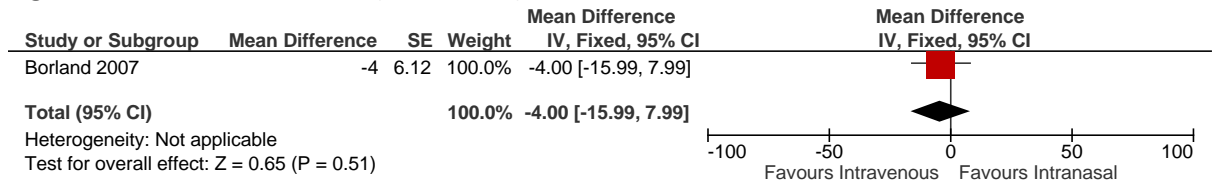
## Appendix J: Forest plots

### J.1 Initial pain management and immobilisation

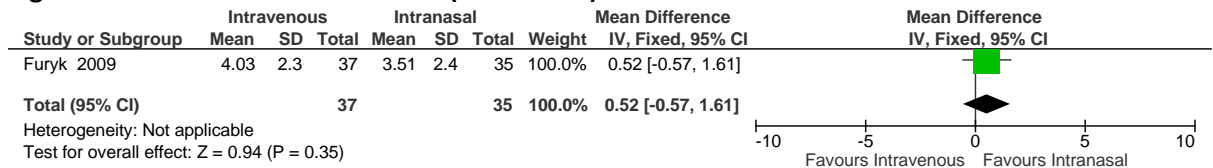
#### J.1.1 Initial pharmacological pain management

##### J.1.1.1 Intranasal Opioid versus Intravenous Opioid - Children

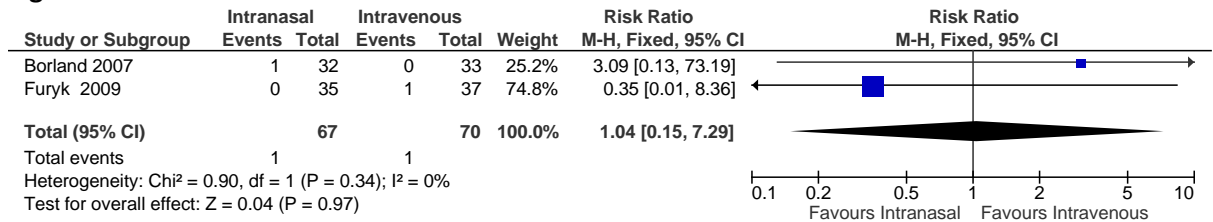
**Figure 1: Pain at 30 minutes (Final Score)**



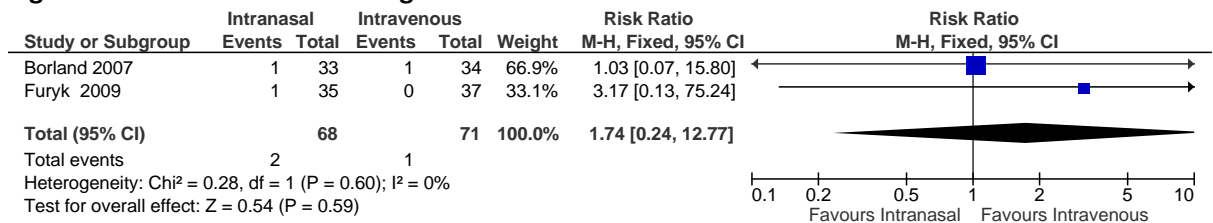
**Figure 2: Pain Score at 30 minutes (Final Score)**



**Figure 3: Nausea**



**Figure 4: Need for further analgesia**



J.1.1.2 Oral Codeine versus Oral Codeine (Children)

Figure 5: Pain at 180 minutes (Change Score)

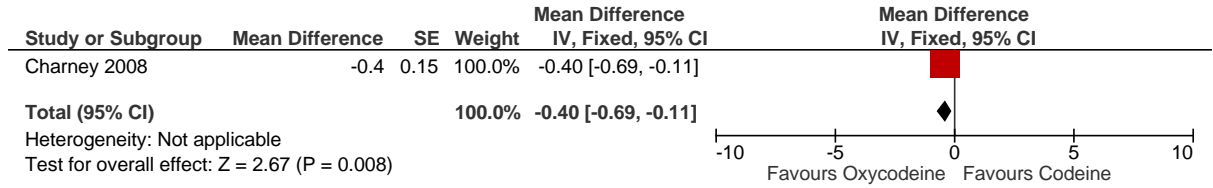
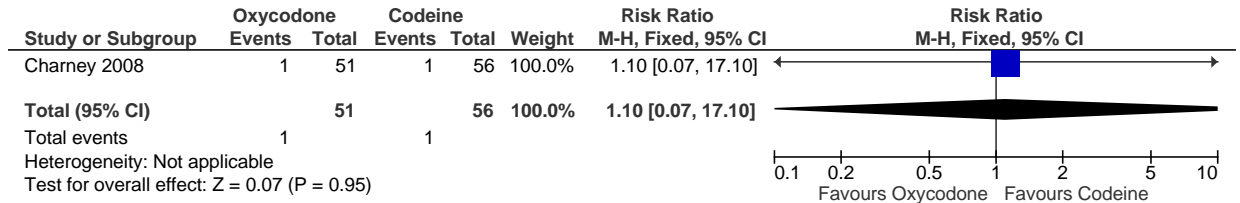


Figure 6: Nausea



J.1.1.3 Oral NSAIDs versus Oral Codeine (Children)

Figure 7: Pain at 60 minutes (Changes Score)

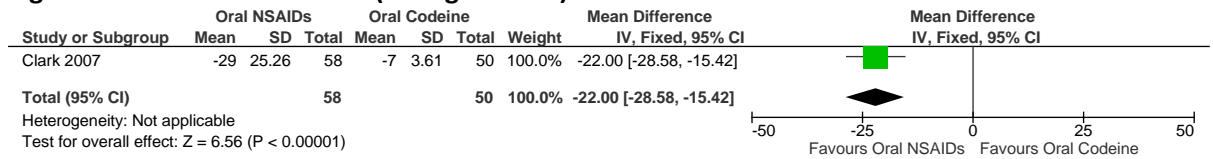


Figure 8: Nausea

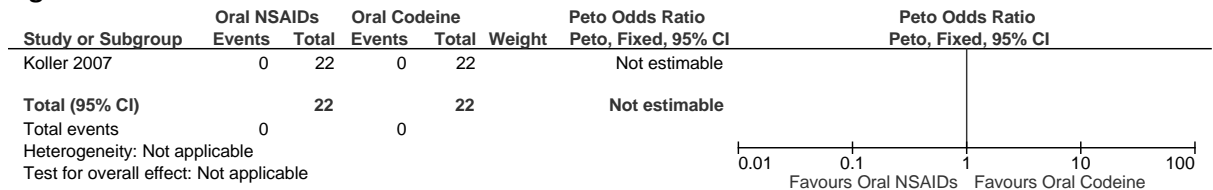
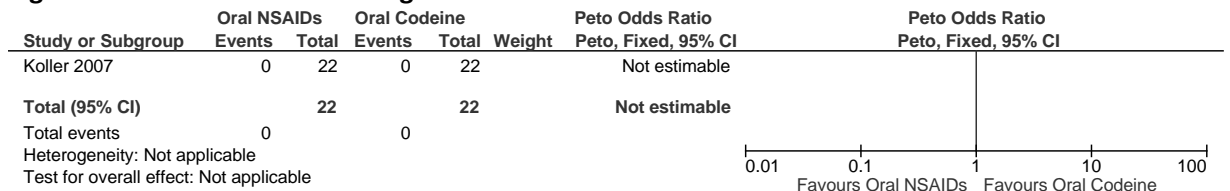


Figure 9: Need for further analgesia



J.1.1.4 Oral NSAIDs versus Oral Paracetamol (Children)

Figure 10: Pain at 60 minutes (Change Score)

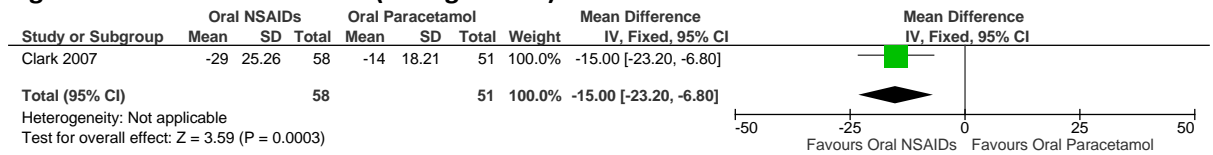


Figure 11: Nausea

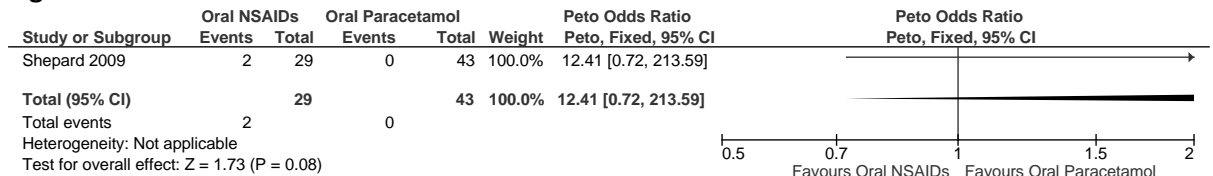


Figure 12: Delayed Union

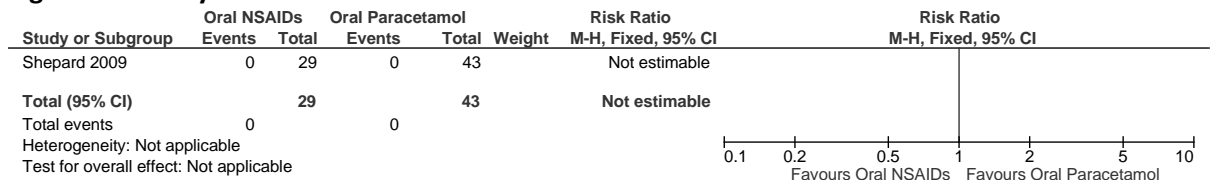
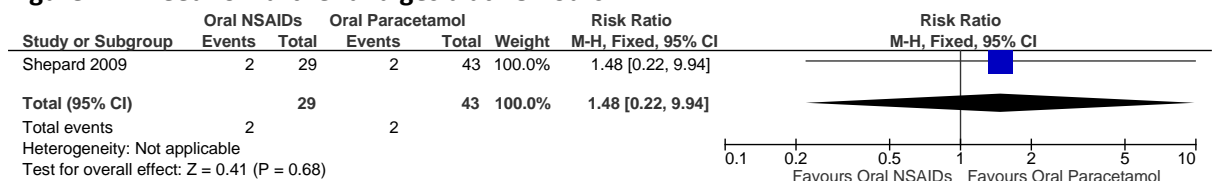


Figure 13: Need for further analgesia at 2 hours

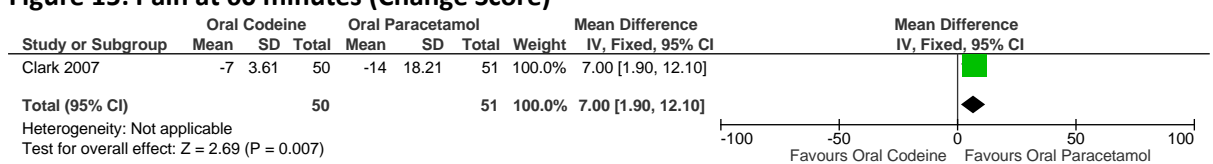


Figure 14: Need for further analgesia at 48 hours



J.1.1.5 Oral Codeine versus Oral Paracetamol (Children)

Figure 15: Pain at 60 minutes (Change Score)



J.1.1.6 Oral Opioid versus Intravenous Opioid (Children)

Figure 16: Pain at 30 minutes (Final Score)

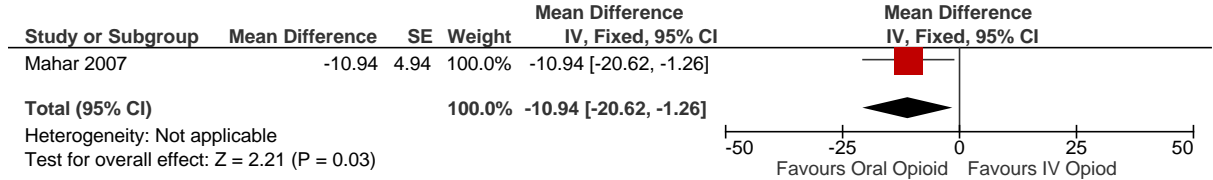


Figure 17: Pain at 60 minutes (Final Score)

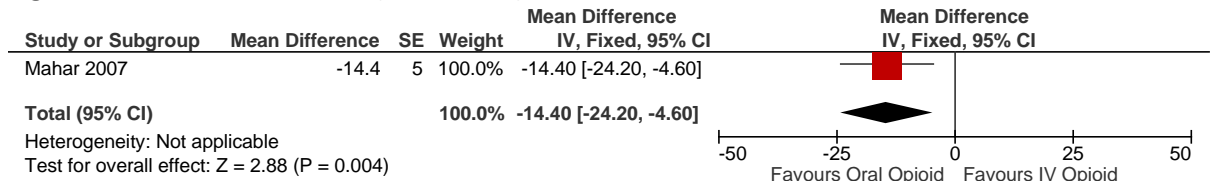
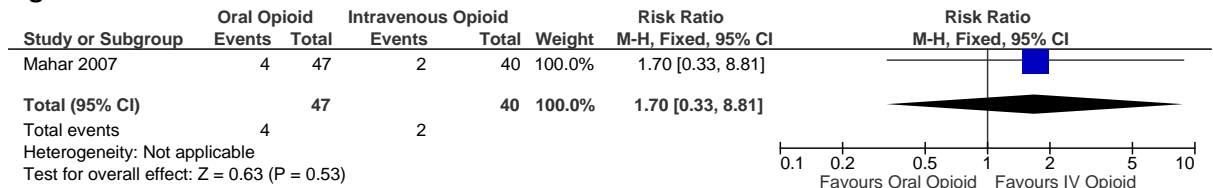


Figure 18: Nausea



J.1.1.7 Oral NSAIDs versus Oral Tramadol (Children)

Figure 19: Nausea

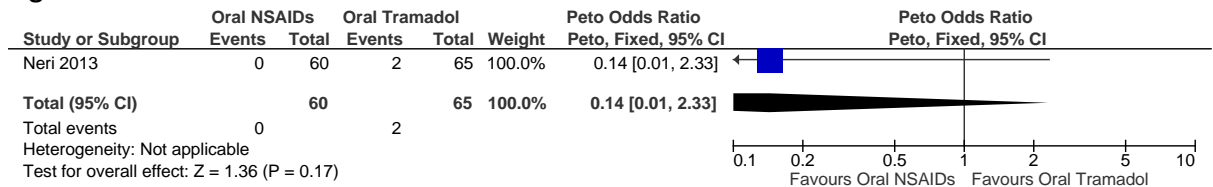


Figure 20: Need for further analgesia





J.1.1.8 Oral NSAIDs versus Oral Paracetamol-Codeine combination (Children)

Figure 21: Pain at 30 Minutes (Change Score)

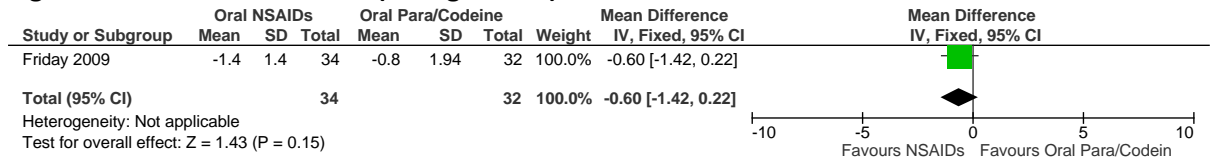


Figure 22: Pain at 60 Minutes (Change Score)

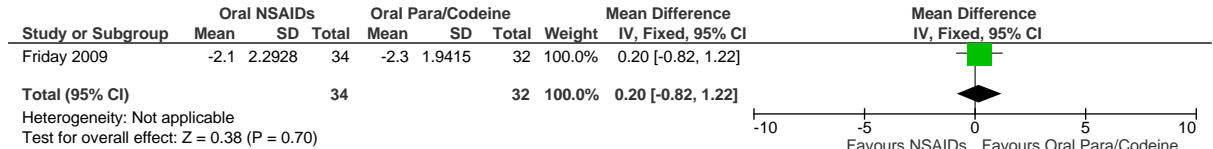
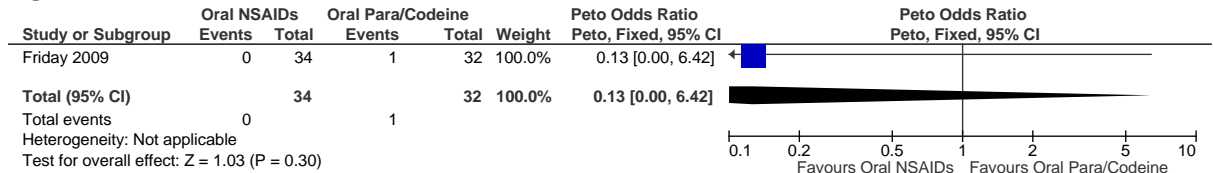


Figure 23: Nausea



J.1.1.9 Oral NSAIDs versus Oral NSAIDs and Codeine combination (Children)

Figure 24: Nausea

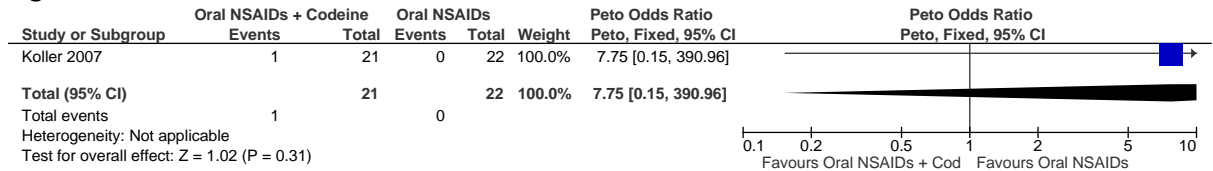
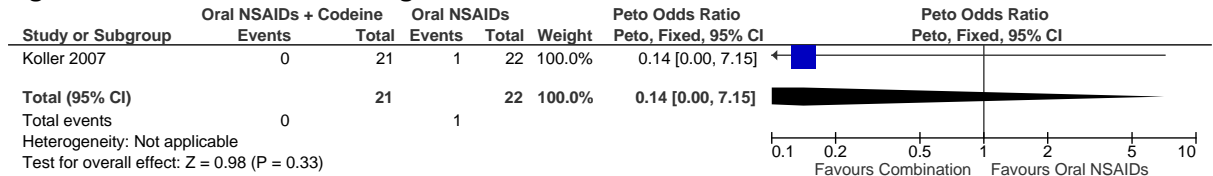


Figure 25: Need for further analgesia



J.1.1.10 Oral Codeine versus Oral NSAIDs Codeine and Oral Codeine combination (Children)

Figure 26: Nausea

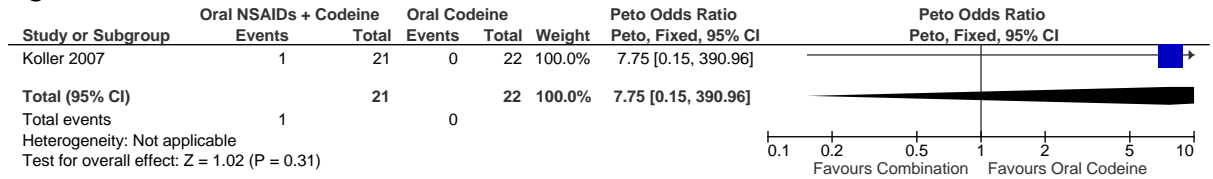
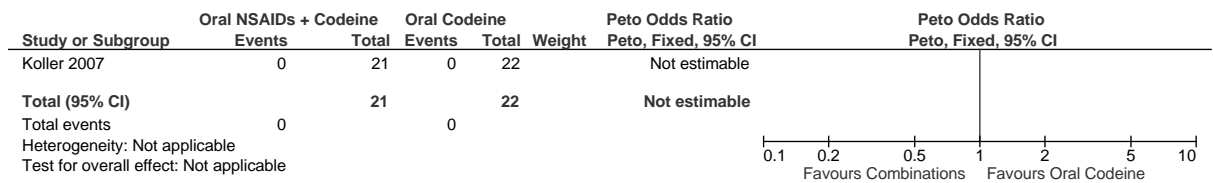


Figure 27: Need for further analgesia



J.1.1.11 Oral NSAIDs versus Oral Morphine (Children)

Figure 28: Pain at 4 hours (Change Score)

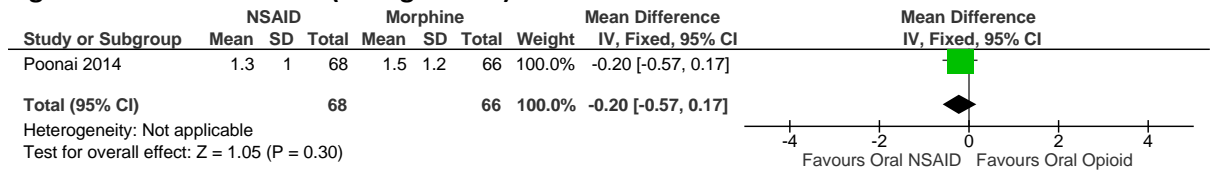


Figure 29: Nausea

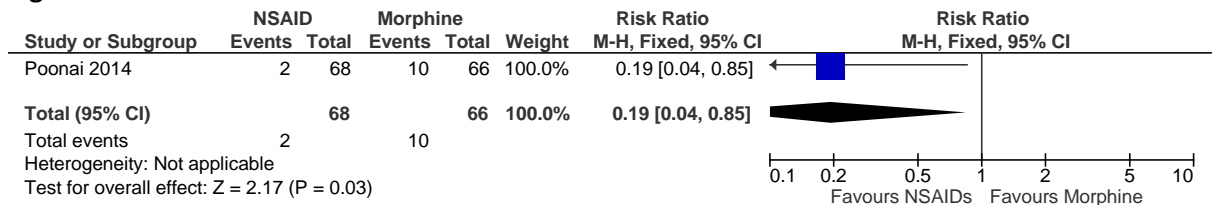
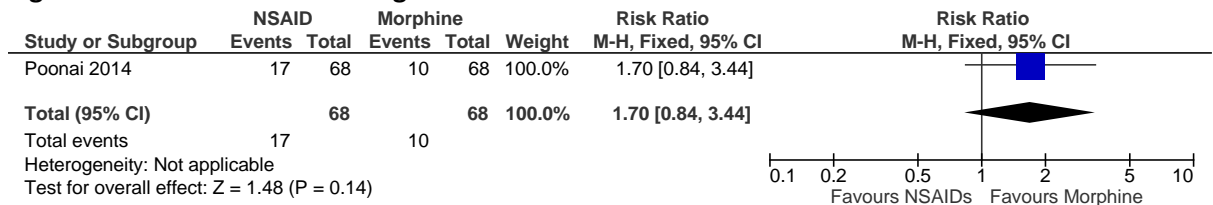


Figure 30: Need for rescue analgesia



J.1.1.12 Oral Opioid versus Intravenous Opioid (Adults)

Figure 31: Pain at 30 minutes (Final Score)

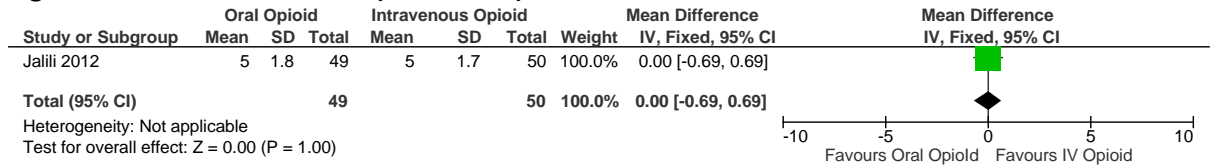


Figure 32: Pain at 60 Minutes (Final Score)

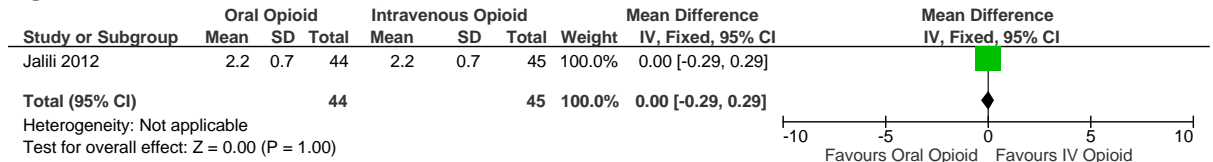


Figure 33: Nausea at 30 minutes

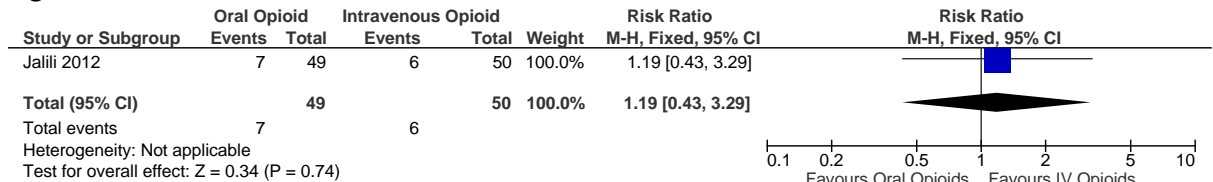
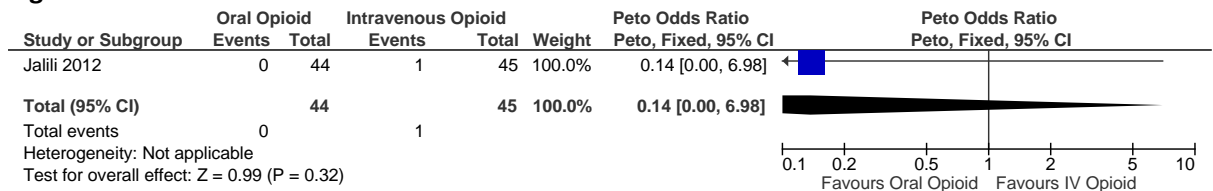


Figure 34: Nausea at 60 Minutes



J.1.1.13 Oral Codeine versus Oral Codeine (Adults)

Figure 35: Pain at 30 Minutes (Change Score)

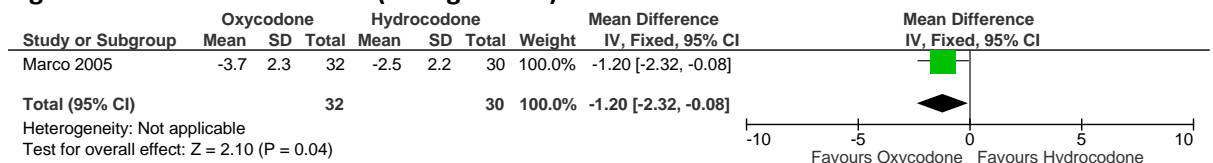
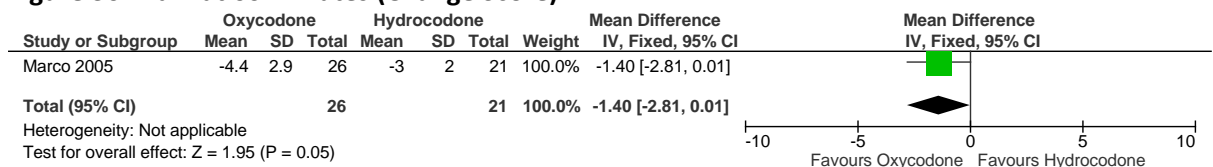
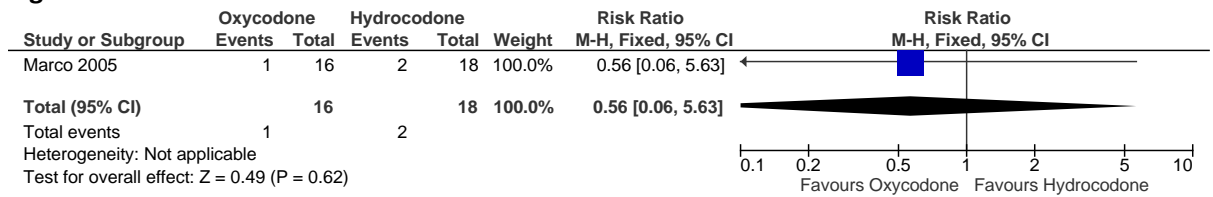


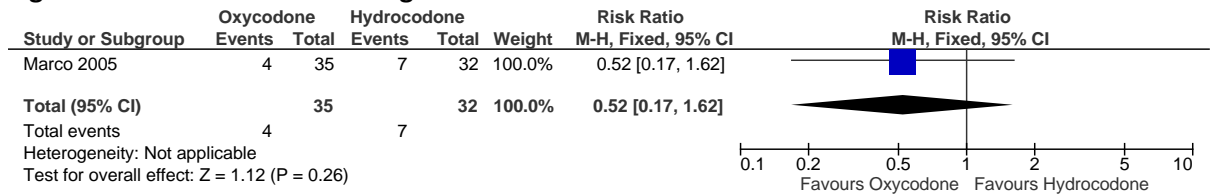
Figure 36: Pain at 60 Minutes (Change Score)



**Figure 37: Nausea**

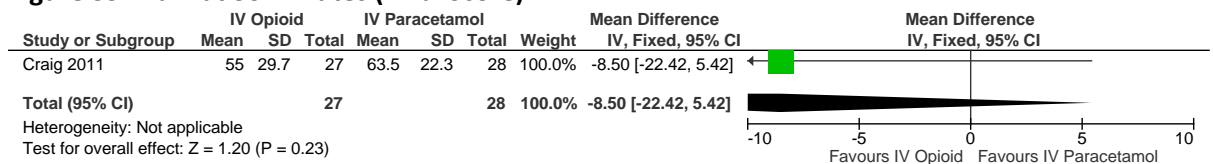


**Figure 38: Need for further analgesia**

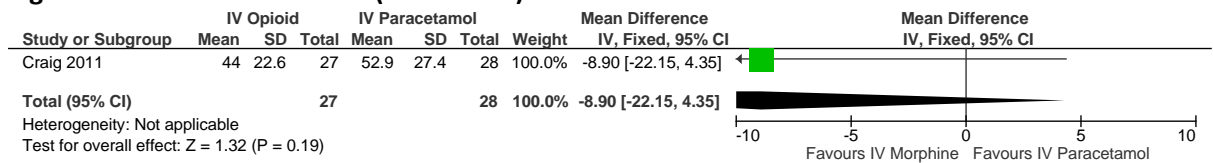


**J.1.1.14 Intravenous Opioids versus Intravenous Paracetamol (Adults)**

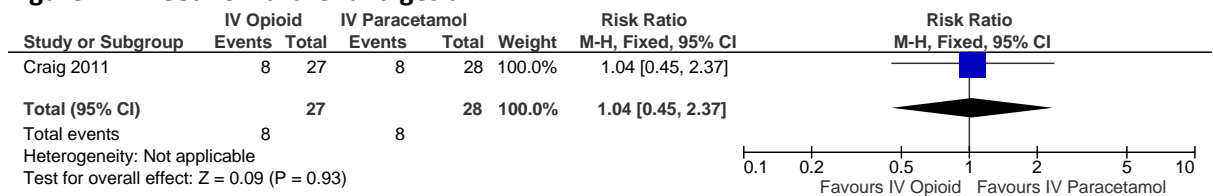
**Figure 39: Pain at 30 minutes (Final Score)**



**Figure 40: Pain at 60 minutes (Final Score)**

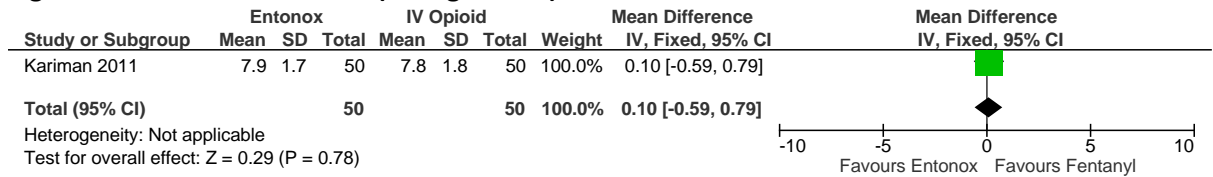


**Figure 41: Need for further analgesia**



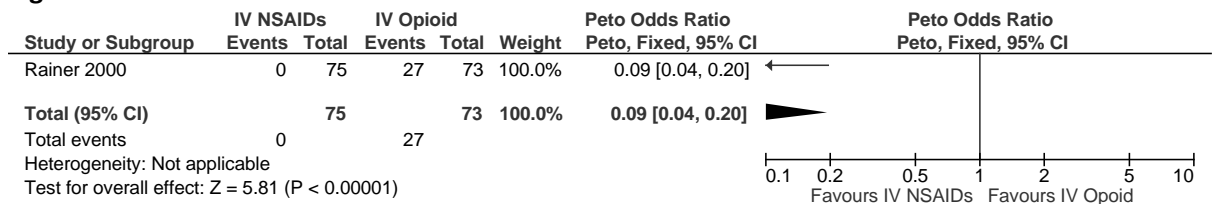
**J.1.1.15 Entonox versus Intravenous Opioid (Adult)**

**Figure 42: Pain at 60 Minutes (Change Score)**



**J.1.1.16 Intravenous NSAIDs versus Intravenous Opioid (Adult)**

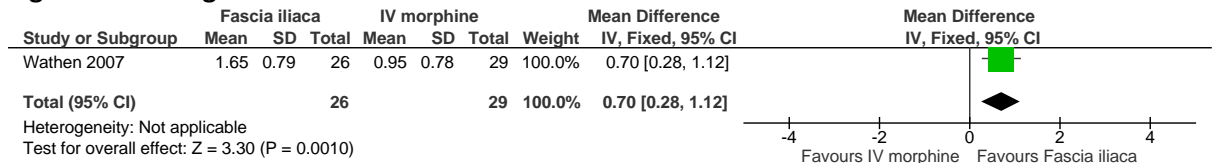
**Figure 43: Nausea**



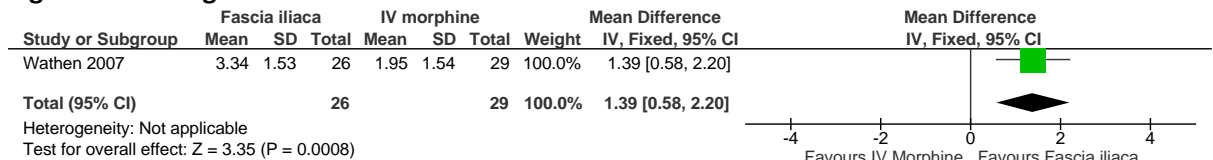
## J.1.2 Paediatric nerve blocks femoral fractures

### J.1.2.1 Fascia iliaca compartment block versus IV morphine

**Figure 44: Change in Pain at 5 minutes**



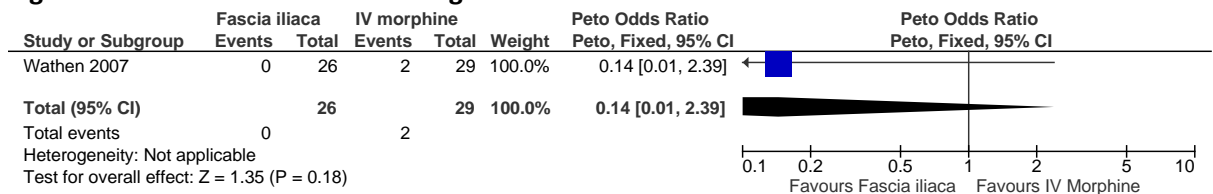
**Figure 45: Change in Pain at 30 minutes**



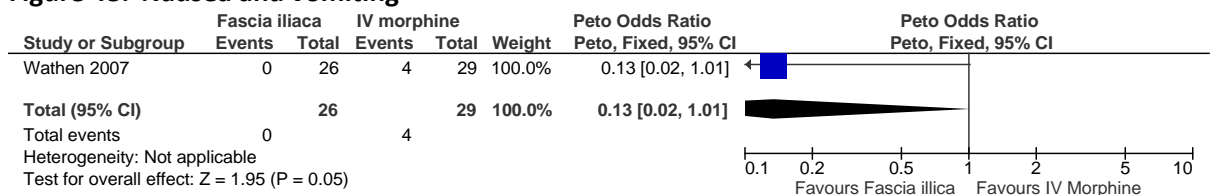
**Figure 46: Respiratory depression**



**Figure 47: Nerve and vascular damage**



**Figure 48: Nausea and vomiting**

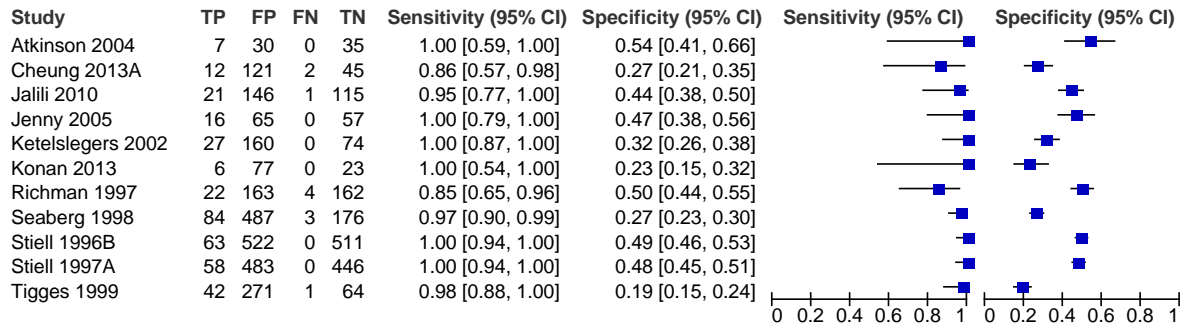


## J.2 Acute stage assessment and diagnostic imaging

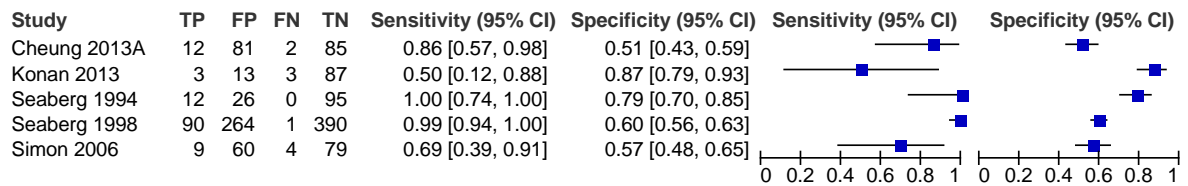
### J.2.1 Selecting patients for imaging - clinical prediction rules for knee fractures

#### J.2.1.1 Diagnostic accuracy of validated knee fracture prediction tools

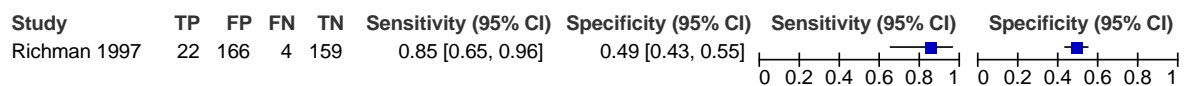
**Figure 49: Diagnostic accuracy of the Ottawa in adults**



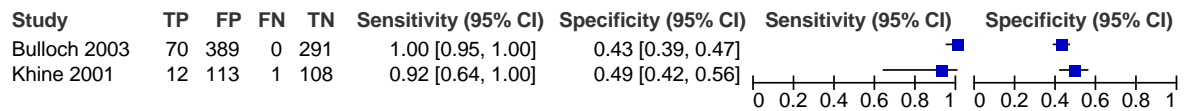
**Figure 50: Diagnostic accuracy of the Pittsburgh in adults**



**Figure 51: Diagnostic accuracy of the Bauer in adults**



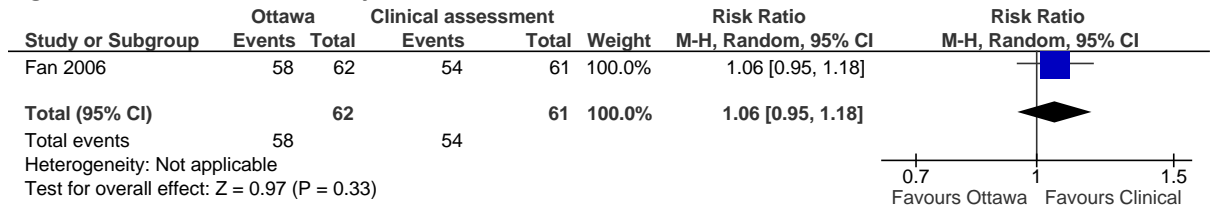
**Figure 52: Diagnostic accuracy of the Ottawa in children**



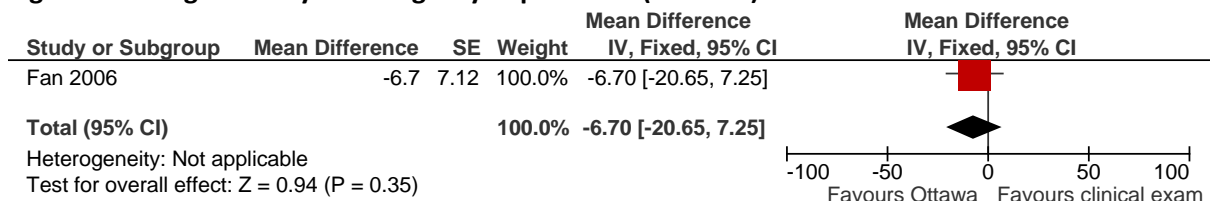
## J.2.2 Selecting patients for imaging - clinical prediction rules for ankle fractures

### J.2.2.1 Ottawa versus clinical assessment

**Figure 53: Number with X-rays**



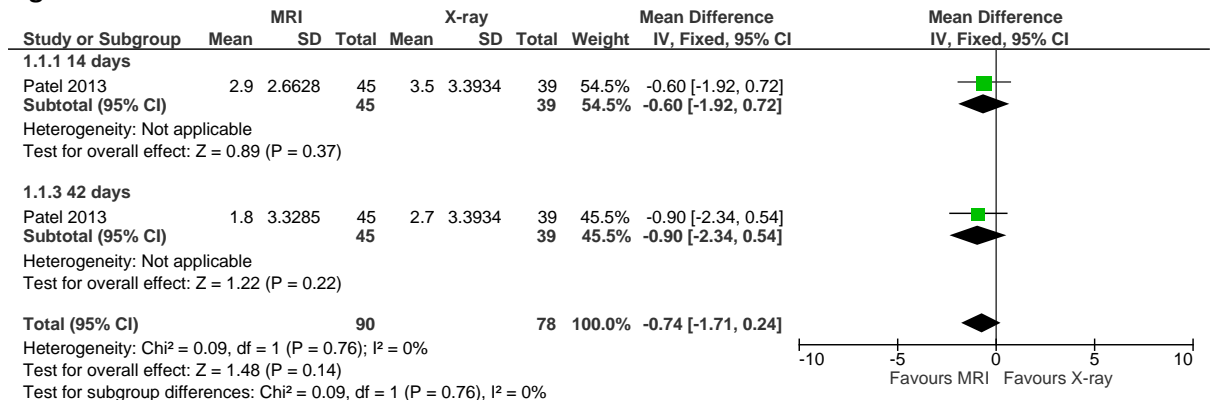
**Figure 54: Length of stay in Emergency department (minutes)**



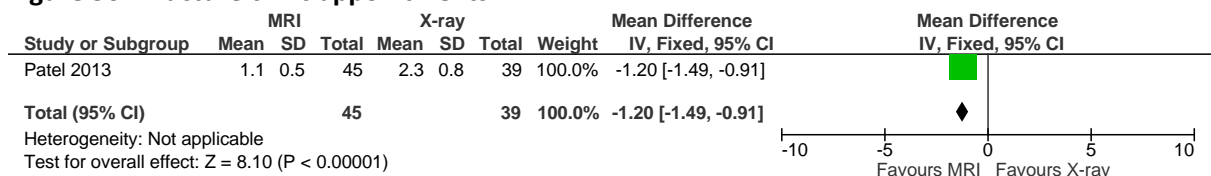
## J.2.3 Imaging of scaphoid

### J.2.3.1 Early MRI versus delayed X-ray

**Figure 55: Pain**

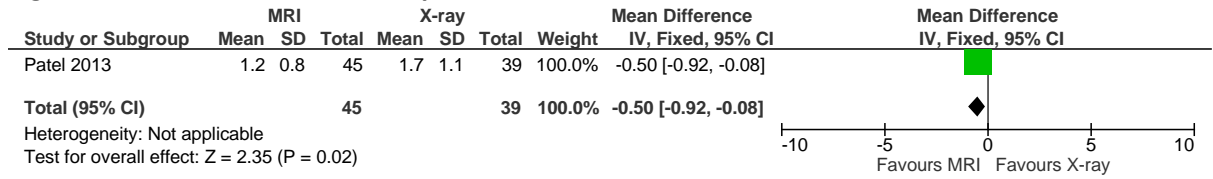


**Figure 56: Fracture clinic appointments**





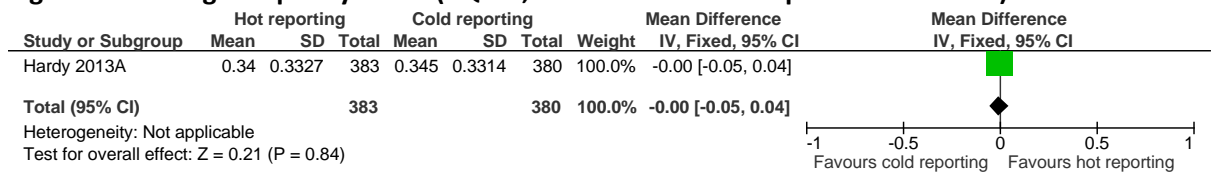
**Figure 57: Additional radiation exposure**



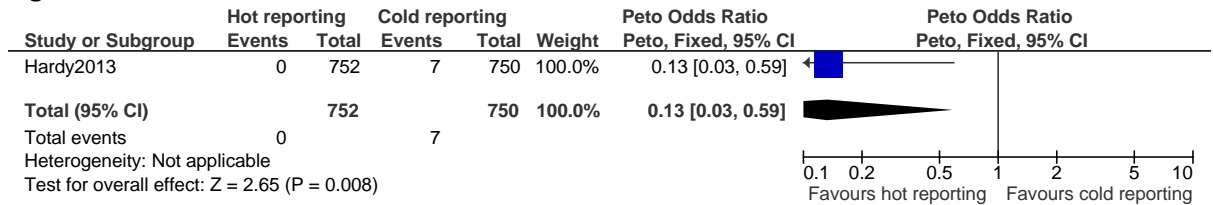
## J.2.4 Hot reporting

### J.2.4.1 Hot reporting versus cold reporting

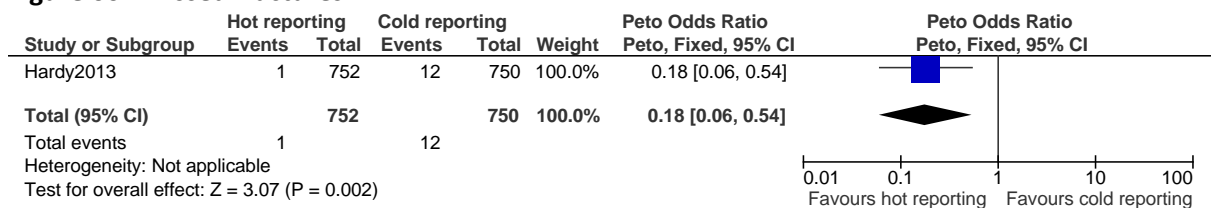
**Figure 58: Change in quality of life (EQ-5D; baseline to 8-weeks post-intervention)**



**Figure 59: Patient recalled**



**Figure 60: Missed fractures**

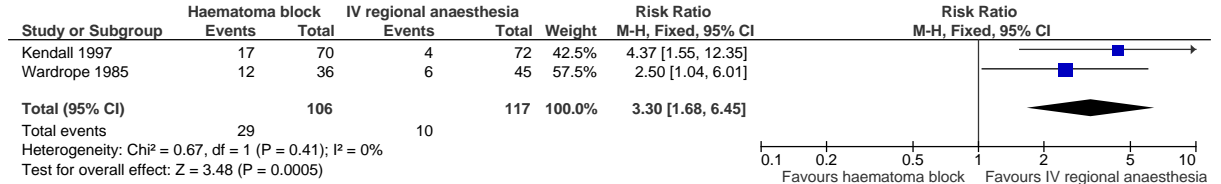


## J.3 Management and treatment plan in the emergency department

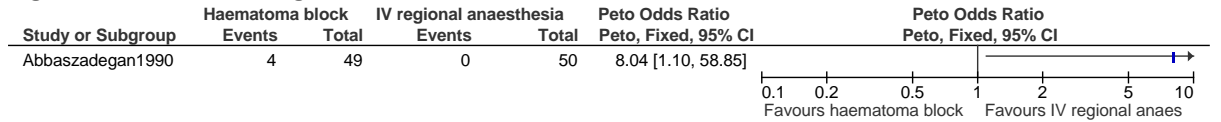
### J.3.1 Reduction anaesthesia – distal radius fractures

#### J.3.1.1 Haematoma block compared to IV regional anaesthesia for reduction of displaced distal radius fractures

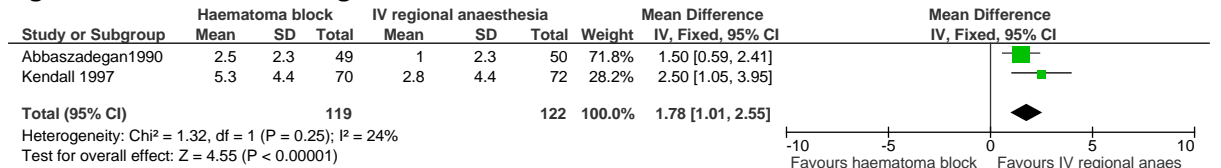
**Figure 61: Need for re-manipulation**



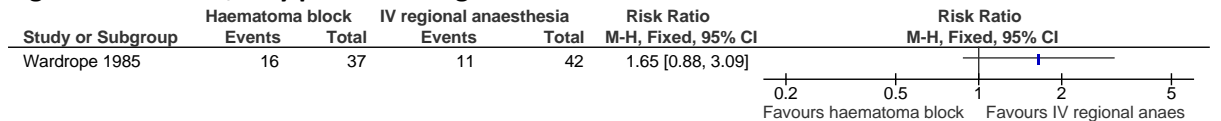
**Figure 62: Need for surgical fixation**



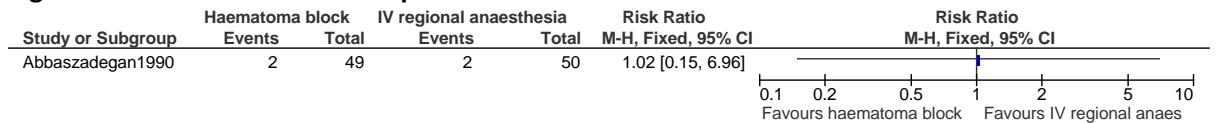
**Figure 63: Pain score during reduction**



**Figure 64: Painful/very painful during reduction**



**Figure 65: Median nerve decompression**



J.3.1.2 Entonox compared to IV regional anaesthesia for reduction of displaced distal radius fractures

Figure 66: Need for re-manipulation

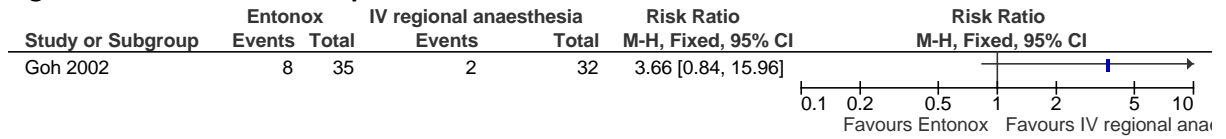


Figure 67: Need for surgical fixation

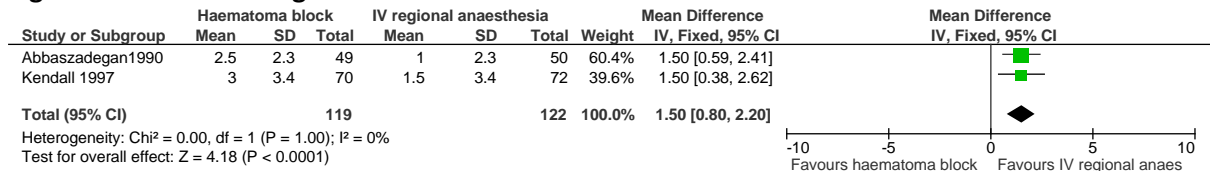
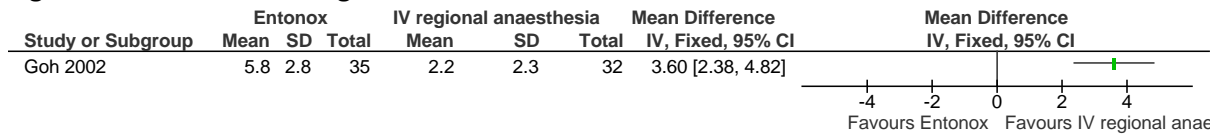
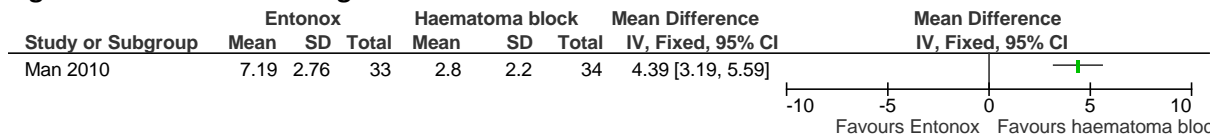


Figure 68: Pain score during reduction



J.3.1.3 Entonox compared to haematoma block for reduction of displaced distal radius fractures

Figure 69: Pain score during reduction



J.3.1.4 Haematoma block compared to regional nerve block for reduction of displaced distal radius fractures

Figure 70: Need for re-manipulation

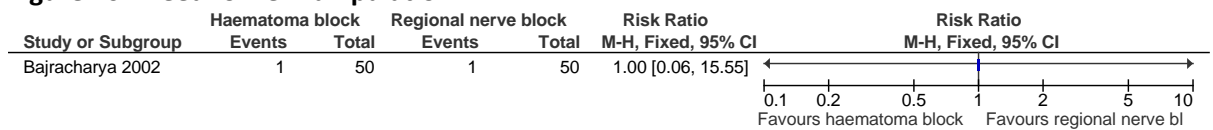


Figure 71: Pain score during reduction

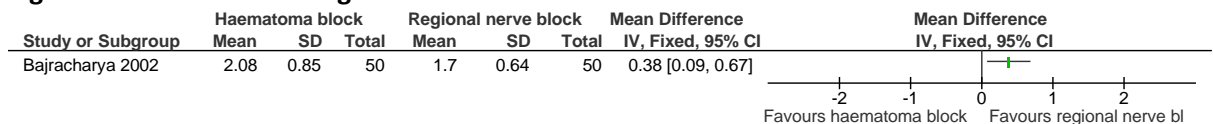
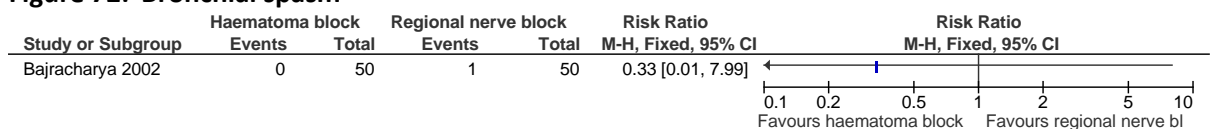
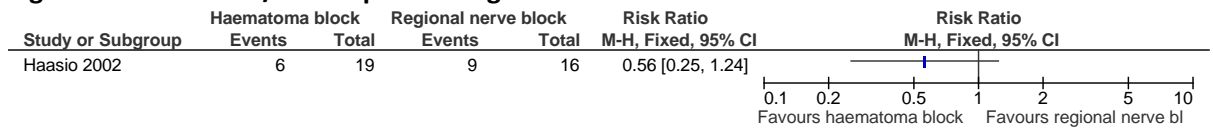


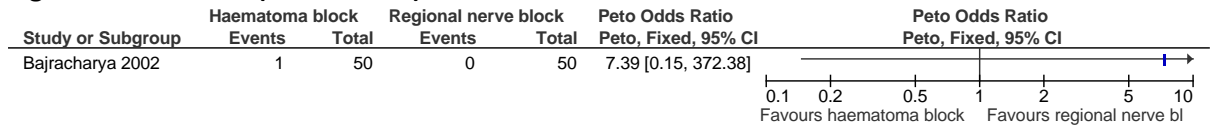
Figure 72: Bronchial spasm



**Figure 73: Moderate/severe pain during reduction**



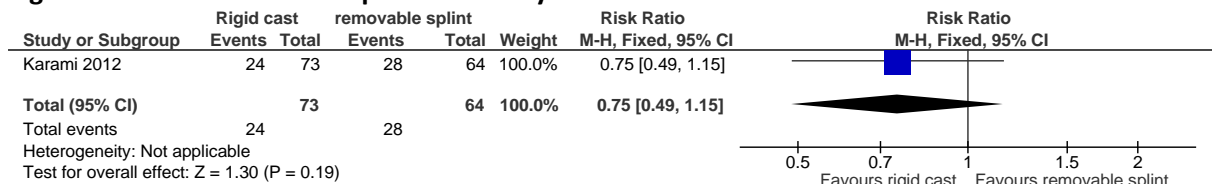
**Figure 74: Infection (at block site)**



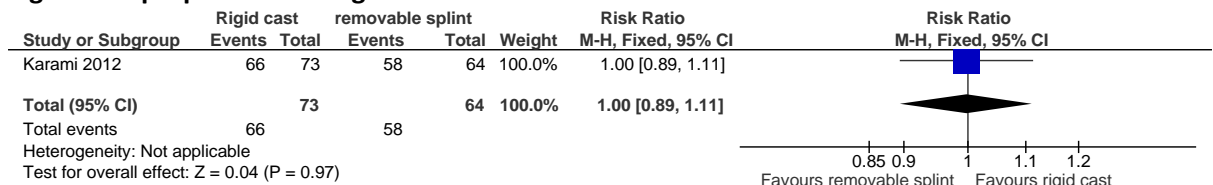
### J.3.2 Treatment of torus fractures

#### J.3.2.1 Rigid cast versus removable splint

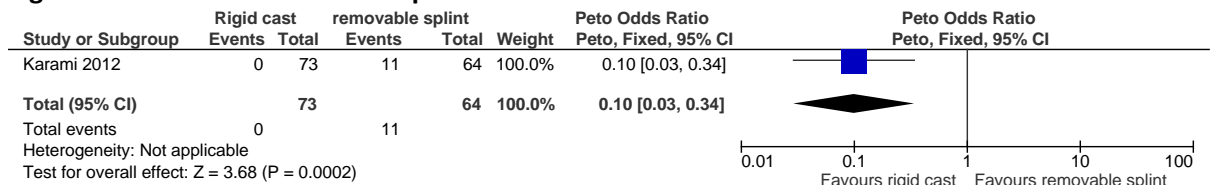
**Figure 75: mild to moderate pain on activity at 3 weeks**



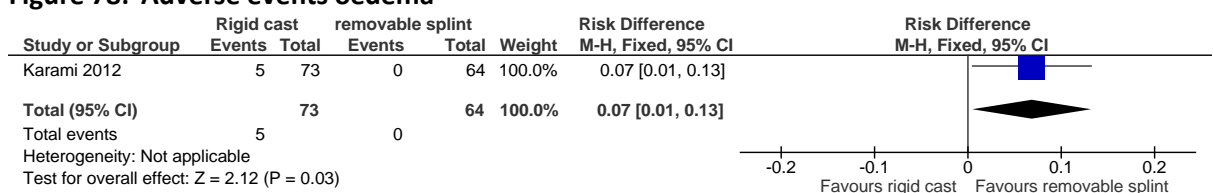
**Figure 76: proportion finding treatment convenient at 3 weeks**



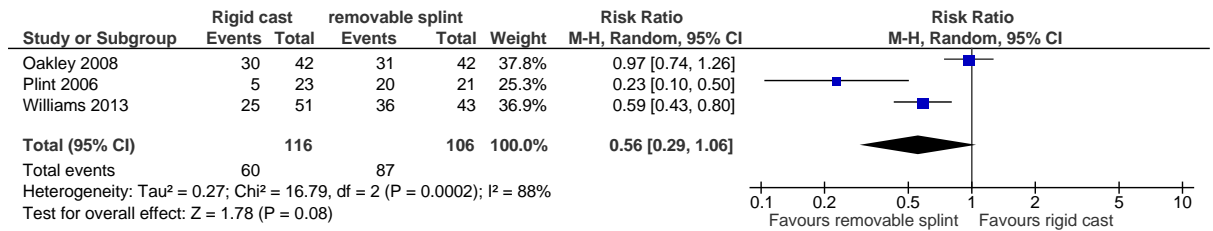
**Figure 77: Adverse events – skin problems**



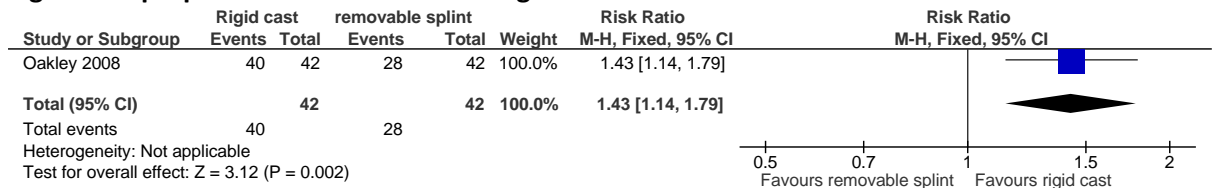
**Figure 78: Adverse events oedema**



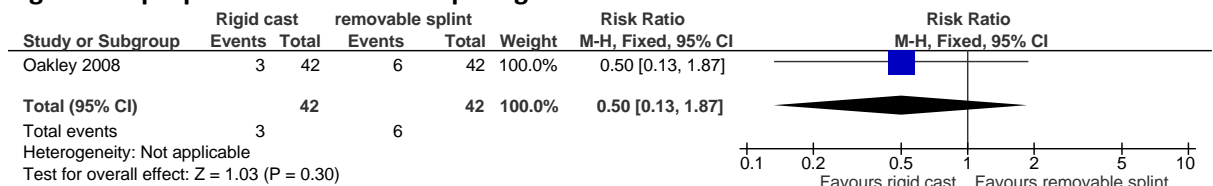
**Figure 79: Proportion at 2-4 weeks who would choose to continue with same form of immobilisation in future**



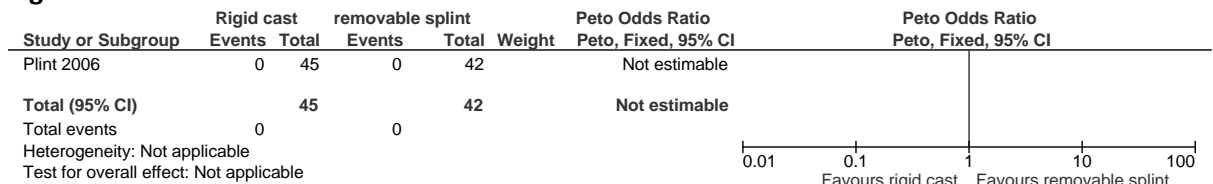
**Figure 80: proportion at 2 weeks resuming normal activities**



**Figure 81: proportion at 2 weeks requiring re-immobilisation**

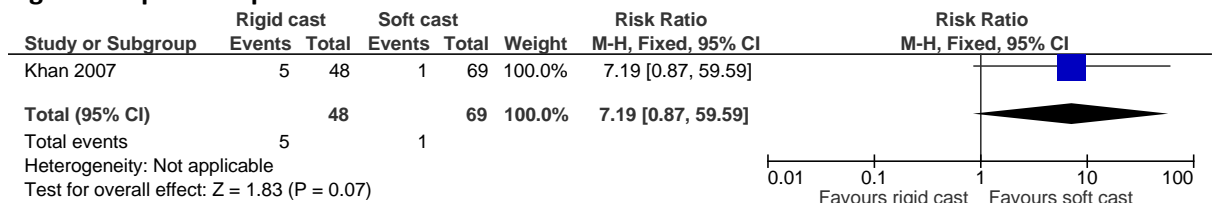


**Figure 82: Adverse events – re-fractures**

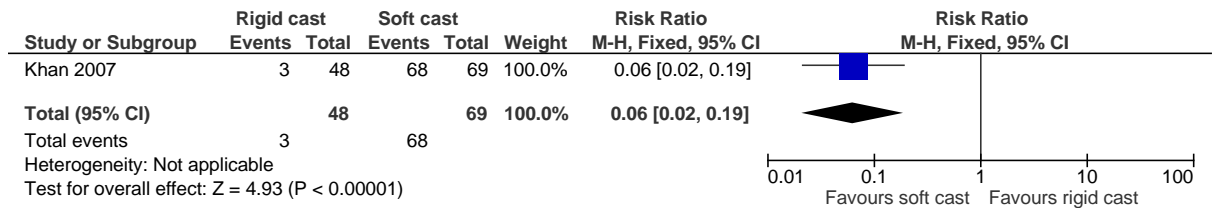


**J.3.2.2 Rigid cast versus soft cast**

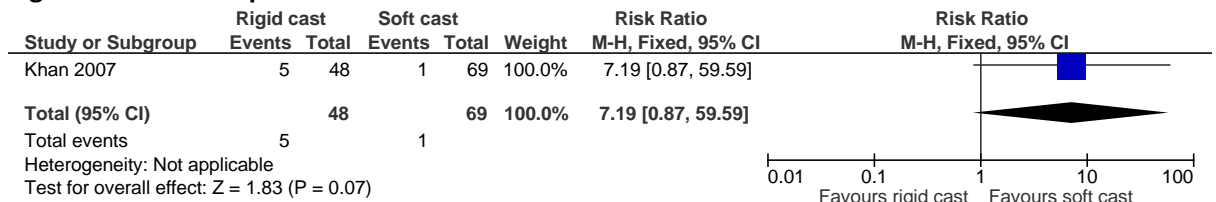
**Figure 83: parental problems with casts at 3 weeks**



**Figure 84: proportion of parents at 3 weeks who would choose to continue the same intervention in the future**

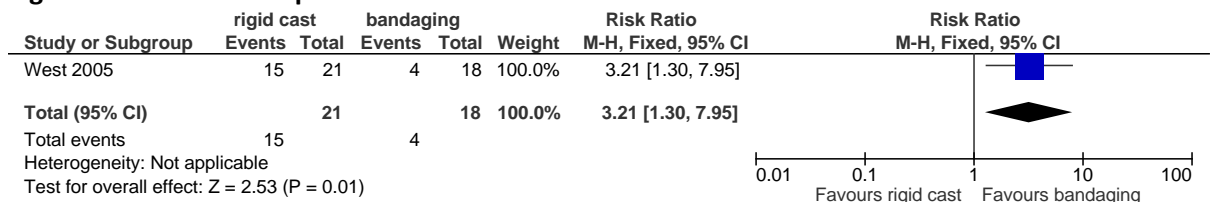


**Figure 85: cast complications at 3 weeks**

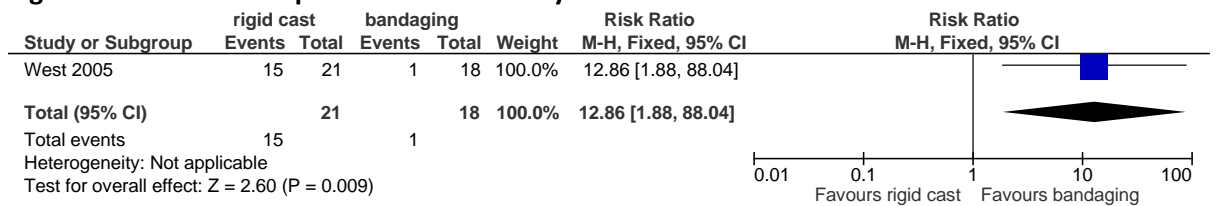


**J.3.2.3 Rigid cast versus bandages**

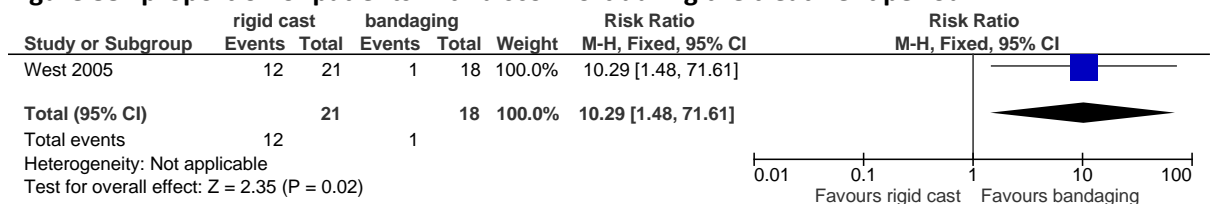
**Figure 86: existence of pain at 4 weeks**



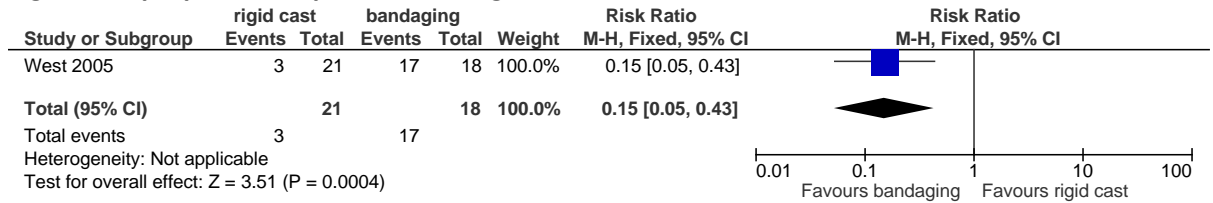
**Figure 87: existence of pain for 2 or more days at 4 weeks**



**Figure 88: proportion of patients with discomfort during the treatment period**



**Figure 89: proportion of patients finding treatment convenient at 4 weeks**

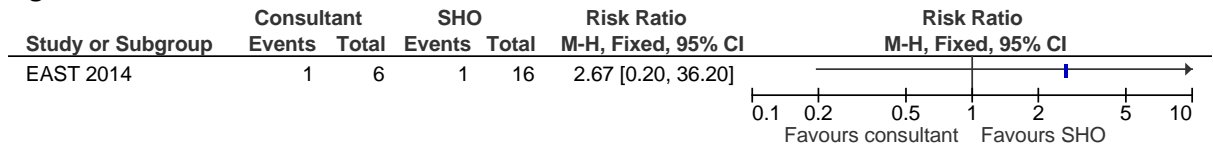


### J.3.3 Referral for on-going management from the emergency department

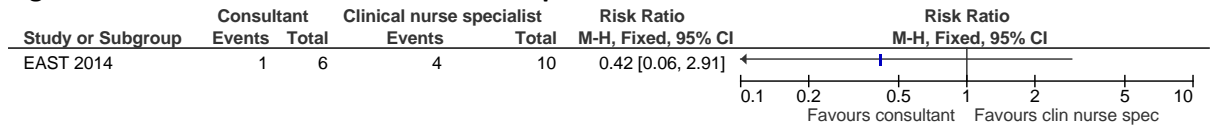
#### J.3.3.1 Referral pathway decision makers MDT

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

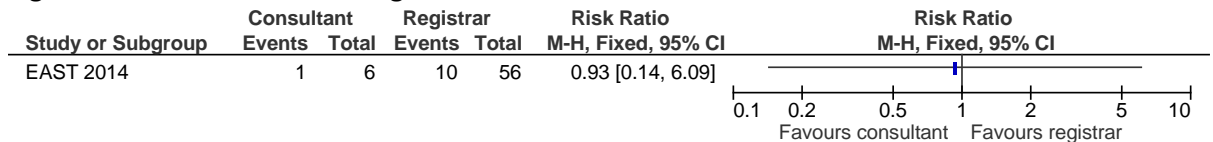
**Figure 90: Consultant versus SHO**



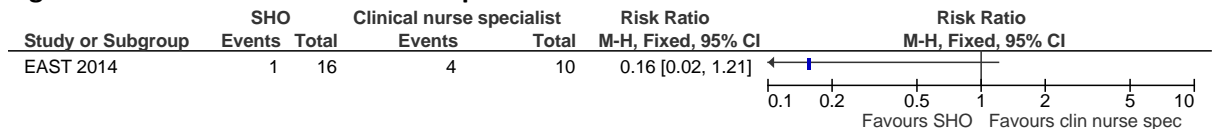
**Figure 91: Consultant versus clinical nurse specialist**



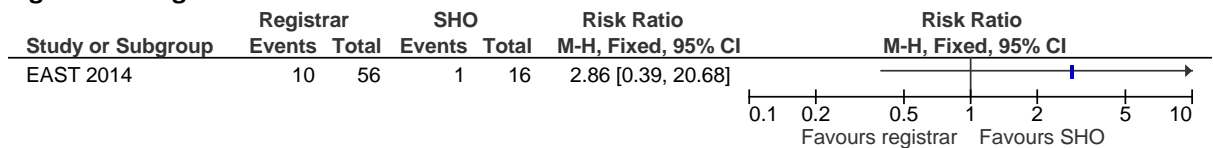
**Figure 92: Consultant versus registrar**



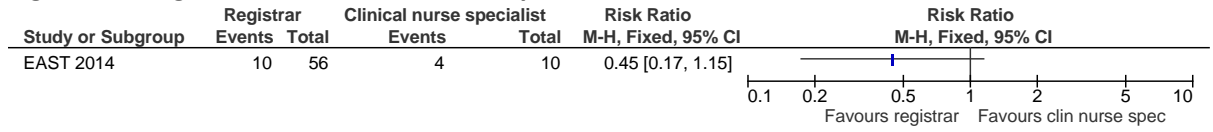
**Figure 93: SHO versus clinical nurse specialist**



**Figure 94: Registrar versus SHO**

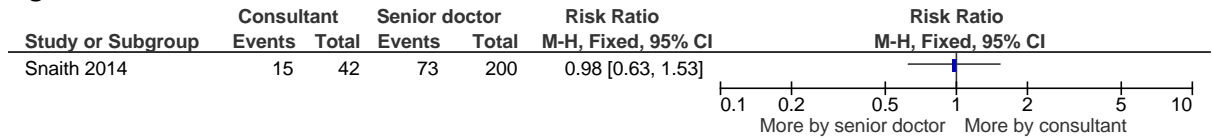


**Figure 95: Registrar versus clinical nurse specialist**

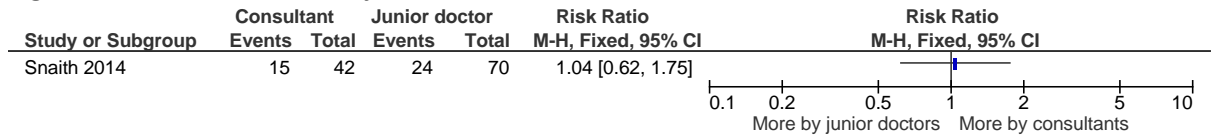


**Number of referrals to specialist clinics**

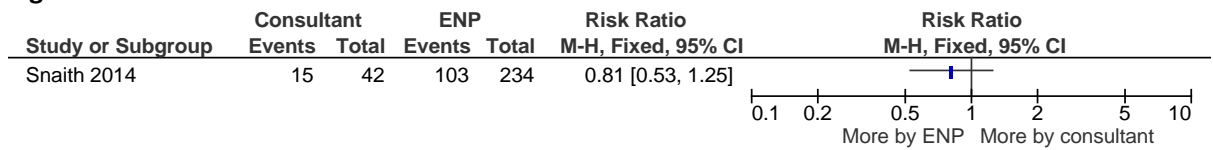
**Figure 96: Consultant versus senior doctor**



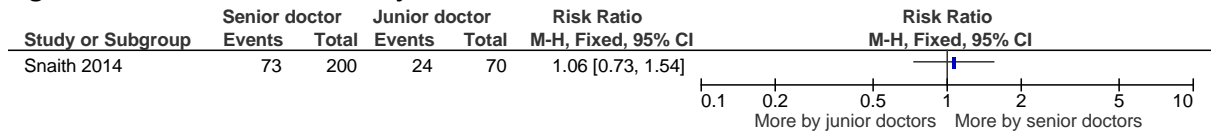
**Figure 97: Consultant versus junior doctor**



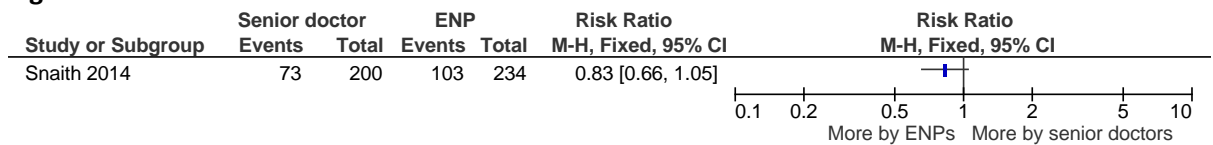
**Figure 98: Consultant versus ENP**



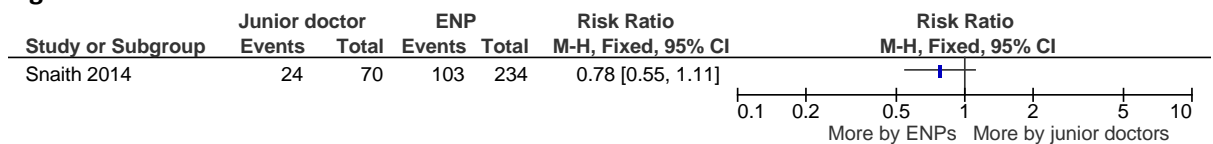
**Figure 99: Senior doctor versus junior doctor**



**Figure 100: Senior doctor versus ENP**



**Figure 101: Junior doctor versus ENP**



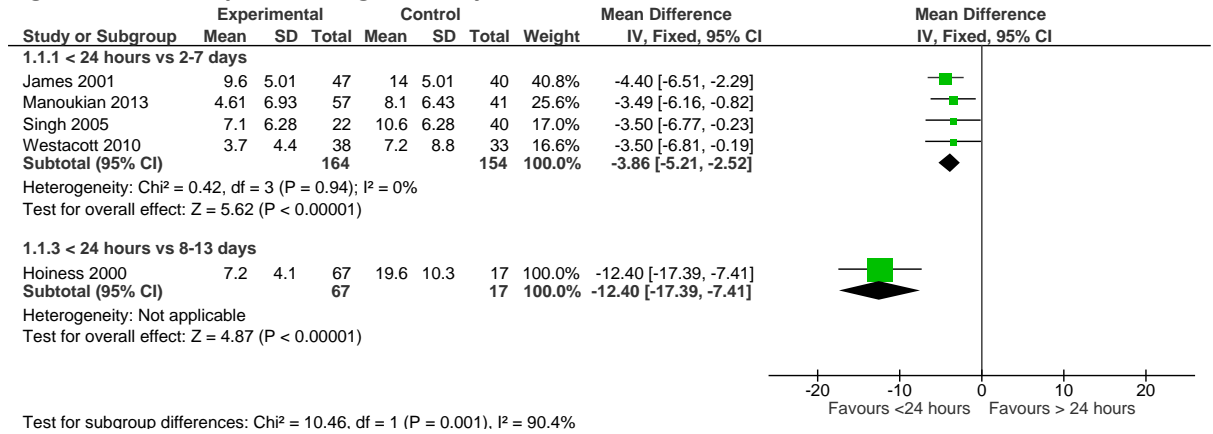


## J.4 On-going management

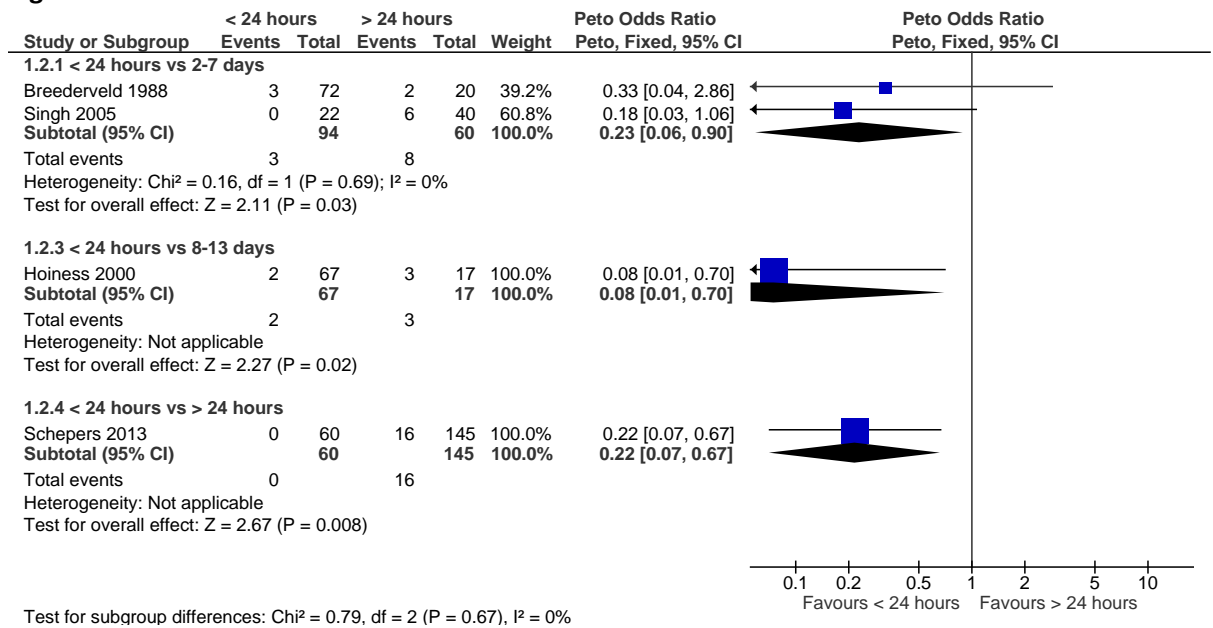
### J.4.1 Timing of surgery – ankle fractures

#### J.4.1.1 Surgery <24 hours versus surgery >24 hours

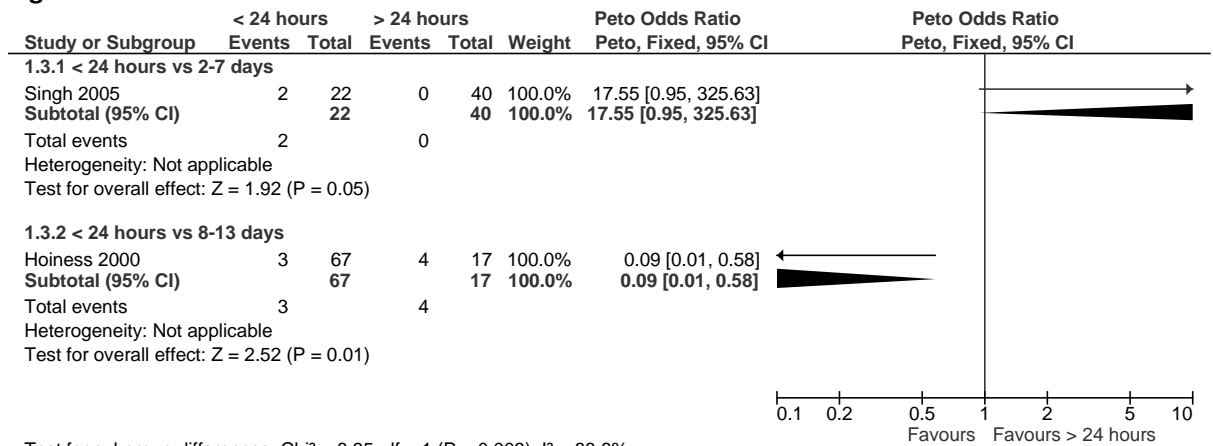
**Figure 102: Inpatient length of stay**



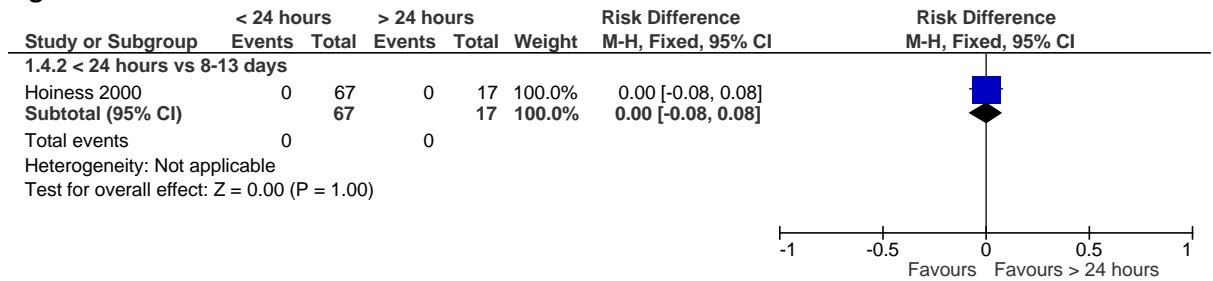
**Figure 103: Infection**



**Figure 104: Wound breakdown**

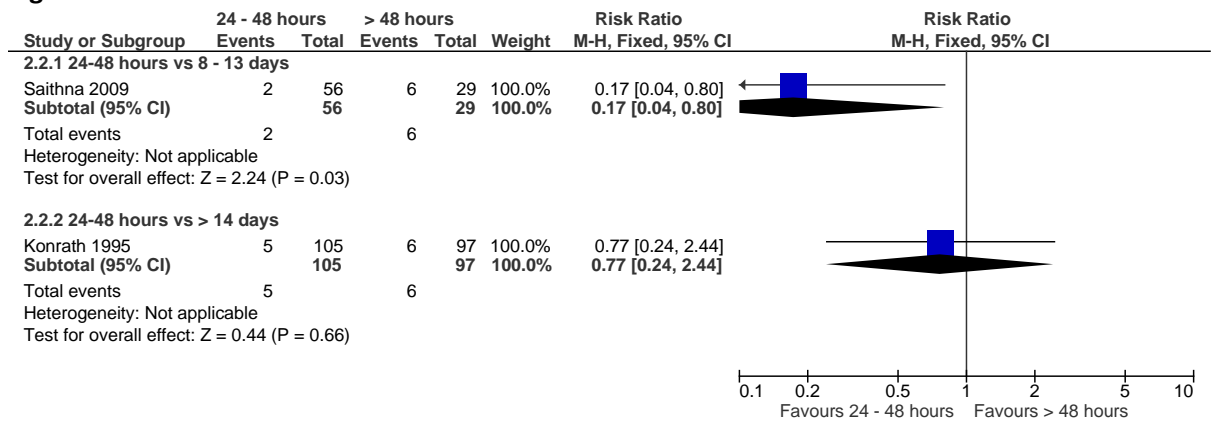


**Figure 105: VTE**



**J.4.1.2 Surgery within 24–48 hours versus surgery >48 hours**

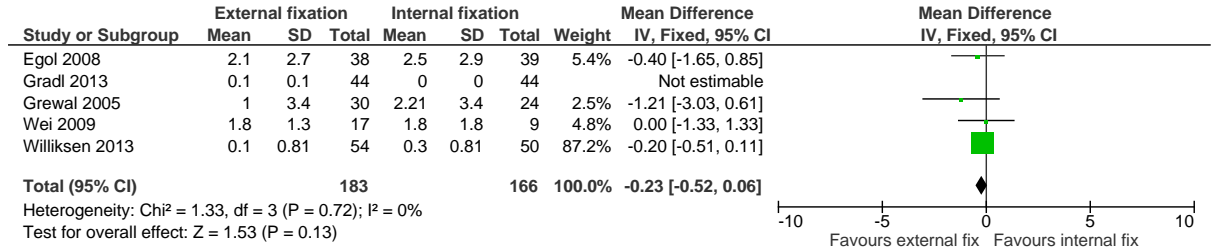
**Figure 106: Infection**



## J.4.2 Definitive treatment - distal radial fractures

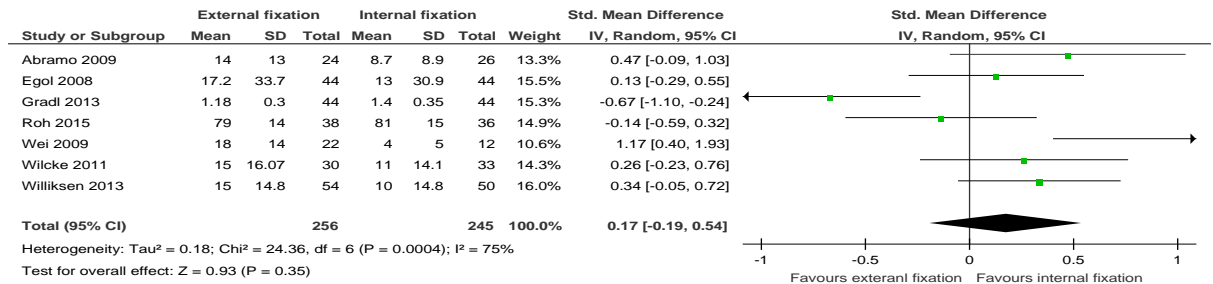
### J.4.2.1 External fixation versus internal fixation in adults

**Figure 107: Pain (at 1–2 years)**

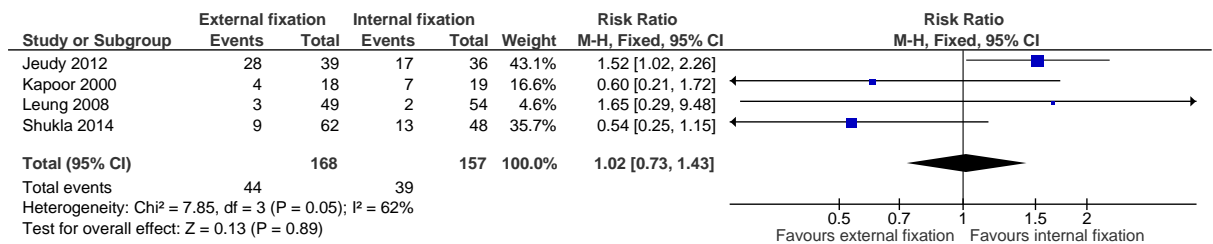


Note: Sample size was estimated or Wei 2009, based on overall attrition rate. Standard deviations were calculated for Grewal 2005 and Williksen 2013.

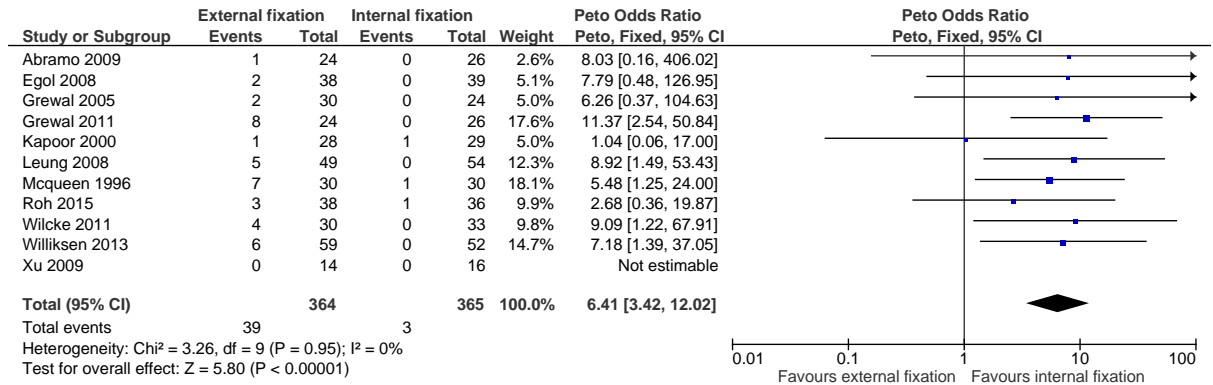
**Figure 6: Hand and wrist function (at 1 year)**



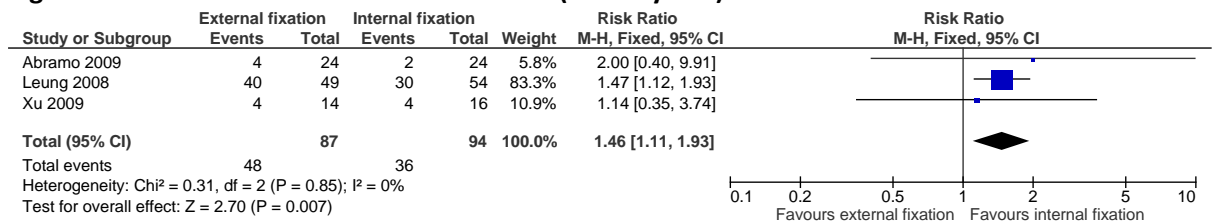
**Figure 108: Hand and wrist function (at 6 weeks – 2 years; fair/poor)**



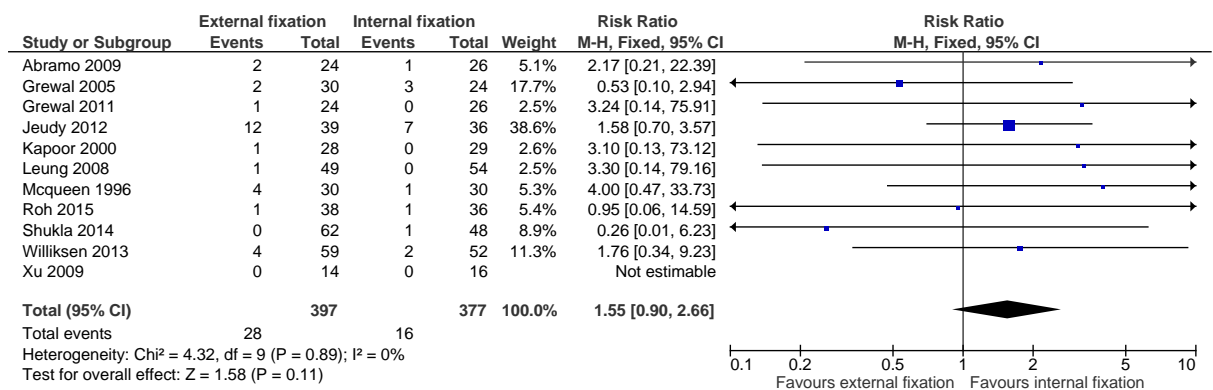
**Figure 109: Pin site infection (at 6 weeks–2 years)**



**Figure 110: Post traumatic osteoarthritis (at 2–7 years)**



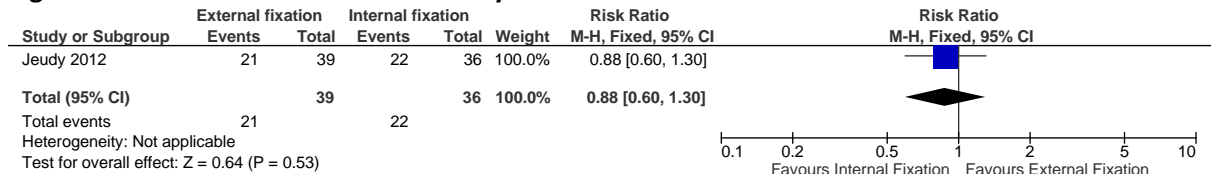
**Figure 111: Complex regional pain syndrome (at 1-2 years)**



**Figure 112: Need for further surgery (at 1–7 years)**

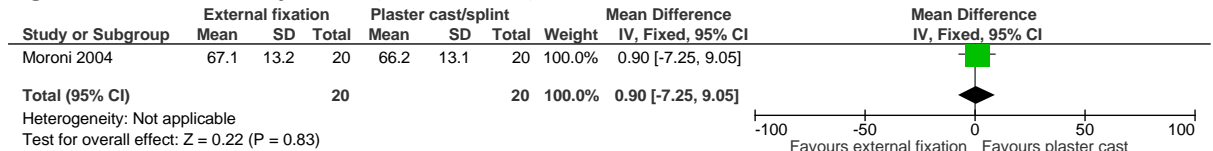


**Figure 113: Return to normal activity**

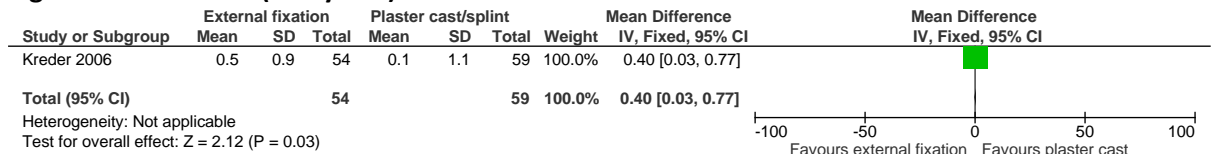


**J.4.2.2 External fixation versus plaster cast/splint in adults**

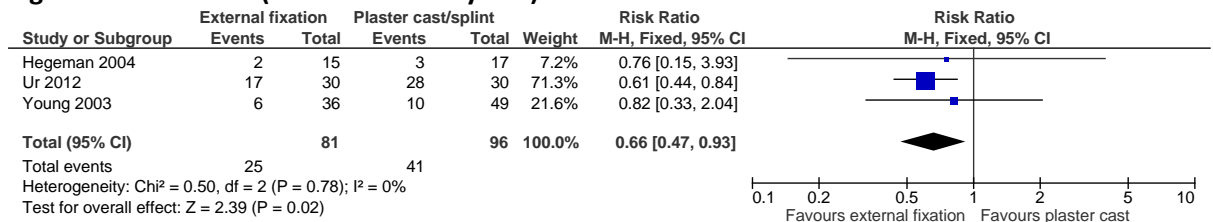
**Figure 114: Quality of life (at 3 months)**



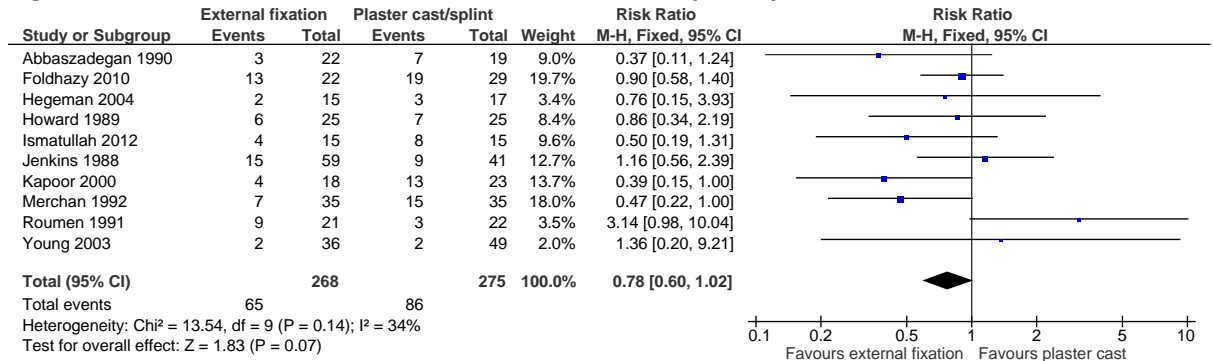
**Figure 115: Pain (at 2 years)**



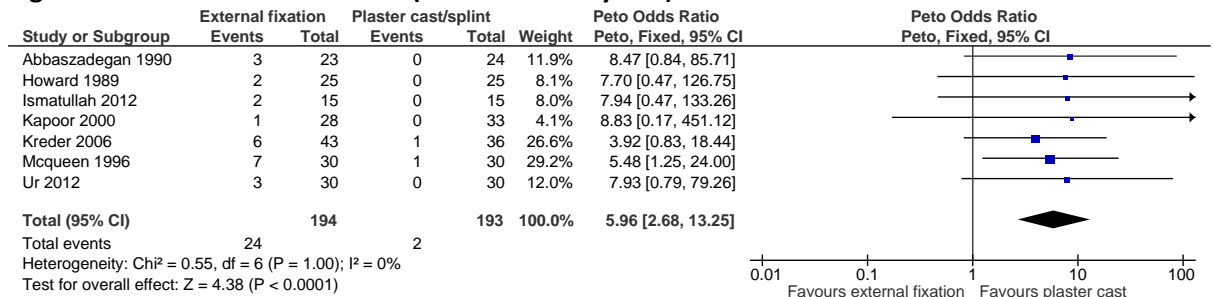
**Figure 116: Pain (at 3 months – 7 years)**



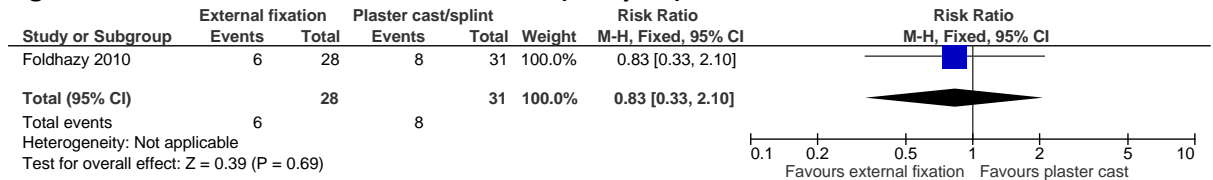
**Figure 117: Hand and wrist function (at 6 weeks – 7 years; poor/fair)**



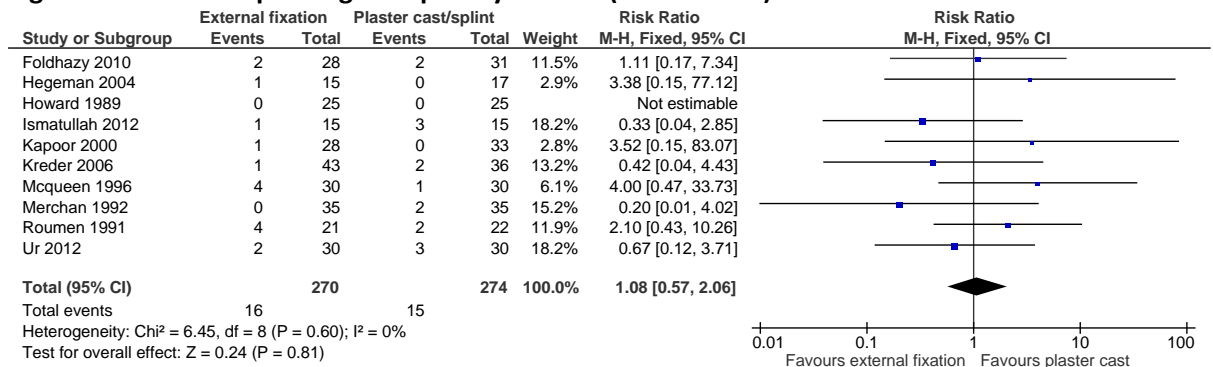
**Figure 118: Pin site infection (at 6 weeks – 2 years)**



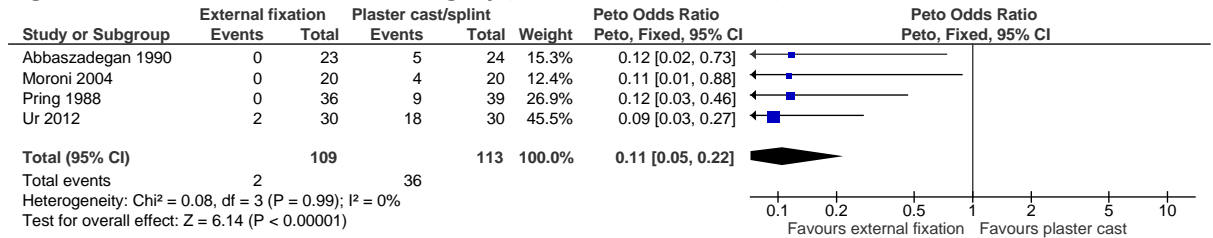
**Figure 119: Post traumatic osteoarthritis (at 1 year)**



**Figure 120: Complex regional pain syndrome (at 6 months)**

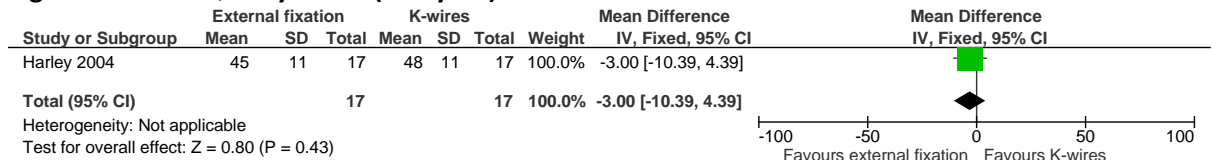


**Figure 121: Need for further surgery (at 8 weeks–6 months)**



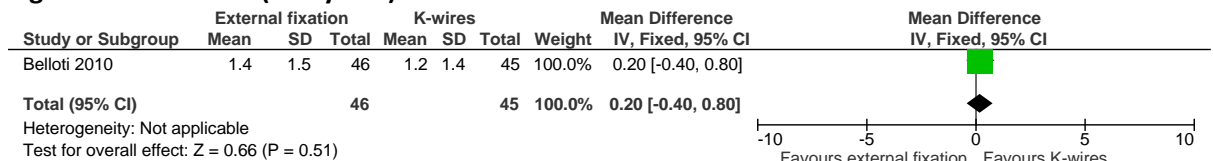
**J.4.2.3 External fixation versus percutaneous wiring in adults**

**Figure 122: Quality of life (at 1 year)**

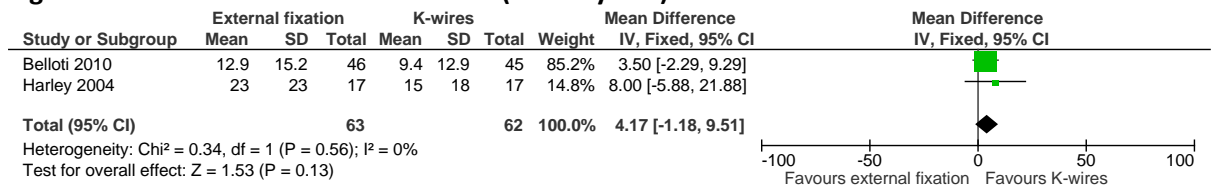


Note: Sample size for Harley 2004 was estimated from overall attrition rate

**Figure 123: Pain (at 2 years)**

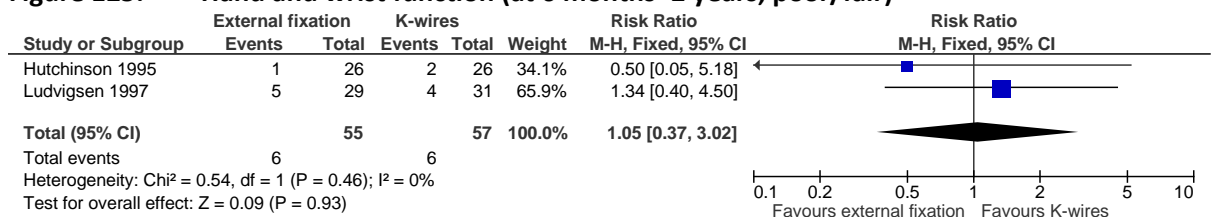


**Figure 124: Hand and wrist function (at 1–2 years)**

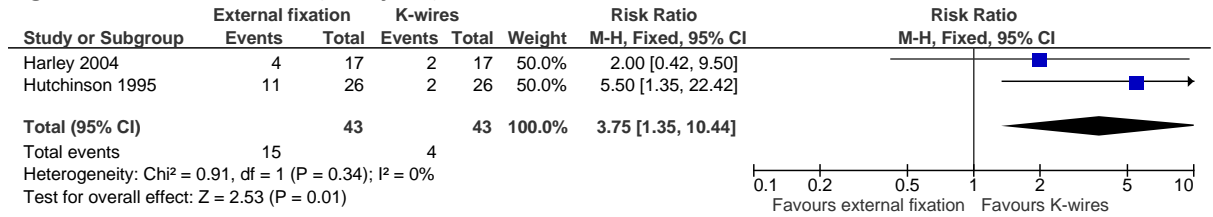


Note: Sample size for Harley 2004 was estimated from overall attrition rate

**Figure 125: Hand and wrist function (at 6 months–2 years; poor/fair)**

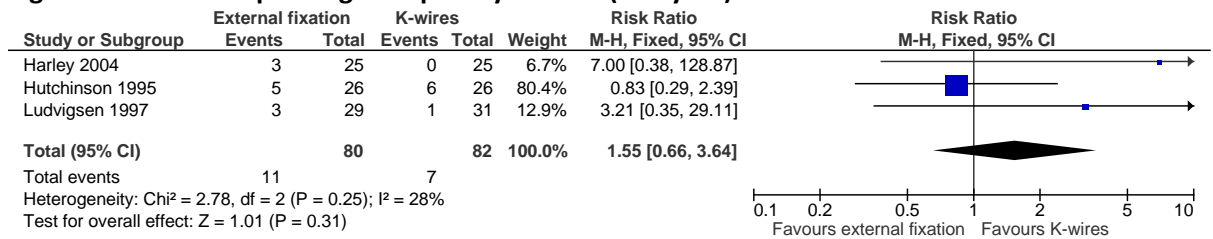


**Figure 126: Infection (at 1 year)**



Note: Sample size for Harley 2004 was estimated from overall attrition rate

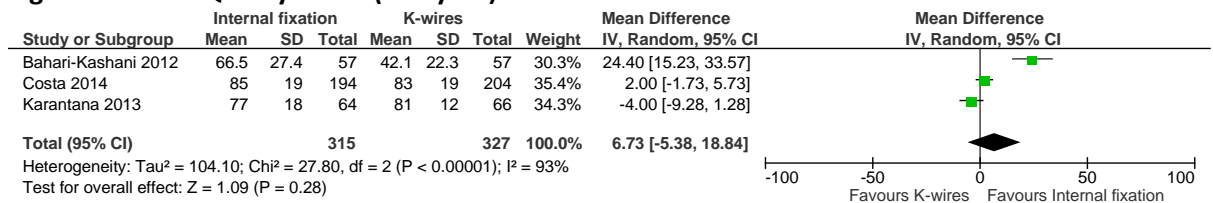
**Figure 127: Complex regional pain syndrome (at 1 year)**



Note: Sample size for Harley 2004 was estimated from overall attrition rate

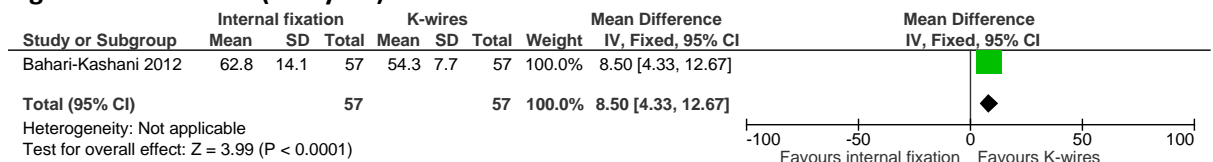
#### J.4.2.4 Internal fixation versus percutaneous wiring in adults

**Figure 128: Quality of life (at 1 year)**



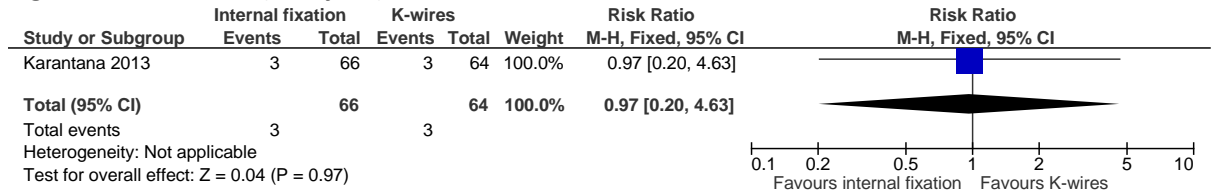
Note: Analysis conducted using random effects model

**Figure 129: Pain (at 1 year)**

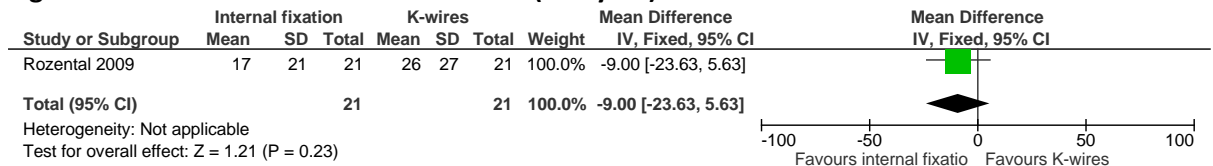




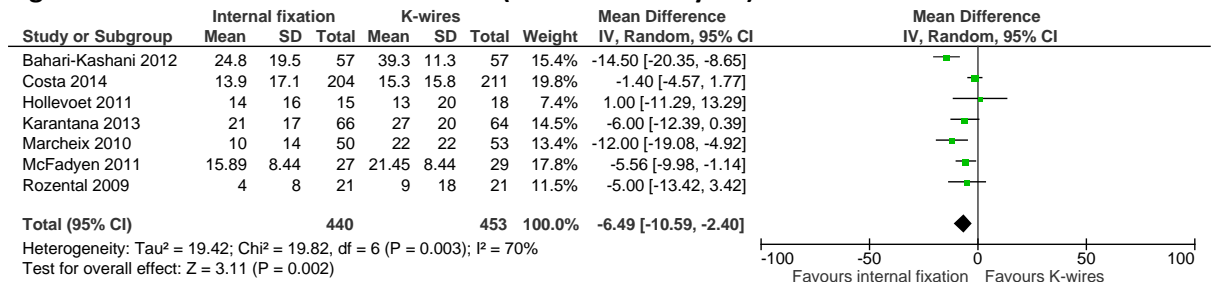
**Figure 130: Pain (at 1 year)**



**Figure 131: Return to normal activities (at 1 year)**

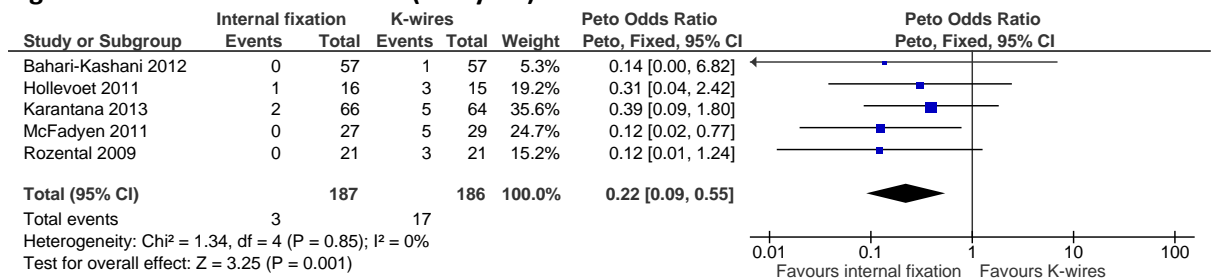


**Figure 132: Hand and wrist function (at 6 months–1 year)**

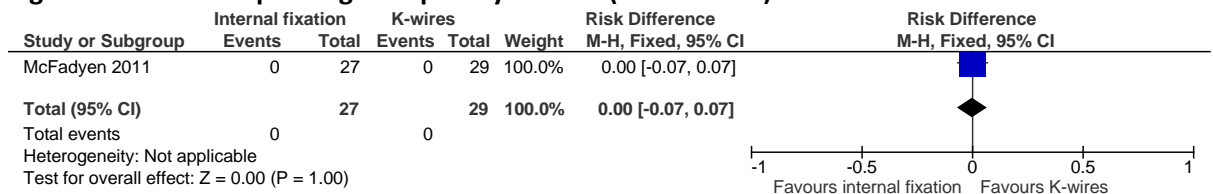


Note: Analysis conducted using random effects model

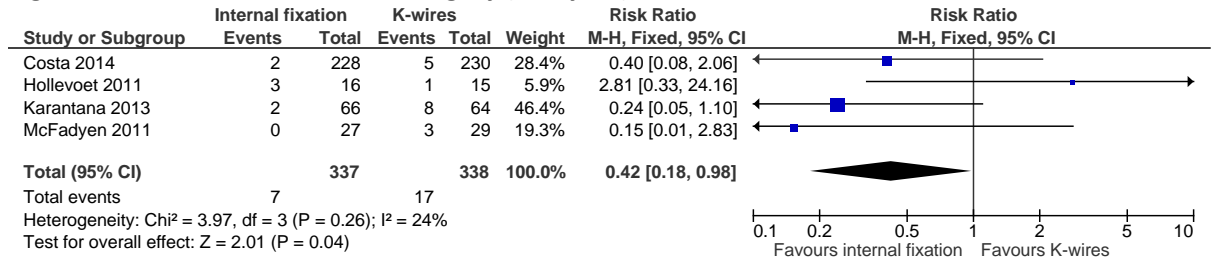
**Figure 133: Pin site infection (at 1 year)**



**Figure 134: Complex regional pain syndrome (at 6 months)**

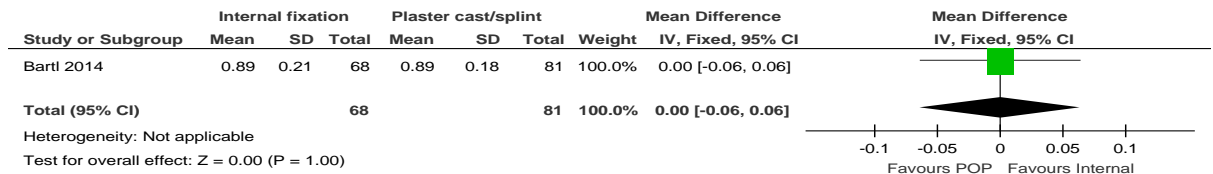


**Figure 135: Need for further surgery (at 1 year)**

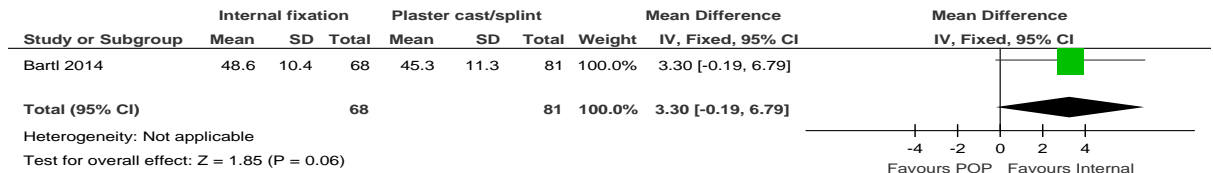


**J.4.2.5 Internal fixation versus plaster cast/splint in adults**

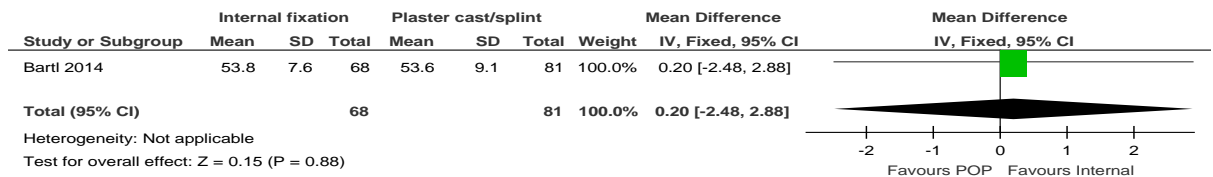
**Figure 136: Quality of life (EQ5D utility at 12 months)**



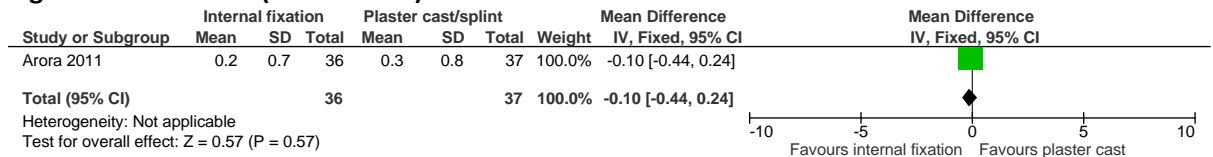
**Figure 137: Quality of life (SF36 physical at 12 months)**



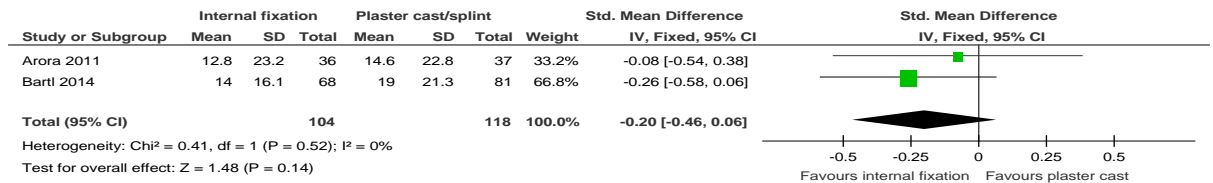
**Figure 138: Quality of life (SF36 mental at 12 months)**



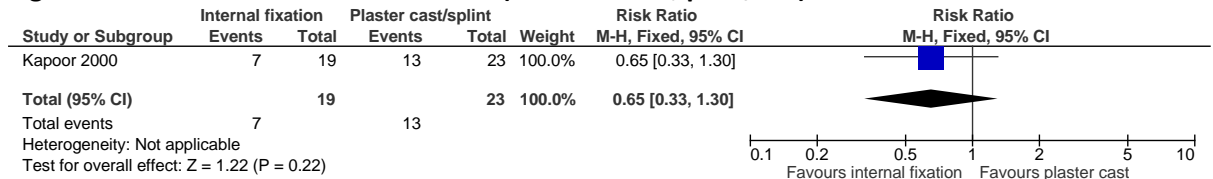
**Figure 139: Pain (at 12 weeks)**



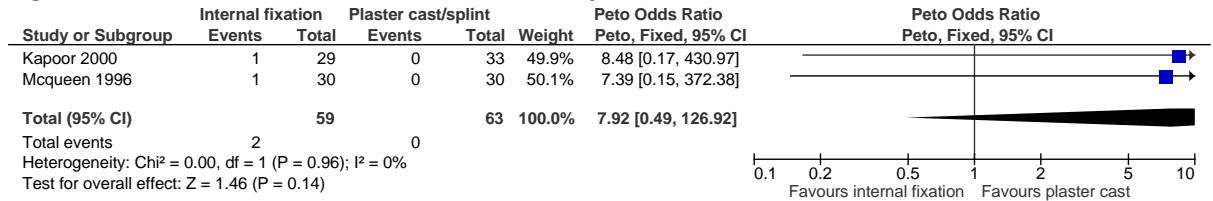
**Figure 140: Hand and wrist function (at 1 year)**



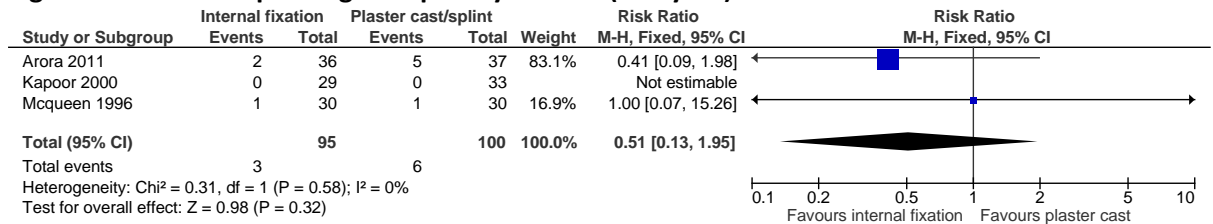
**Figure 141: Hand and wrist function (at 6–7 weeks; poor/fair)**



**Figure 142: Pin site infection (at 6 weeks–1 year)**

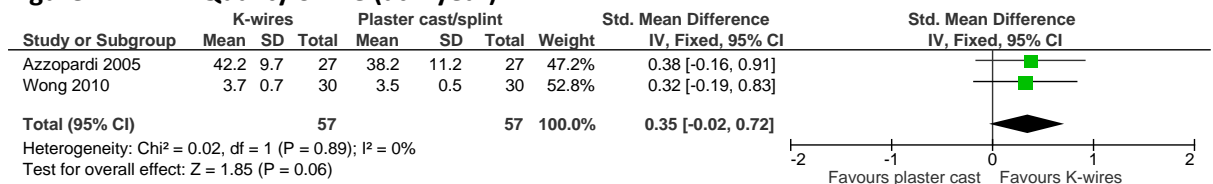


**Figure 143: Complex regional pain syndrome (at 1 year)**



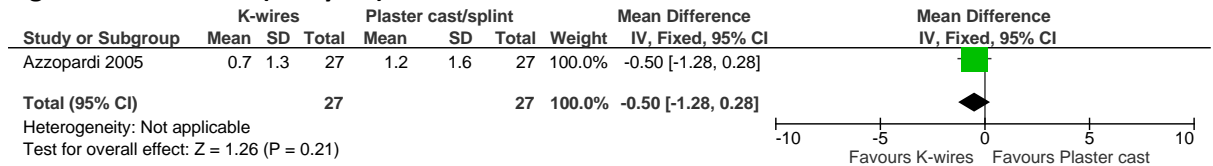
**J.4.2.6 K-wires versus plaster cast/splint in adults**

**Figure 144: Quality of life (at 1 year)**

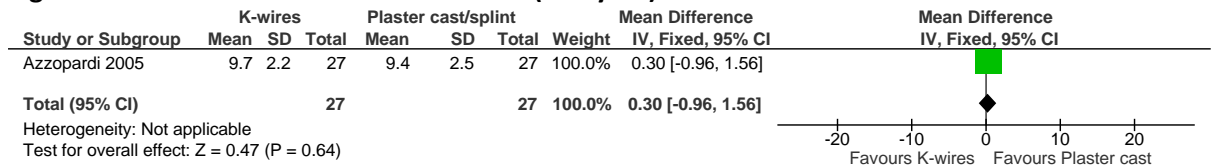


Note: Azzopardi 2005 assessed the physical component of the SF-36. Scale and calculation of final quality of life score in Wong 2010 unclear.

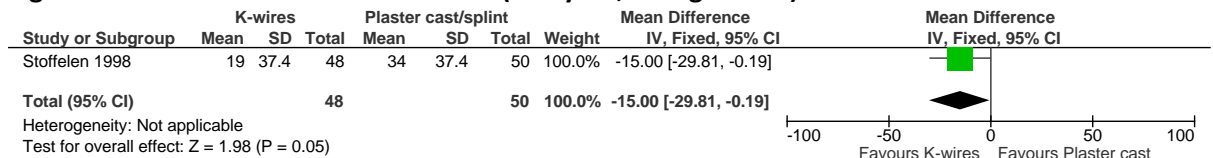
**Figure 145: Pain (at 1 year)**



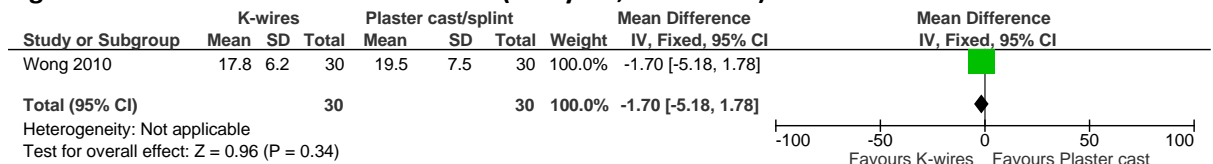
**Figure 146: Return to normal activities (at 1 year)**



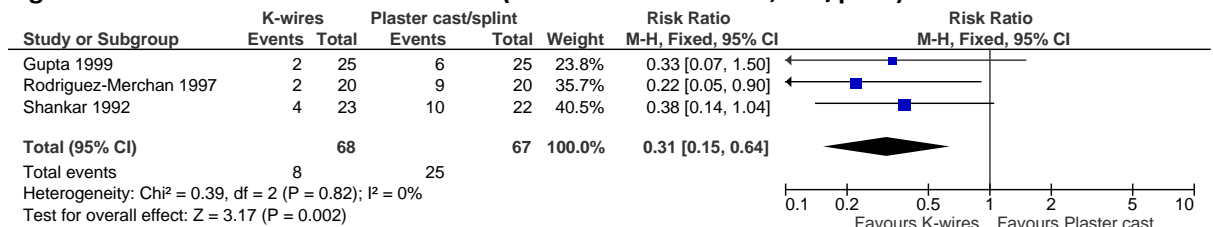
**Figure 147: Hand and wrist function (at 1 year; change score)**



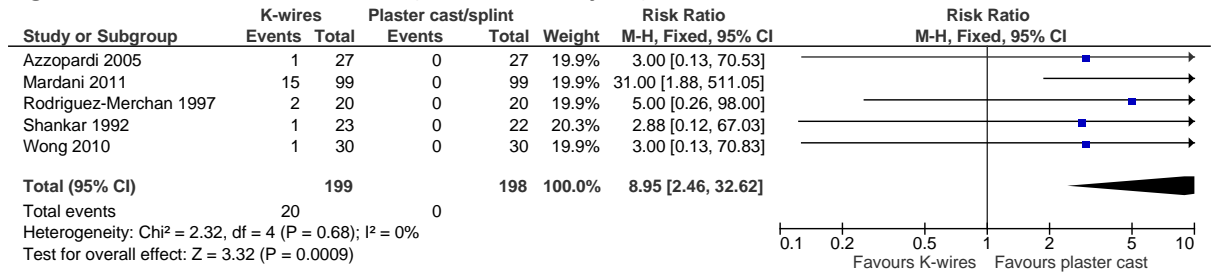
**Figure 148: Hand and wrist function (at 1 year; final value)**



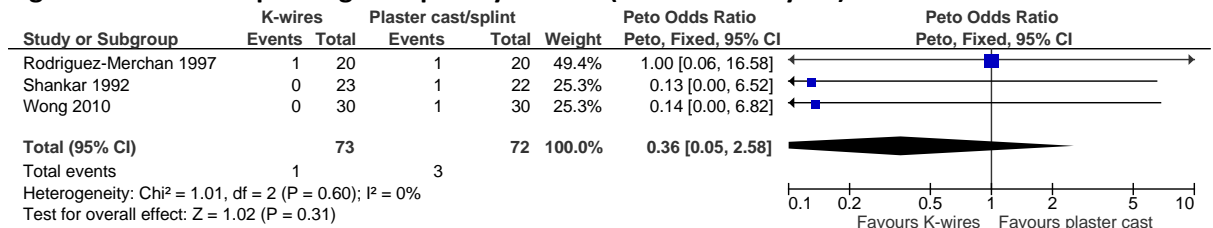
**Figure 149: Hand and wrist function (at 7 weeks–6 months; fair/poor)**



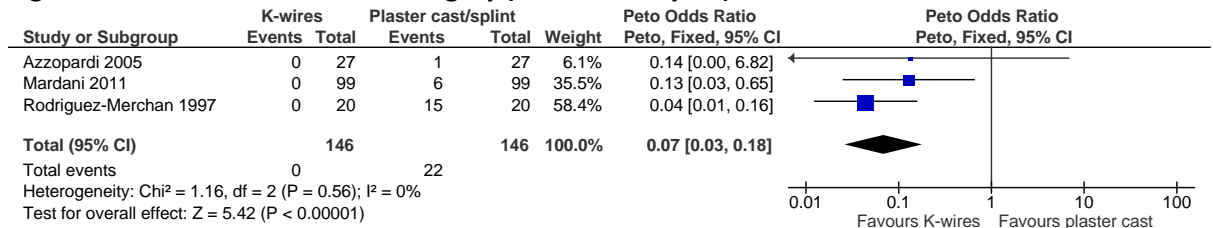
**Figure 150: Pin site infection (at 7 weeks–1 year)**



**Figure 151: Complex regional pain syndrome (at 7 weeks–1 year)**

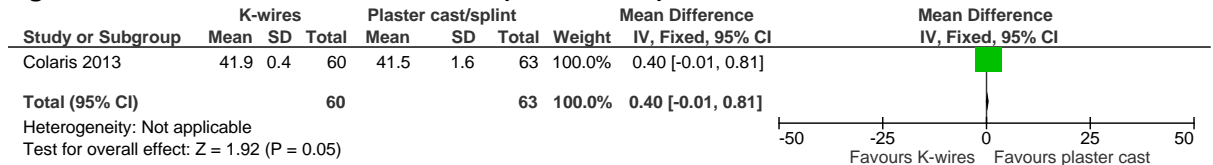


**Figure 152: Need for further surgery (at 1 week–1 year)**

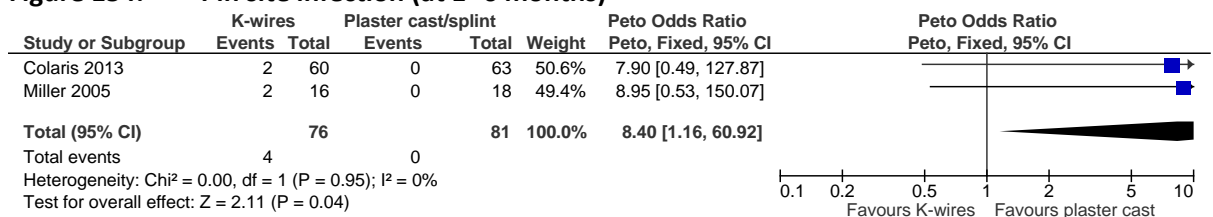


**J.4.2.7 Percutaneous wiring versus plaster cast/splint in children**

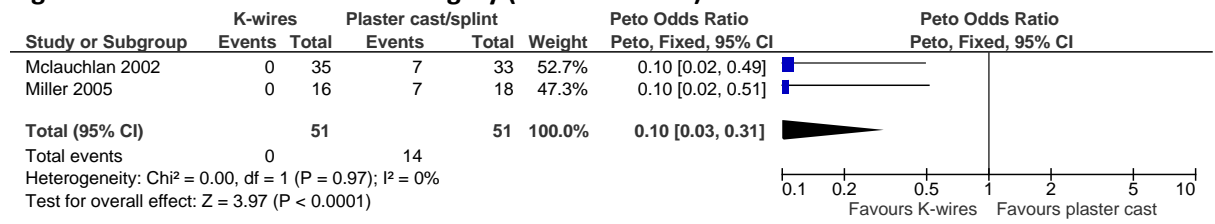
**Figure 153: Hand and wrist function (at 6 months)**



**Figure 154: Pin site infection (at 1–6 months)**



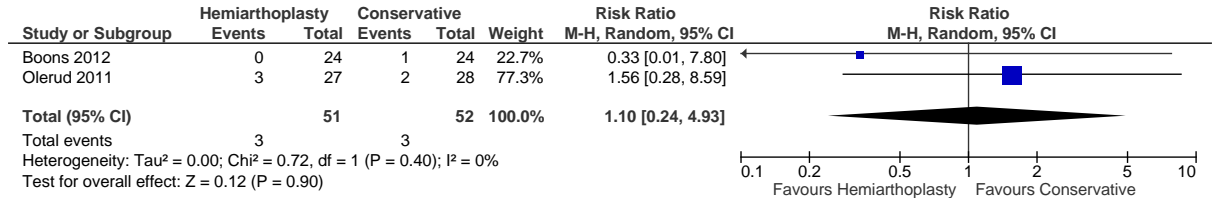
**Figure 155: Need for further surgery (at 1–3 months)**



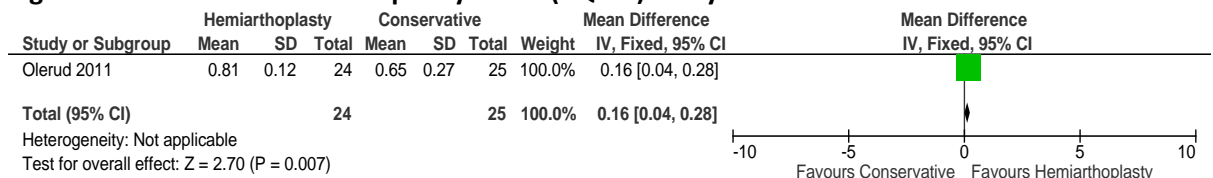
### J.4.3 Definitive treatment - humerus fractures

#### J.4.3.1 Hemiarthroplasty versus Conservative

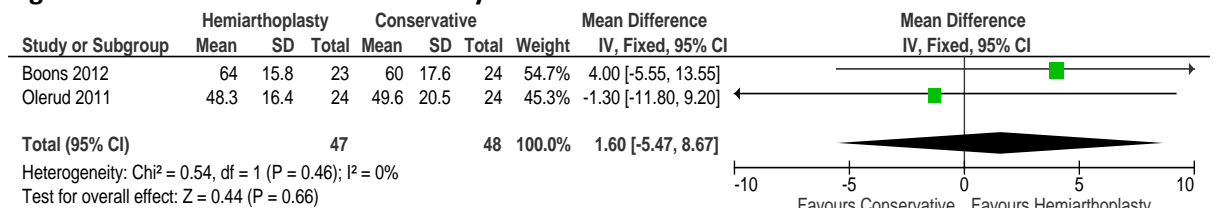
**Figure 156: Mortality at 1–2 years**



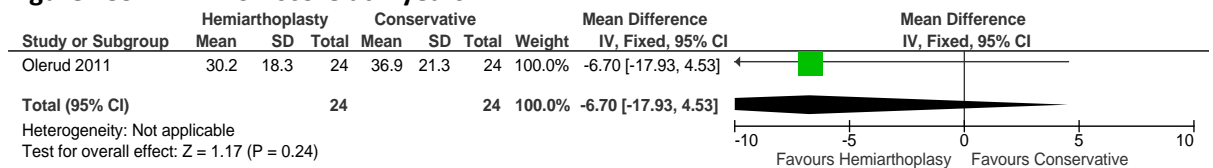
**Figure 157: Health related quality of life (EQ-5D) at 2 years**



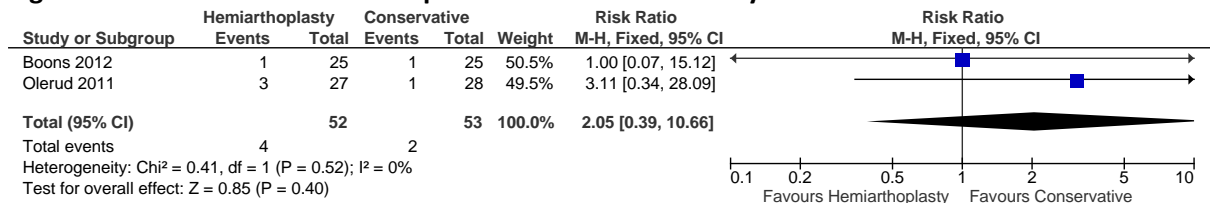
**Figure 158: Constant score at 1–2 years**



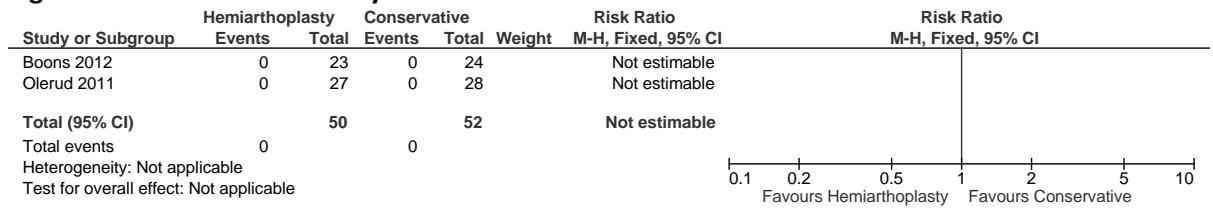
**Figure 159: DASH score at 2 years**



**Figure 160: Need for further operative treatment at 1–2 years**

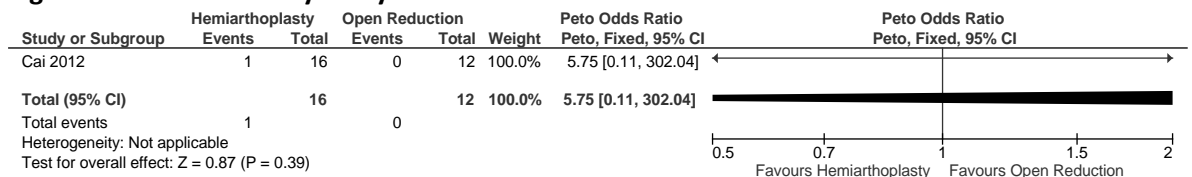


**Figure 161: Infection at 2 years**

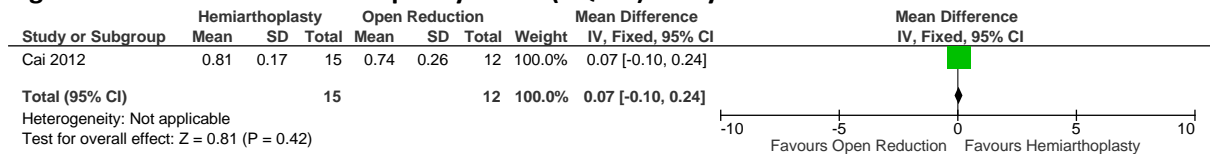


**J.4.3.2 Hemiarthoplasty versus Open Reduction**

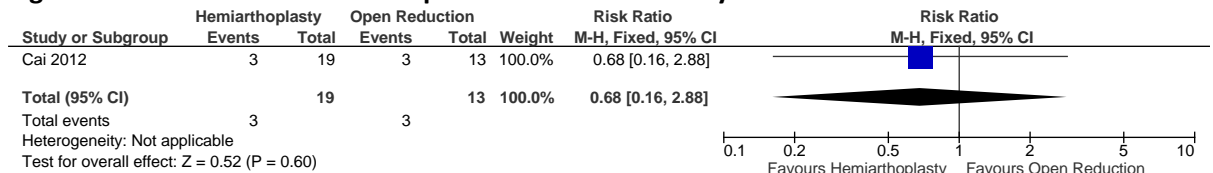
**Figure 162: Mortality at 2 years**



**Figure 163: Health related quality of life (EQ-5D) at 2 years**

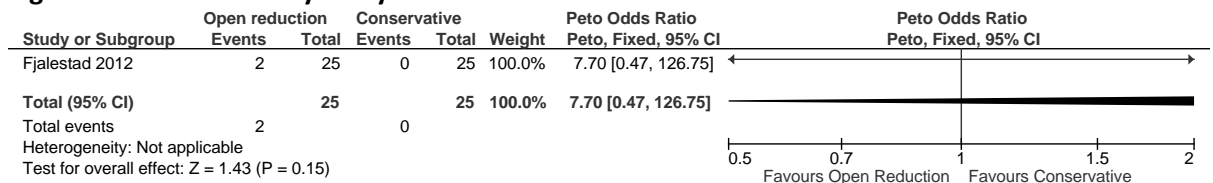


**Figure 164: Need for further operative treatment at 2 years**



**J.4.3.3 Open Reduction versus Conservative**

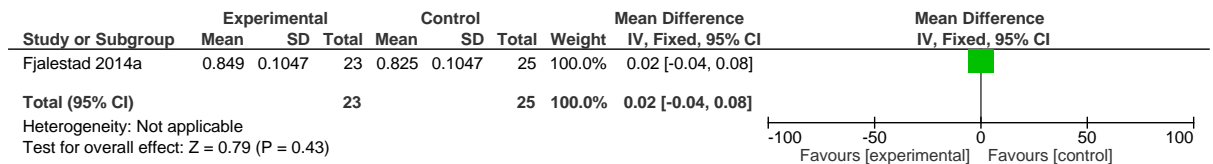
**Figure 165: Mortality at 1 year**



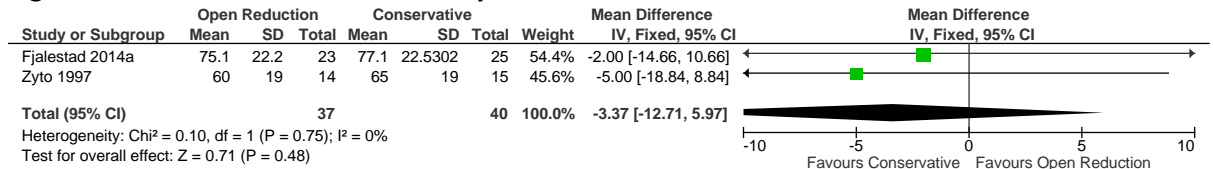
**Figure 166: Health related quality of life**

<Click here and insert picture with the Graphic tools on the Toolbar Ribbon>

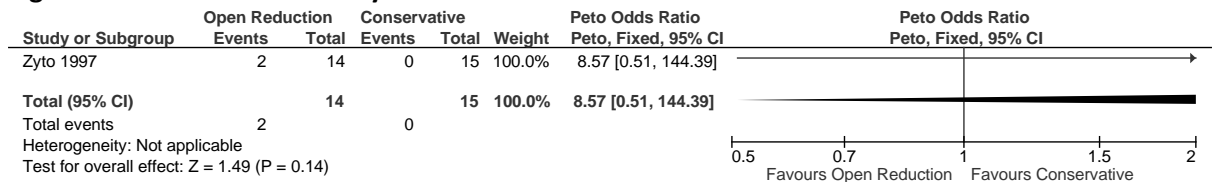




**Figure 167: Constant Score at 2–4 years**



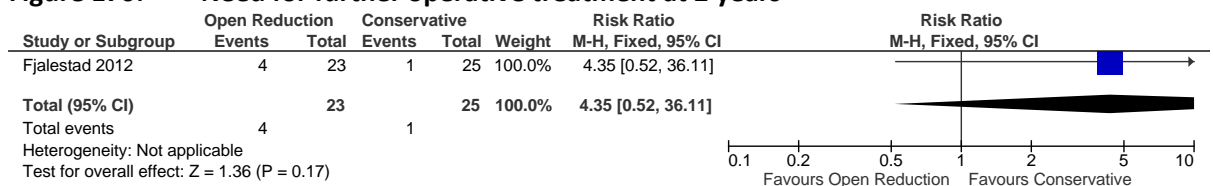
**Figure 168: Infection at 4 years**



**Figure 169: Avascular necrosis at 2 years**



**Figure 170: Need for further operative treatment at 2 years**

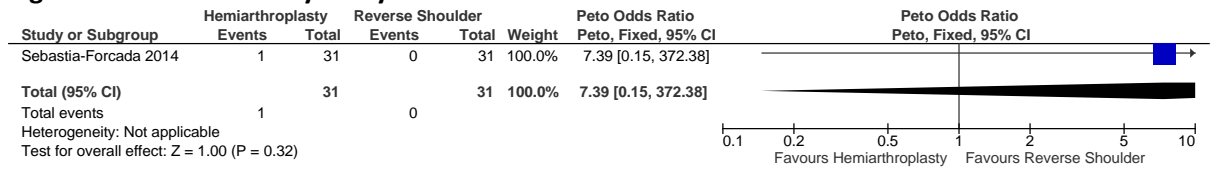


**Figure 171: Nerve damage at 1 year**

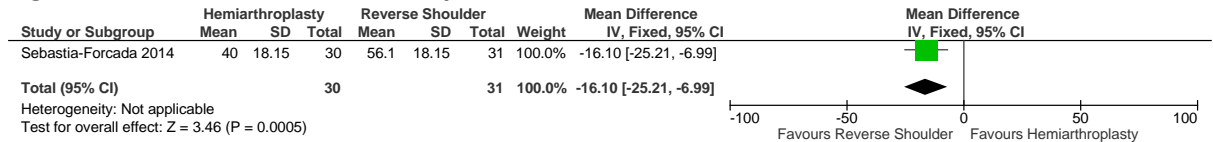


J.4.3.4 Reverse shoulder replacement versus Hemiarthroplasty

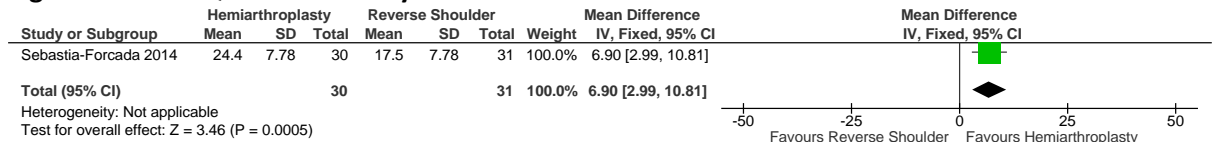
**Figure 172: Mortality at 1 year**



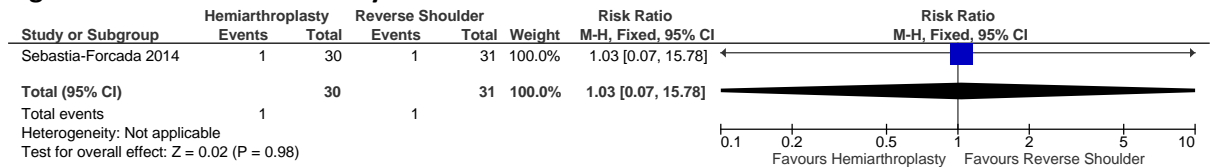
**Figure 173: Constant score at 2 years**



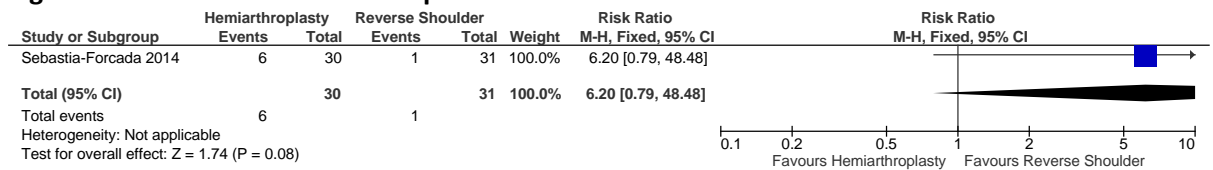
**Figure 174: QuickDASH at 2 years**



**Figure 175: Infection at 2 years**



**Figure 176: Need for further operative treatment**



J.4.3.5 Surgical (Combined) versus Conservative

Figure 177: Mortality at 1–2 Years

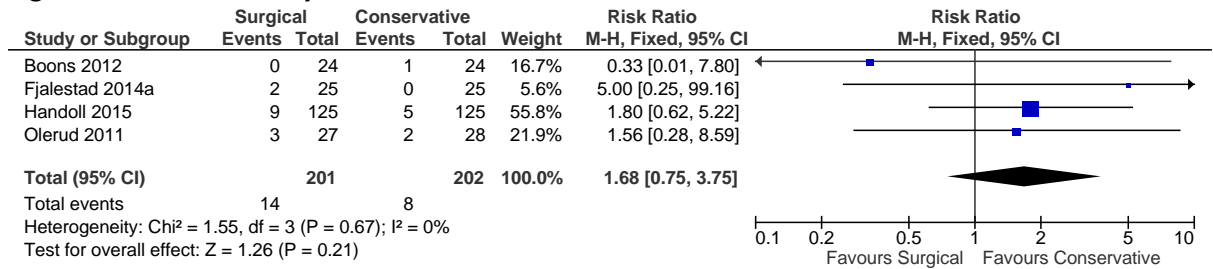


Figure 178: Health related quality of life (EQ-5D) at 2 years

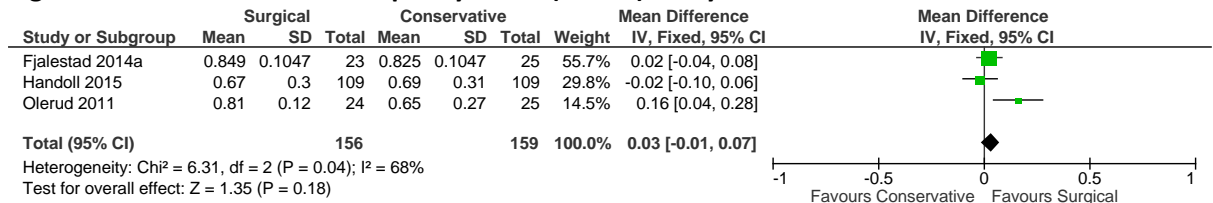


Figure 179: Health related quality of life (SF-12 components) at 2 years

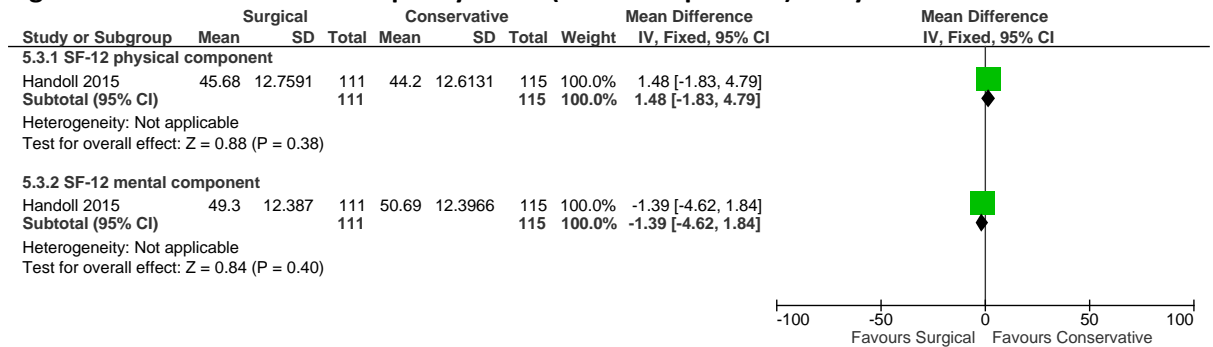


Figure 180: Oxford Shoulder Score at 2 years

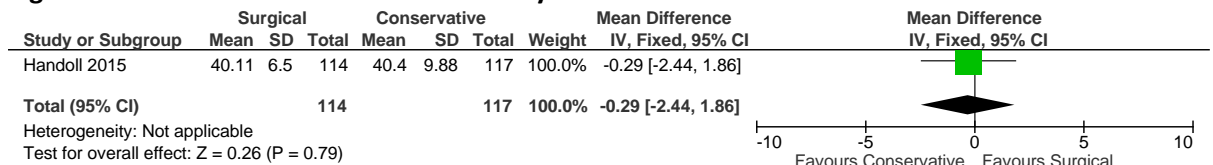
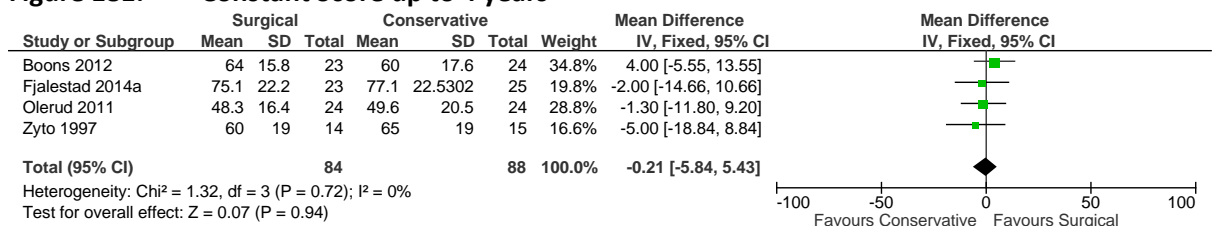
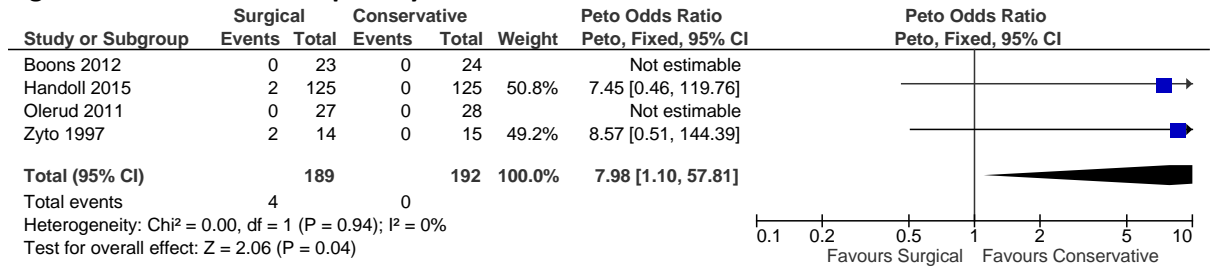


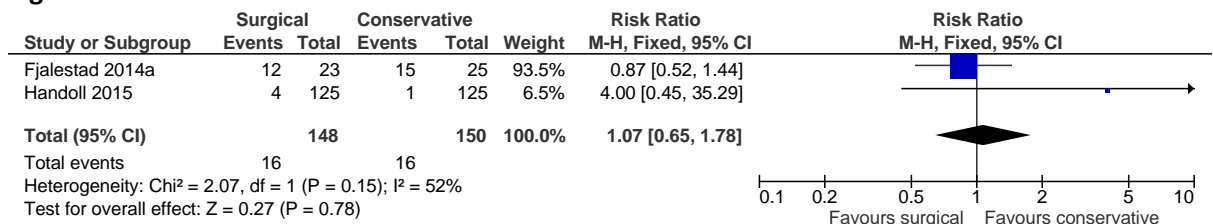
Figure 181: Constant Score up to 4 years



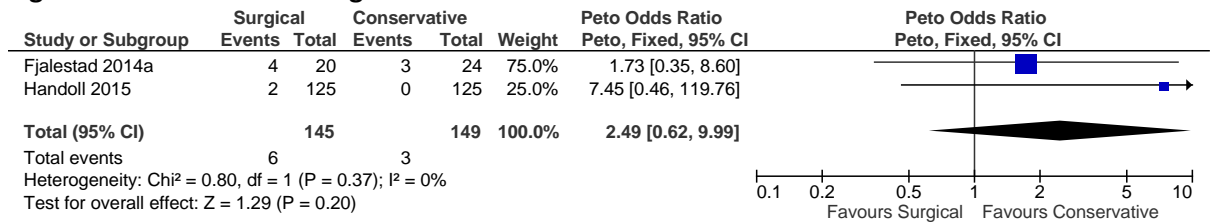
**Figure 182: Infection up to 4 years**



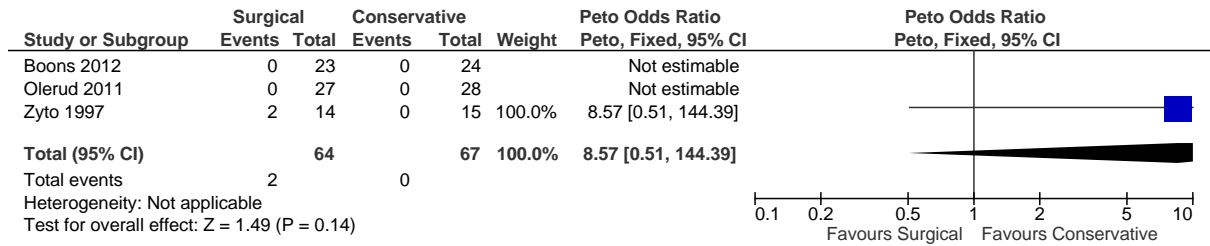
**Figure 183: Avascular necrosis**



**Figure 184: Nerve damage**



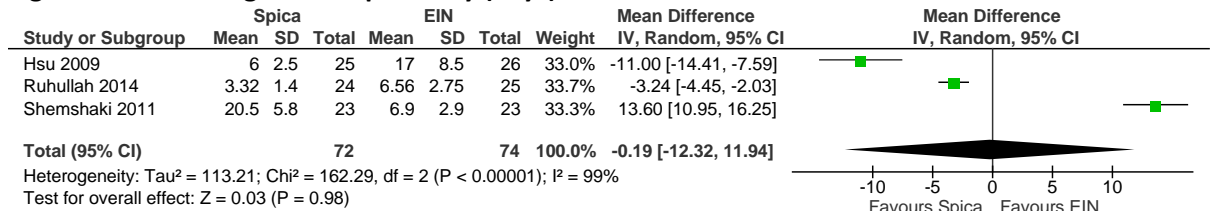
**Figure 185: Need for further Operation**



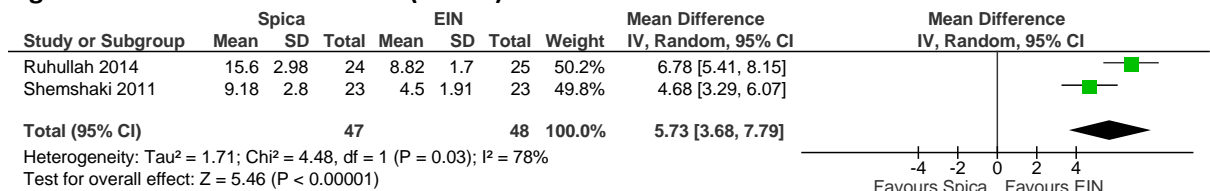
#### J.4.4 Definitive treatment - paediatric femoral fractures

##### J.4.4.1 Spica versus elastic intramedullary nail (EIN)

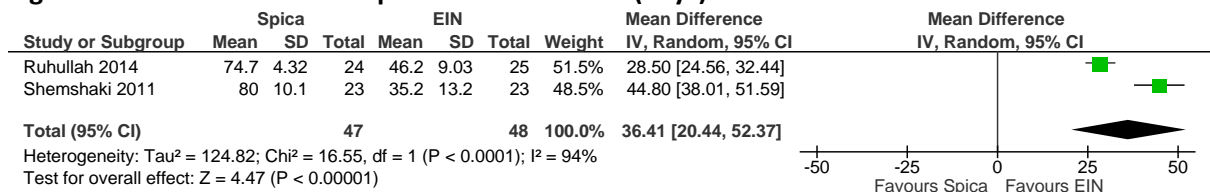
**Figure 186: Length of hospital stay (days)**



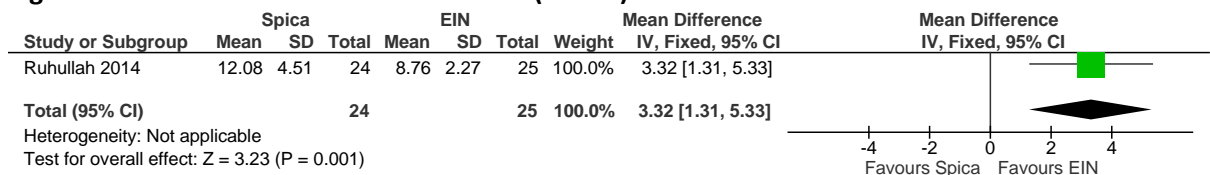
**Figure 187: Return to school (weeks)**



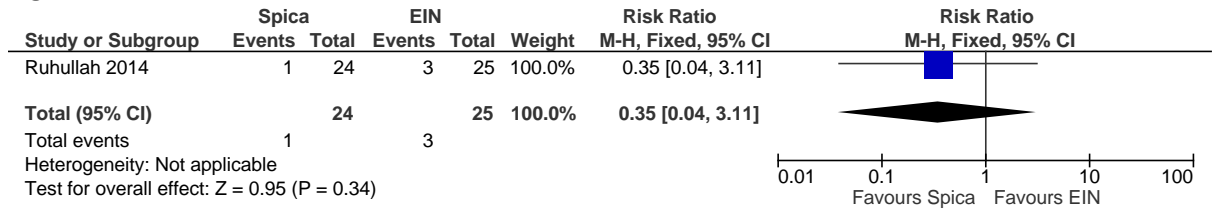
**Figure 188: Return to independent ambulation (days)**



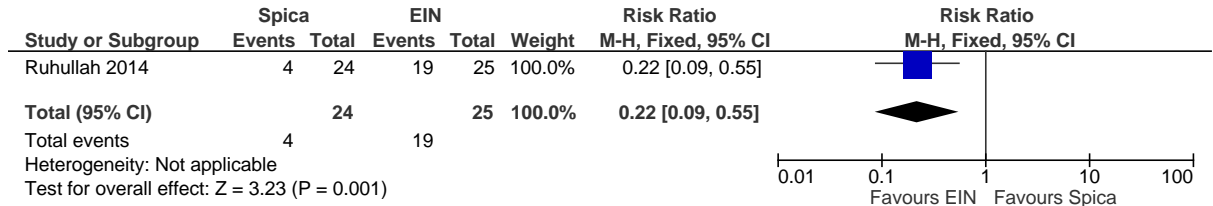
**Figure 189: Return to normal activities (weeks)**



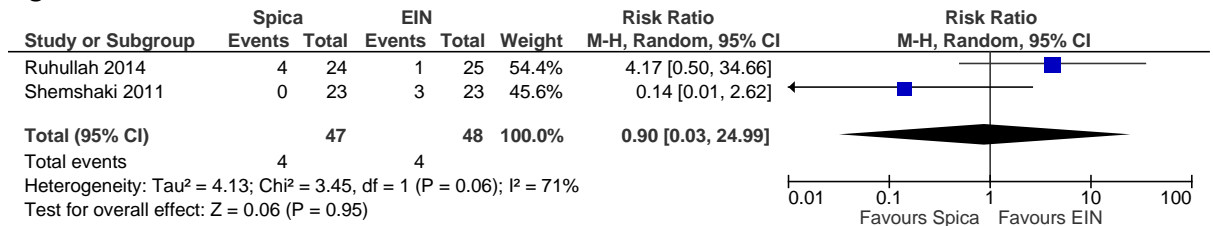
**Figure 190: Further treatment**



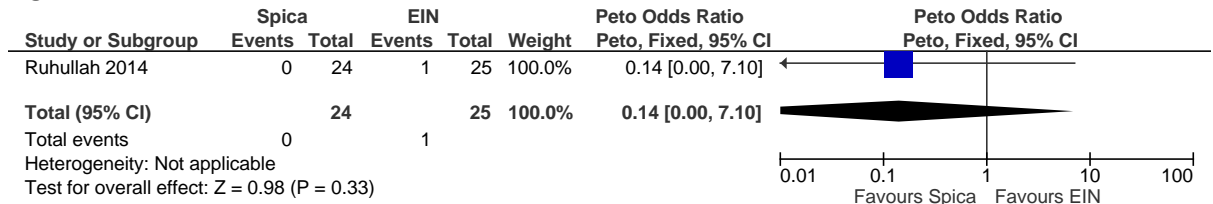
**Figure 191: Flynn grading classed as 'excellent'**



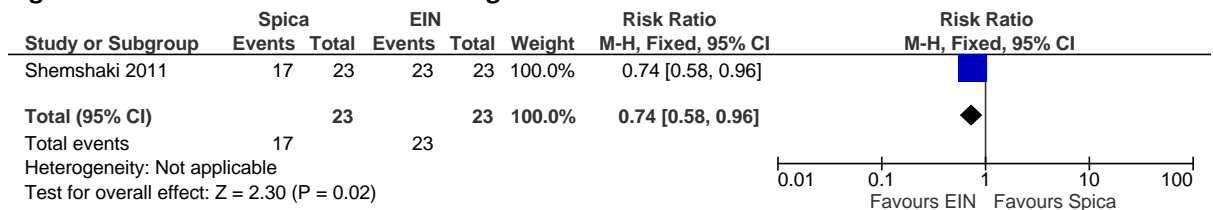
**Figure 192: Malunion**



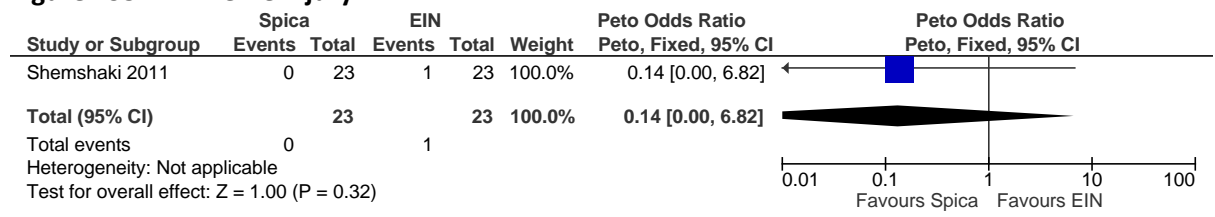
**Figure 193: Avascular necrosis**



**Figure 194: Parental satisfaction – 'good or excellent'**



**Figure 195: Nerve injury**



J.4.4.2 Spica versus Ext fixation

Figure 196: Malunion

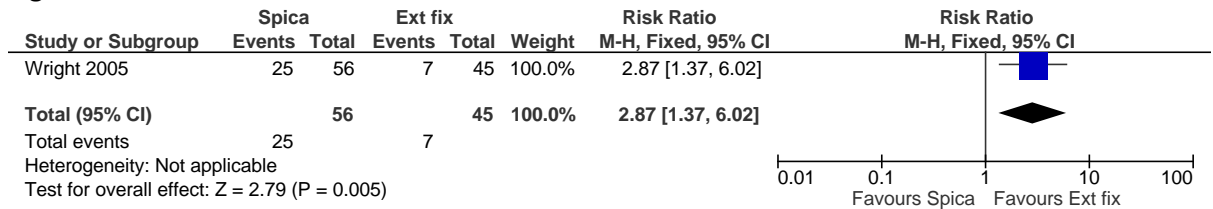


Figure 197: Rand child health status (higher worse)

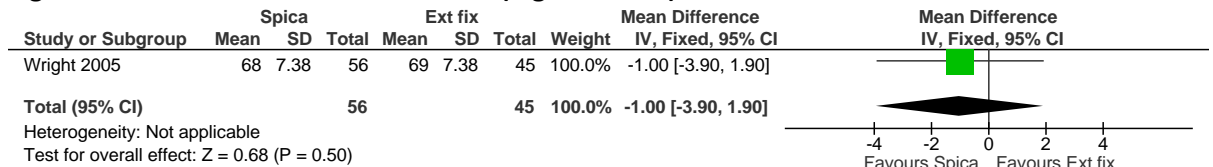
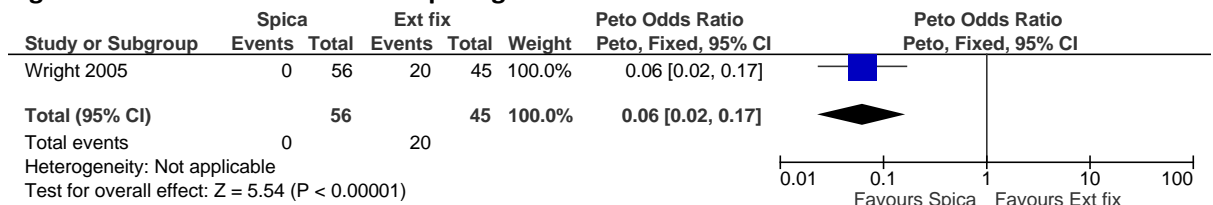


Figure 198: Adverse events requiring further treatment

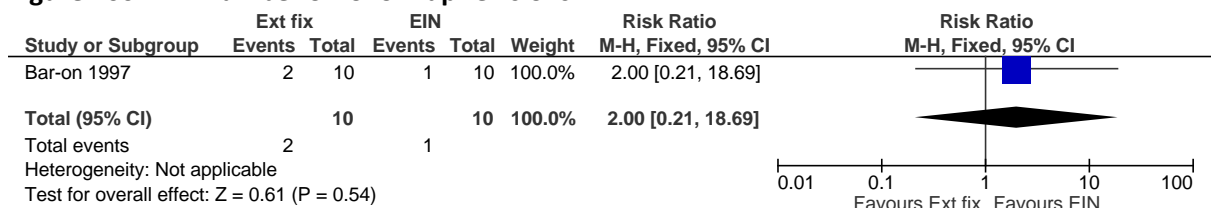


J.4.4.3 Ext fixation versus EIN

Figure 199: Parental satisfaction – numbers who would choose same treatment again

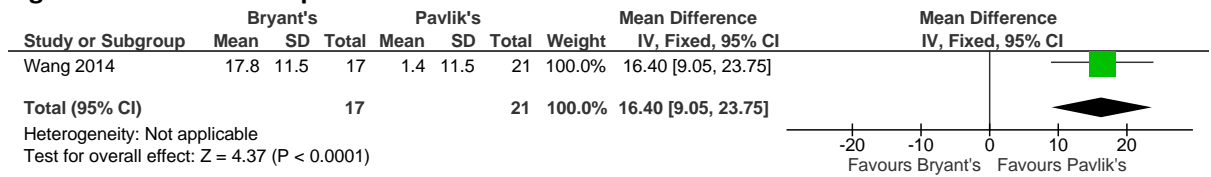


Figure 200: Number of follow-up revisions

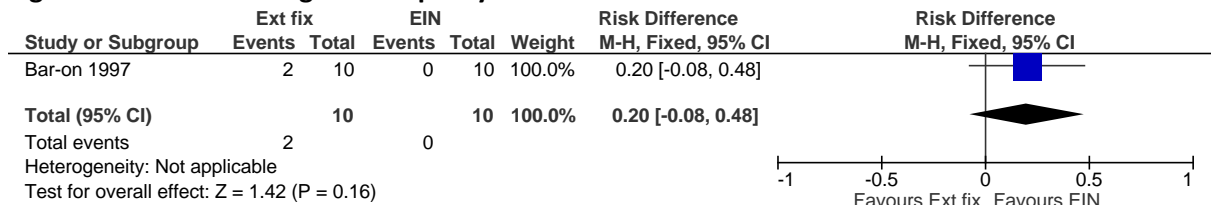




**Figure 201: foot drop**

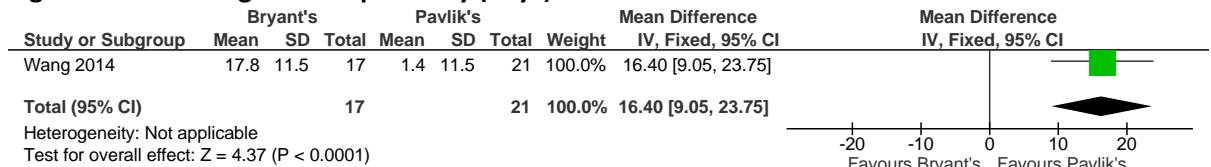


**Figure 202: limb length discrepancy**

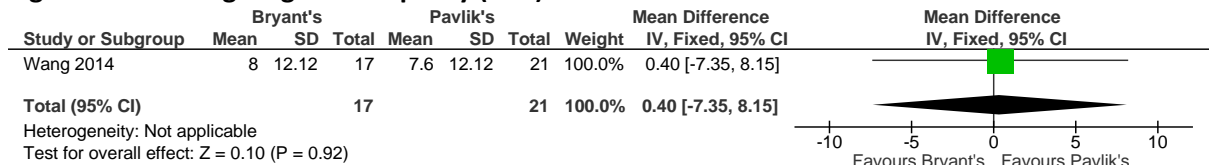


**J.4.4.4 Bryant's traction versus Pavlik's harness**

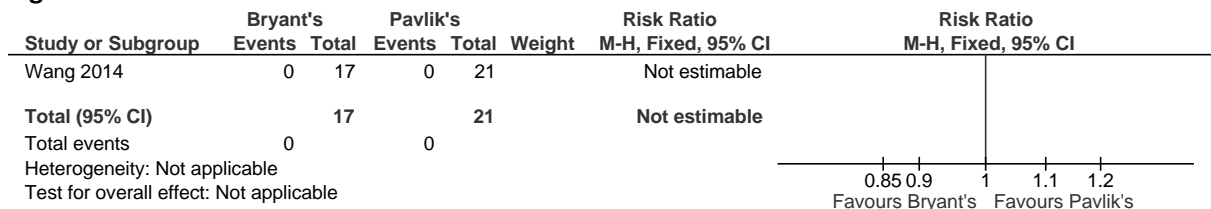
**Figure 203: length of hospital stay (days)**



**Figure 204: leg length discrepancy (mm)**

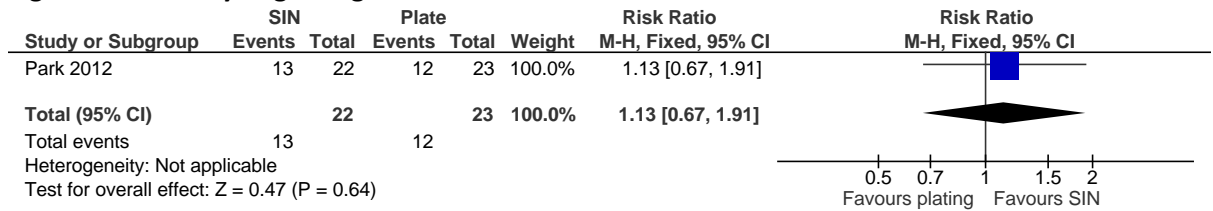


**Figure 205: malunion**

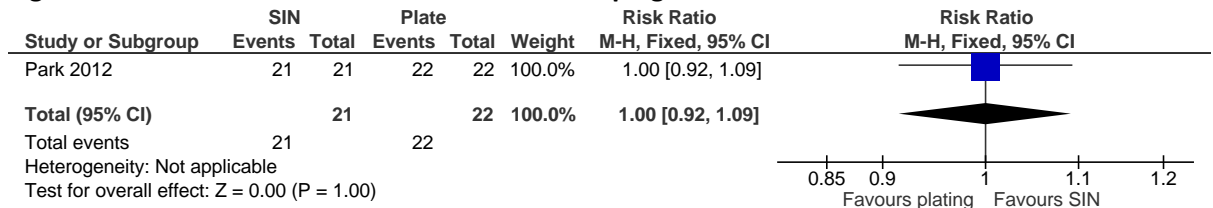


J.4.4.5 SIN versus plating

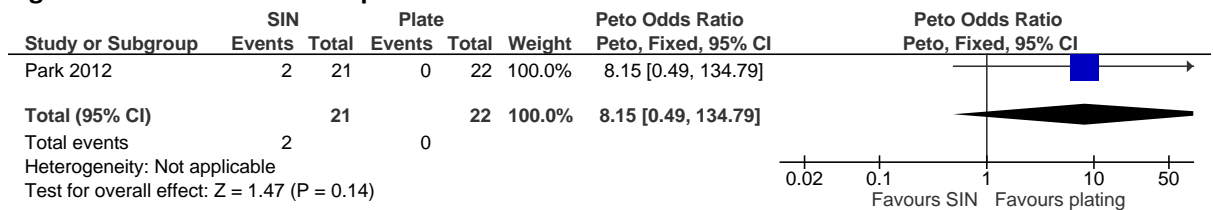
**Figure 206: Flynn grading of excellent**



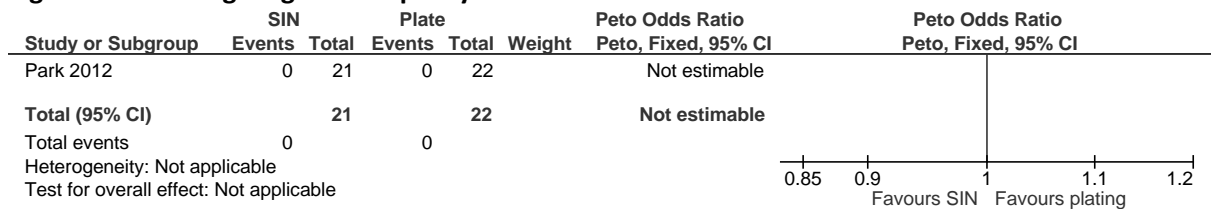
**Figure 207: Return to ambulation without limping**



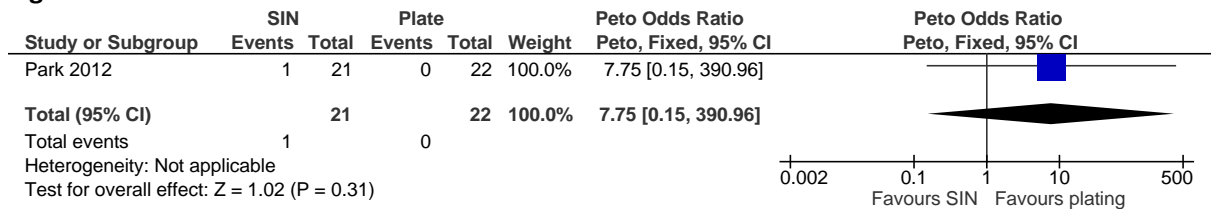
**Figure 208: need for re-operation**



**Figure 209: leg length discrepancy > 1cm**



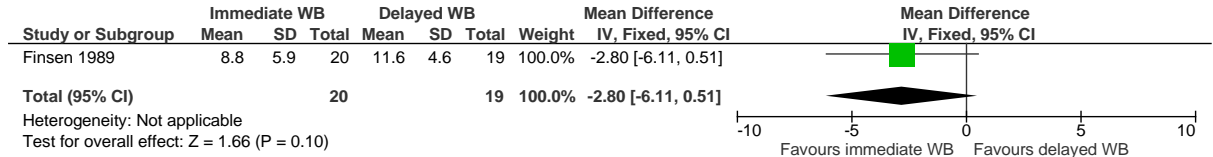
**Figure 210: Non union**



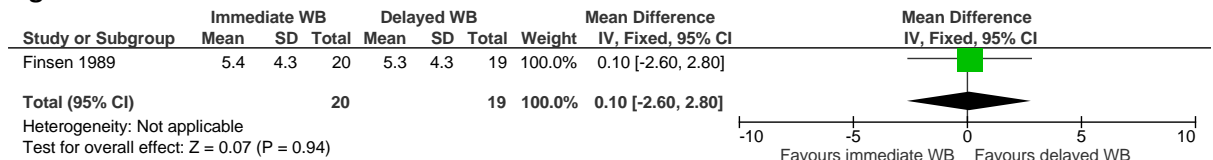
## J.4.5 Post operative mobilisation – ankle fractures

### J.4.5.1 Immediate unrestricted weight bearing versus delayed unrestricted weight bearing

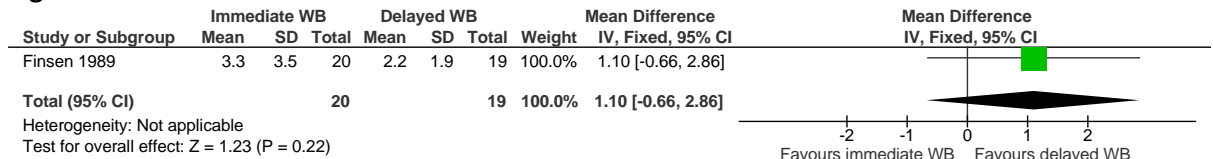
**Figure 211: Ankle score at 9 weeks**



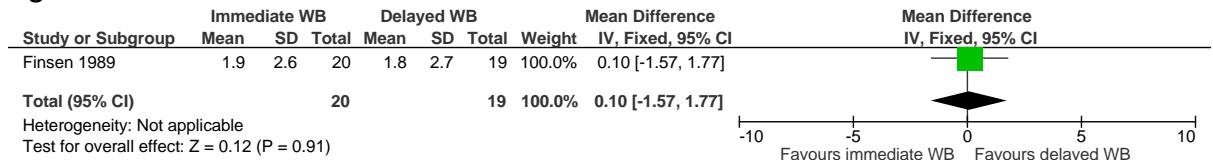
**Figure 212: Ankle score at 18 weeks**



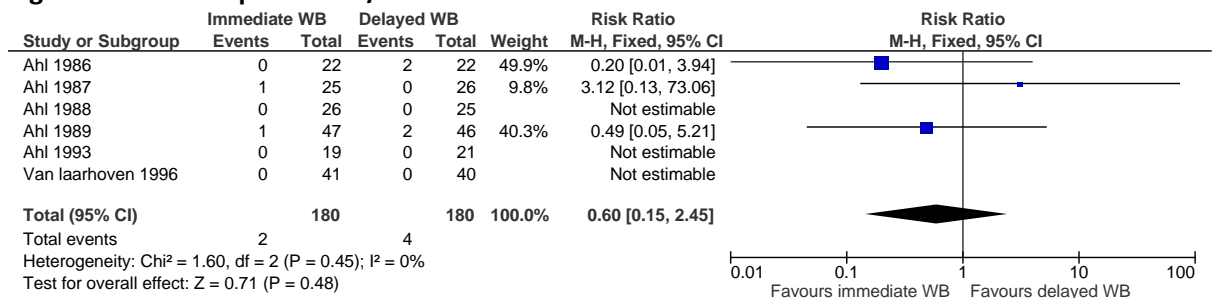
**Figure 213: Ankle score at 36 weeks**



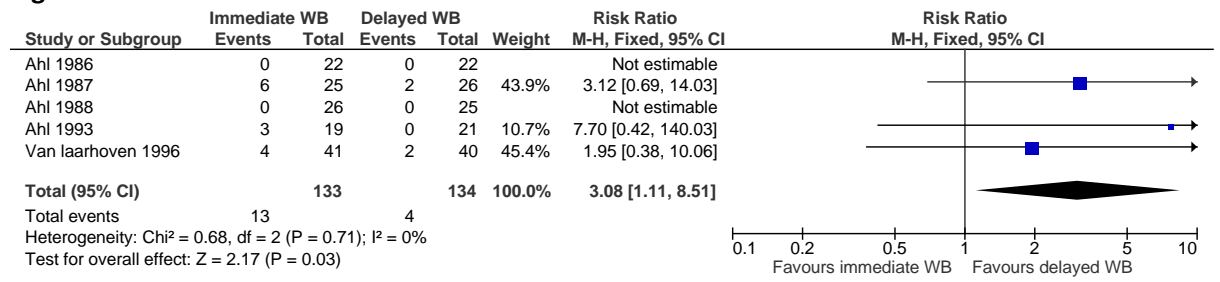
**Figure 214: Ankle score at 52 weeks**



**Figure 215: Displacement/re-dislocation**



**Figure 216: Wound infection**



## Appendix K: Excluded clinical studies

### K.1 Initial pain management and immobilisation

#### K.1.1 Initial pharmacological pain management

**Table 1: Studies excluded from the clinical review**

Study	Reason for exclusion
Adolphson 1993 <sup>4</sup>	Not initial pain management
Baharuddin 2014 <sup>34</sup>	Majority non-fracture
Barrington 1980 <sup>40</sup>	Not initial pain management
Borland 2011 <sup>69</sup>	Dose comparison
Bounes 2010 <sup>71</sup>	Pre-hospital study
Burton 1998 <sup>97</sup>	Non- fracture population (Lacerations)
Davis 1988 <sup>138</sup>	Not initial pain management
Derakhshanfar 2014 <sup>144</sup>	Abstract
Derakhshanfar 2014 <sup>143</sup>	Abstract
Devellis 1998 <sup>146</sup>	Non-randomised study; pre-hospital population
Drendel 2009 <sup>158</sup>	Not initial pain management (following ED discharge).
Duda 1987 <sup>160</sup>	Study not in English
Evans 2005 <sup>165</sup>	Compares mechanism of analgesic delivery.
Farahmand 2014 <sup>170</sup>	Less than 50% fracture population.
Farsi 2013 <sup>171</sup>	Dose comparison
Graudins 2013 <sup>204</sup>	Study protocol
Graudins 2015 <sup>205</sup>	Study protocol
Hamdan 2012 <sup>214</sup>	Abstract
Hansen 2012 <sup>223</sup>	Systematic review - Non-trauma population
Hoogewijs 2000 <sup>238</sup>	Non-fracture population
Indelicato 1986 <sup>250</sup>	Non-trauma population
Jadon 2014 <sup>251</sup>	Femur/Nerve blocks
Kendall 2001 <sup>267</sup>	Incorrect interventions. Morphine delivered intramuscular
Kidd 2009 <sup>271</sup>	Biochemical study. No applicable outcomes.
Lacey 1984 <sup>294</sup>	Non-fracture population
Le may 2013 <sup>301</sup>	Non- fracture population
Leman 2003 <sup>310</sup>	Non=fracture population (<20%)
Lemay 2010 <sup>311</sup>	Abstract
Majidi 2015 <sup>332</sup>	Incorrect interventions
Man 2004 <sup>336</sup>	Abstract
Mcilwain 1988 <sup>348</sup>	Non-fracture population (Musculoskeletal)
Melnychuck 2012 <sup>354</sup>	Abstract
Migita 2006 <sup>356</sup>	Use of pharmacological agents in reductions/sedation
Moustafa 2014 <sup>368</sup>	Abstract
Ortiz 2010 <sup>401</sup>	Study does not report outcomes applicable to study protocol.. High level

Study	Reason for exclusion
	of bias (flawed methodology)
Petrack 1997 <sup>415</sup>	Retrospective chart review
Ponce-monter 2012 <sup>423</sup>	Incorrect interventions. Considers the effect of Vitamin D addition to Diclofenac
Rainer 2000 <sup>431</sup>	Cost-effectiveness study - No outcomes applicable to protocol.
Ridderikhof 2013 <sup>438</sup>	Study protocol
Sleet 1980 <sup>466</sup>	Majority non-fracture
Stableforth 1977 <sup>478</sup>	Soft tissue injury
Staunstrup 1999 <sup>480</sup>	Elective surgery group (Non fracture)
Suresh 2014 <sup>491</sup>	Femur/Nerve blocks
Tsertsvadze 2013 <sup>511</sup>	Systematic review of long-term fracture management.
Vergnion 2001 <sup>522</sup>	Pre-hospital
Wilson 1997 <sup>539</sup>	Incorrect interventions. Intramuscular Morphine (Incorrect Comparision)
Woo 2005 <sup>541</sup>	Non-fracture population (<10%)
Yost 2008 <sup>551</sup>	Exclude study abstract (Included under Borland 2007)
Younge 1999 <sup>553</sup>	Incorrect interventions. Intramuscular morphine

### K.1.2 Paediatric nerve blocks femoral fractures

**Table 2: Studies excluded from the clinical review**

Study	Reason for exclusion
Amiri 2012 <sup>19</sup>	Incorrect age group
Barker 2008 <sup>39</sup>	Incorrect age group. Not guideline population. Non-femoral.
Beaudoin 2013 <sup>47</sup>	Incorrect age group
Bech 2009 <sup>48</sup>	Incorrect age group
Bech 2011 <sup>49</sup>	Conference Abstract
Cao 2008 <sup>102</sup>	Not in English
Coad 1991 <sup>121</sup>	Not initial pain management - Post operative analgesia.
Derakhshanfar 2014 <sup>143</sup>	Incorrect interventions
Drendel 2009 <sup>158</sup>	Incorrect interventions
Durrani 2013 <sup>161</sup>	Incorrect age group
Fletcher 2003 <sup>180</sup>	Incorrect age group
Ghimire 2012 <sup>195</sup>	Conference Abstract
Haddad 1995 <sup>212</sup>	Incorrect age group
Iamaroon 2010 <sup>247</sup>	Incorrect age group
Kidd 2009 <sup>271</sup>	Incorrect interventions
Majeed 2013 <sup>331</sup>	Conference Abstract
Mittal 2014 <sup>361</sup>	Review article
Mosaffa 2009 <sup>367</sup>	Conference Abstract
Mutty 2007 <sup>373</sup>	Incorrect age group
Mutty 2008 <sup>374</sup>	Review article.
Newman 2013 <sup>386</sup>	Incorrect age group

Study	Reason for exclusion
Paul 2013 <sup>410</sup>	Conference Abstract
Paul 2013 <sup>411</sup>	Conference Abstract
Sahota 2014 <sup>447</sup>	Trial protocol
Samuel 2013 <sup>450</sup>	Conference Abstract
Schiferer 2007 <sup>453</sup>	Incorrect age group
Stanhope 2010 <sup>479</sup>	Abstract only
Stewart 2007 <sup>482</sup>	Incorrect interventions. Study investigated continuous versus single injection block of the femur
Szucs 2014 <sup>494</sup>	Incorrect age group
Van leeuwen 2000 <sup>517</sup>	Incorrect age group
Woo 2005 <sup>541</sup>	Incorrect interventions
Yost 2008 <sup>551</sup>	Incorrect interventions
Younge 2001 <sup>552</sup>	Incorrect interventions
Yun 2009 <sup>556</sup>	Incorrect age group

## K.2 Acute stage assessment and diagnostic imaging

### K.2.1 Selecting patients for imaging - clinical prediction rules for knee fractures

**Table 3: Studies excluded from the clinical review**

Reference	Reason for exclusion
Bachmann 2004 <sup>30</sup>	Out-dated systematic review – reference list checked
Bauer 1995 <sup>45</sup>	Validation study. Bauer criteria decided on the basis of which combination of criteria gave optimal accuracy – this will have led to the play of chance contributing to accuracy of Bauer criteria to a greater extent than would be expected
Cohen 1998 <sup>123</sup>	Assessed single diagnostic test criteria, which were non-validated
Crossley 2004 <sup>129</sup>	Review of a single paper
Kec 2003 <sup>266</sup>	In terms of sensitivity, the gold standard was the physician interpretation of the rule (this study was examining the diagnostic accuracy of the tool when performed by triage nurses). This is an inappropriate gold standard and this question is not aimed at examining the accuracy of the tools between different personnel
Matteucci 2003 <sup>345</sup>	No diagnostic accuracy data
Moore 2005 <sup>365</sup>	Assessed single criteria from the Ottawa scale, which were non-validated
Nagpal 2007 <sup>377</sup>	Non RCT and no diagnostic accuracy data
Nichol 1999 <sup>388</sup>	Non RCT comparison study; no diagnostic data
Nugent 2004 <sup>395</sup>	Review – references checked
Perry 2006 <sup>412</sup>	Review – references checked
Stevermer 1996 <sup>481</sup>	Review of a single article
Stiell 2007 <sup>489</sup>	Review – reference list checked
Stiell 1995 <sup>488</sup>	Derivation study with no validation in another sample
Tandeter 1999 <sup>496</sup>	Review – reference list checked

Reference	Reason for exclusion
Tigges 2001 <sup>505</sup>	Non RCT comparison study; no diagnostic data
Vijayasankar 2009 <sup>525</sup>	Review – reference list checked
Weber 1995 <sup>534</sup>	Derivation study with no validation in another sample
Yao 2012 <sup>547</sup>	Review – reference list checked

## K.2.2 Selecting patients for imaging - clinical prediction rules for ankle fractures

**Table 4: Studies excluded from the clinical review**

Reference	Reason for exclusion
Allerston 2000 <sup>15</sup>	Not relevant to protocol question
Anis,1995 <sup>23</sup>	Non-randomised study
Auleley 1998 <sup>27</sup>	Diagnostic accuracy study
Auleley 1997 <sup>28</sup>	Cluster randomised and only 5 clusters. Also there was no coercion to use the Ottawa in the hospitals randomised to Ottawa
Bachmann 2003 <sup>31</sup>	Diagnostic accuracy study
Bachmann 2003 <sup>32</sup>	Diagnostic accuracy study
Bessen 2009 <sup>55</sup>	Diagnostic accuracy study
Boutis 2013 <sup>72</sup>	Diagnostic accuracy study
Boutis 2001 <sup>73</sup>	Non-randomised study
Broomhead 2003 <sup>84</sup>	Diagnostic accuracy study
Can 2008 <sup>100</sup>	Diagnostic accuracy study
Canagasabay 2011 <sup>101</sup>	Imaging study, not clinical prediction rules study
Chan 2010 <sup>108</sup>	Diagnostic accuracy study
Clark 2003 <sup>119</sup>	Diagnostic accuracy study
Dayan 2004 <sup>139</sup>	Diagnostic accuracy study
Diehr 1988 <sup>150</sup>	Diagnostic accuracy study
Dissmann 2006 <sup>151</sup>	Diagnostic accuracy study
Dowling 2009 <sup>157</sup>	Diagnostic accuracy systematic review
Fiesseler 2004 <sup>174</sup>	Non-randomised study
Goksel 2009 <sup>197</sup>	Diagnostic accuracy study
Gwilym 2003 <sup>211</sup>	Non-randomised study
Heyworth 2003 <sup>231</sup>	Opinion narrative
Hopkins 2010 <sup>239</sup>	Non-randomised study and not relevant to protocol
Karpas 2002 <sup>263</sup>	Diagnostic accuracy study
Kerr 1994 <sup>270</sup>	Diagnostic accuracy study
Keogh 1998 <sup>269</sup>	Diagnostic accuracy study
Klassen 1993 <sup>276</sup>	Not restricted to ankle.
Lau 2013 <sup>299</sup>	Non-randomised study
Leddy 2002 <sup>303</sup>	Non-randomised study
Leddy 1998 <sup>302</sup>	Diagnostic accuracy study
Leisey 2004 <sup>309</sup>	Diagnostic accuracy study
Libetta, 1999 <sup>317</sup>	Diagnostic accuracy study



Reference	Reason for exclusion
Lucchesi 1995 <sup>327</sup>	Diagnostic accuracy study
Mann, 1998 <sup>337</sup>	Diagnostic accuracy study
Marinelli 2011 <sup>340</sup>	Diagnostic accuracy study
Marinelli 2007 <sup>341</sup>	Diagnostic accuracy study
Markert 1998 <sup>342</sup>	Diagnostic accuracy study
McBride 1997 <sup>346</sup>	Diagnostic accuracy study
Milne 1996 <sup>359</sup>	Diagnostic accuracy study
Morris 2013 <sup>366</sup>	Non-randomised study
Myers 2005 <sup>376</sup>	Diagnostic accuracy study
Negahban 2010 <sup>384</sup>	Not an ankle fracture prediction tool study
Northrup 2005 <sup>392</sup>	Non-systematic review
Northrup 2005 <sup>391</sup>	Non-systematic review
Nugent 2004 <sup>394</sup>	Diagnostic accuracy study
Papacostas 2001 <sup>405</sup>	Diagnostic accuracy study
Parron 2008 <sup>406</sup>	Diagnostic accuracy study
Perry 2006 <sup>412</sup>	Non-systematic review
Perry 1999 <sup>413</sup>	Diagnostic accuracy study
Pigman 1994 <sup>417</sup>	Diagnostic accuracy study
Pijnenburg 2002 <sup>419</sup>	Diagnostic accuracy study
Plint 1999 <sup>420</sup>	Diagnostic accuracy study
Pope 2002 <sup>425</sup>	Diagnostic accuracy study
Rajasekaran 2006 <sup>433</sup>	Not appropriate to protocol
Rodrigues 2011 <sup>441</sup>	Non-English language
Rosin 1999 <sup>442</sup>	Diagnostic accuracy study
Salt 1997 <sup>449</sup>	Diagnostic accuracy study
Shetty 2013 <sup>460</sup>	validation study
Singh-Ranger 1999 <sup>465</sup>	Diagnostic accuracy study
Smith 2011 <sup>470</sup>	Non-randomised study
Sorensen 2012 <sup>476</sup>	Non-randomised study
Springer 2000 <sup>477</sup>	Diagnostic accuracy study
Stiell 1995 <sup>484</sup>	Non-randomised study
Stiell 1996 <sup>483</sup>	Background review
Stiell 1993 <sup>485</sup>	Developmental and diagnostic accuracy study
Stiell 1992 <sup>486</sup>	Developmental study
Stiell 1994 <sup>487</sup>	Non-randomised study
Tay 1999 <sup>498</sup>	Diagnostic accuracy study
Tollefson 2012 <sup>506</sup>	Diagnostic accuracy study
Tsui 2011 <sup>512</sup>	Non-systematic review
van der Wees 2012 <sup>514</sup> van der Wees P,	Validity study
Van Der Wees 2011 <sup>515</sup>	Non-randomised study
Verbeek 1997 <sup>521</sup>	Not relevant to protocol
Verma 1997 <sup>523</sup>	Diagnostic accuracy study

Reference	Reason for exclusion
Wang 2013 <sup>531</sup>	Diagnostic accuracy study
Wynn-Thomas 2002 <sup>544</sup>	Diagnostic accuracy study
Yazdani 2006 <sup>548</sup>	Diagnostic accuracy study
Yuen 2001 <sup>554</sup>	Diagnostic accuracy study
Yuen 2001 <sup>555</sup>	Diagnostic accuracy study

### K.2.3 Imaging of scaphoid

**Table 5: Studies excluded from the clinical review**

Study	Reason for exclusion
Amrami 2005 <sup>20</sup>	Study is not relevant to review question or unclear PICO
Dorsay 2001 <sup>156</sup>	Systematic review is not relevant to review question or unclear PICO
Geijer 2013 <sup>194</sup>	Systematic review is not relevant to review question or unclear PICO
Gooding 2014 <sup>201</sup>	Incorrect study design (historical cohort study)
Hansen 2009 <sup>224</sup>	Incorrect study design (cohort study)
Hiscox 2013 <sup>232</sup>	Inappropriate comparison (bone scintigraphy versus. delayed X-ray)
Kitsis 1998 <sup>275</sup>	Incorrect study design (case series)
Mallee 2012 <sup>335</sup>	Incorrect study design (Cochrane review protocol)
Raby 2001 <sup>430</sup>	Incorrect study design (historical cohort study)
Raja 2013 <sup>432</sup>	Study is not relevant to review question or unclear PICO
Yin 2010 <sup>549</sup>	Systematic review is not relevant to review question or unclear PICO
Yin 2012 <sup>550</sup>	Systematic review is not relevant to review question or unclear PICO

**Table 6: Studies excluded from the clinical review (diagnostic accuracy)**

Reference	Reason for exclusion
Beeres 2008a <sup>51</sup>	Inappropriate comparison (used combination methods as the gold standard, not MRI alone)
Bhat 2004 <sup>58</sup>	Incorrect population (scaphoid fracture visible on initial X-ray)
Breederveld 2004 <sup>79</sup>	Inappropriate comparison (used combination methods as the gold standard, not MRI alone)
Breitseher 1997 <sup>80</sup>	Inappropriate comparison (did not use MRI as gold standard)
Bretlau 1999 <sup>81</sup>	Inappropriate comparison (did not use MRI as gold standard)
Buijze 2011 <sup>94</sup>	Inappropriate comparison (used combination methods as the gold standard, not MRI alone)
Buijze 2012 <sup>93</sup>	Incorrect population (patients with a definitive diagnosis of scaphoid fracture)
Calderon 2007 <sup>98</sup>	Incorrect study design (non-systematic review)
Cerezal 2000 <sup>106</sup>	Incorrect population (patients with non-union of scaphoid fracture >6-months post-injury)
Cook 1997 <sup>124</sup>	Inappropriate comparison (did not use MRI as gold standard)
Cruickshank 2007 <sup>130</sup>	Inappropriate comparison (did not use MRI as gold standard)
Dias 1990 <sup>148</sup>	Incorrect study design (no reference standard)
Duckworth 2011 <sup>159</sup>	Incorrect study design (non-systematic review)

Reference	Reason for exclusion
Fowler 1998 <sup>183</sup>	Inappropriate comparison (used combination methods as the gold standard, not MRI alone)
Gabler 2001 <sup>191</sup>	Inappropriate comparison (did not use MRI as gold standard)
Gaebler 1996 <sup>192</sup>	Inappropriate comparison (did not use MRI as gold standard)
Groves 2005 <sup>209</sup>	Incorrect study design (no reference standard)
Jenkins 2008 <sup>258</sup>	Incorrect study design (no reference standard)
Kitsis 1998 <sup>275</sup>	Incorrect study design (case series)
Kumar 2005 <sup>291</sup>	Incorrect study design (case series)
Kusunoli 1992 <sup>293</sup>	Incorrect study design (case series)
Low 2005 <sup>324</sup>	Inappropriate comparison (delayed X-ray taken 10-50 days post-injury; mean = 34.5 days)
Lozano-Calderon 2006 <sup>325</sup>	Inappropriate comparison (did not use MRI as gold standard)
Mallee 2011 <sup>334</sup>	Inappropriate comparison (did not use MRI as gold standard)
Mallee 2012 <sup>335</sup>	Incorrect study design (Cochrane review protocol)
Memarsadeghi 2006 <sup>355</sup>	Inappropriate comparison (did not use MRI as gold standard)
Moller 2004 <sup>363</sup>	Inappropriate comparison (did not use MRI as gold standard)
Munk 1995 <sup>369</sup>	Incorrect study design (case series)
Nguyen 2008 <sup>387</sup>	Incorrect study design (case series)
Rhemrev 2010 <sup>436</sup>	Inappropriate comparison (did not use MRI as gold standard)
Temple 2005 <sup>499</sup>	Incorrect population (cadavers)
Thorpe 1996 <sup>501</sup>	Inappropriate comparison (did not use MRI as gold standard)
Tiel-van Buul 1993 <sup>503</sup>	Inappropriate comparison (did not use MRI as gold standard)
Tiel-Van Buul 1996 <sup>504</sup>	Inappropriate comparison (did not use MRI as gold standard)
Trigg 2007 <sup>509</sup>	Incorrect study design (survey)

## K.2.4 Hot reporting

**Table 7: Studies excluded from the clinical review**

Reference	Reason for exclusion
Benger 2003 <sup>54</sup>	Incorrect study design (diagnostic accuracy)
Brealey 2005 <sup>78</sup>	Intervention does not match protocol (intervention and comparison both used cold reporting)
Dabbo 2013 <sup>134</sup>	Incorrect study design (retrospective cohort study)
Henderson 2013A <sup>229</sup>	Intervention does not match protocol (intervention included management of soft tissue injuries)
Lamb 2014 <sup>297</sup>	Incorrect study design (retrospective cohort study)
Snaith 2014 <sup>471</sup>	No relevant outcomes

## K.3 Management and treatment plan in the emergency department

### K.3.1 Timing of reduction and imaging guidance- distal radius fractures

**Table 8: Studies excluded from the clinical review**

Reference	Reason for exclusion
Ang 2010 <sup>22</sup>	Inappropriate comparison. Image guided rather than image

Reference	Reason for exclusion
	intensification
Auge 2000 <sup>26</sup>	Study design: case series
Bain 1997 <sup>35</sup>	Inappropriate comparison. Not review population
Beerekamp 2011 <sup>50</sup>	Trial protocol
Bevan 2013 <sup>56</sup>	Literature review
Blakeney 2009 <sup>63</sup>	Incorrect interventions: no varied timing or image intensification
Brady 1998 <sup>75</sup>	Conference abstract
Brahm 2011 <sup>76</sup>	Conference abstract
Chartier 2012 <sup>110</sup>	Literature review
Chinnock 2011 <sup>112</sup>	Inappropriate comparison. Image guided rather than image intensification
Handoll helen 2003 <sup>217</sup>	Systematic review is not relevant to review question or unclear PICO
Kodama 2014 <sup>277</sup>	Non-randomised study does not account for key confounder (anaesthetic type)
Mcmillan 1996 <sup>350</sup>	Conference abstract
Mikkelsen 1991 <sup>357</sup>	Incorrect intervention: not closed reduction
Montazeri 2014 <sup>364</sup>	Non-comparative study
Ruch 2004 <sup>444</sup>	Incorrect intervention: arthroscopic reduction
Sadeghifar 2014 <sup>445</sup>	Not English language
Tai-chang 2002 <sup>495</sup>	Incorrect study design: case series
Varitimidis 2008 <sup>520</sup>	Incorrect intervention: open reduction

### K.3.2 Reduction anaesthesia – distal radius fractures

**Table 9: Studies excluded from the clinical effectiveness review**

Study	Reason for exclusion
Blyth 1995 <sup>66</sup>	Incorrect interventions. Only IV regional anaesthesia
Brady 1998 <sup>75</sup>	Conference abstract
Bultitude 1972 <sup>95</sup>	Incorrect interventions. General anaesthetic
Case 1985 <sup>105</sup>	Study design not relevant to review. Non-randomised study. Interventions covered by RCTs
Chong 2007 <sup>114</sup>	Incorrect interventions. Only IV regional anaesthesia
Cobb 1985 <sup>122</sup>	Conference abstract
Funk 1997 <sup>189</sup>	Non-randomised study does not account for key confounder: age
Furia 1997 <sup>190</sup>	Incorrect population. Radius and ankle fractures.
Handoll 2002 <sup>219</sup>	Systematic review is not relevant to review question or unclear PICO
Hollingworth 1982 <sup>236</sup>	Incorrect interventions. Only Bier block
Johnson 1991 <sup>259</sup>	Study design not relevant to review. Non-comparative study
Jones 1996 <sup>260</sup>	Incorrect interventions. Only IV regional anaesthesia. Not review population
Liles 1969 <sup>318</sup>	Study design not relevant to review. Not a clinical trial
London 1996 <sup>322</sup>	Inappropriate comparison. Haematoma block versus haematoma block
Myderrizi 2011 <sup>375</sup>	Incorrect interventions. General anaesthesia

Study	Reason for exclusion
Quinton 1988 <sup>429</sup>	Incorrect interventions. Only haematoma block
Sadeghifar 2014 <sup>445</sup>	Not English language
Sherry 1989 <sup>459</sup>	Incorrect interventions. Only conscious sedation
Singh 1992 <sup>464</sup>	Unable to obtain paper

**Table 10: Studies excluded from the adverse events review**

Study	Exclusion reason
Weaver 2011 <sup>533</sup>	No outcomes of interest

### K.3.3 Treatment of torus fractures

**Table 11: Studies excluded from the clinical review**

Reference	Reason for exclusion
Abraham 2008 <sup>2</sup>	Withdrawn from publication as out-of-date
Bae 2012 <sup>33</sup>	Non-systematic review article –checked for references
Davidson 2001 <sup>137</sup>	No relevant outcomes included
Derksen 2013 <sup>145</sup>	Included greenstick fractures with no sub-grouping for fracture type
Firmin 2009 <sup>177</sup>	Systematic review – checked for references
Hamilton 2013 <sup>215</sup>	Included greenstick fractures with no sub-grouping for fracture type
Howes 2008 <sup>243</sup>	Non-systematic review article –checked for references
Kennedy 2010 <sup>268</sup>	Systematic review - checked for references
Neal 2014 <sup>383</sup>	Non-systematic review article –checked for references
Plint 2004 <sup>421</sup>	Retrospective cohort study; already have RCTs for the comparison covered in this study
Pountos 2010 <sup>427</sup>	Included greenstick fractures with no sub-grouping for fracture type
Sutherland 2011 <sup>492</sup>	Not torus fracture population
Symons 2001 <sup>493</sup>	Wrong intervention and comparator
Taranu 2011 <sup>497</sup>	Non RCT; non comparative
Vernooij 2012 <sup>524</sup>	Non RCT; already have RCTs for the comparison covered in this study
West 2004 <sup>537</sup>	Abstract; full paper included

Reference	Reason for exclusion
Witney-Lagen 2013 <sup>540</sup>	Non RCT; already have RCTs for the comparison covered in this study
Wright 2011 <sup>542</sup>	Non-systematic review article –checked for references

### K.3.4 Referral for ongoing management from the emergency department

**Table 12: Studies excluded from the clinical review: Referral pathway decision-makers (MDT)**

Study	Reason for exclusion
Bayreuther 2009 <sup>46</sup>	Study does not extend to referral pathway decision-makers
Brandis 1998 <sup>77</sup>	Post-referral focussed study
Brooke 2014 <sup>82</sup>	Study takes place after the primary management plan has been formulated
Lambrecht 1998 <sup>298</sup>	Non-comparative study
Malkin 2003 <sup>333</sup>	Non-comparative study

**Table 13: Studies excluded from the clinical review: Referral to virtual clinics versus face to face clinics**

Reference	Reason for exclusion
Rouleau 2010 <sup>443</sup>	Not relevant to review question
Bancroft 2000 <sup>38</sup>	Not relevant to review question
Blank 2011 <sup>64</sup>	Descriptive. No outcomes covered
Good2012 <sup>200</sup>	GDG felt the evidence for Skype clinics was not relevant to the review question
Heath 1997 <sup>225</sup>	Not relevant to review question
Ricci 2002 <sup>437</sup>	Non comparative
Palombo 2003 <sup>404</sup>	Not relevant to review question
Jayaram 2014 <sup>255</sup>	Non comparative
Zennaro 2014 <sup>557</sup>	No comparison to face to face clinics
Sathiyakumar 2015 <sup>451</sup>	First post-discharge appointment was face to face in both groups; only later follow ups differed between groups.
Vardy 2014 <sup>519</sup>	Not relevant to review question – focussed on ED performance not accuracy of achieving appropriate management plan

**Table 14: Studies excluded from the clinical review: Referral destinations (Specialist clinics versus general fracture clinics)**

Reference	Reason for exclusion
Rouleau 2010 <sup>443</sup>	Not relevant to review question
Bancroft 2000 <sup>38</sup>	Not relevant to review question
Blank 2011 <sup>64</sup>	Descriptive. No outcomes covered

Reference	Reason for exclusion
Heath 1997 <sup>225</sup>	Not relevant to review question
Good 2012 <sup>200</sup>	Not relevant to this question; included in virtual clinics question
Ricci 2002 <sup>437</sup>	Non comparative
Palombo 2003 <sup>404</sup>	Not relevant to review question
Jayaram 2014 <sup>255</sup>	Non comparative
Beiri 2006 <sup>52</sup>	Not relevant to this question; included in virtual clinics question
Murray 2012 <sup>371</sup>	Not relevant to this question; included in virtual clinics question

## K.4 On-going management

### K.4.1 Non-surgical management of unimalleolar ankle fractures

**Table 15: Studies excluded from the clinical review**

Reference	Reason for exclusion
Ahl 1986 <sup>8</sup>	Post-surgery population
Ahl 1987 <sup>9</sup>	Post-surgery population
Ahl 1988 <sup>11</sup>	Post-surgery population
Ahl 1989 <sup>12</sup>	Post-surgery population
Ahl 1993 <sup>10</sup>	Post-surgery population
Black 2013 <sup>62</sup>	Systematic review is not relevant to review question or unclear PICO
Cimino 1991 <sup>118</sup>	Post-surgery population
Distasio 1994 <sup>152</sup>	Unable to obtain paper from BL
Dogra 1999 <sup>153</sup>	Post-surgery population
Finsen 1989 <sup>176</sup>	Post-surgery population
Finsen 1989 <sup>175</sup>	Post-surgery population
Fox 2005 <sup>184</sup>	Incorrect study design
Honigmann 2007 <sup>237</sup>	Post-surgery population
Kimmel 2012 <sup>273</sup>	Post-surgery population
Krannitz 2007 <sup>283</sup>	No relevant outcomes
Lee 2012 <sup>304</sup>	Post-surgery population
Lin 2012 <sup>320</sup>	Systematic review is not relevant to review question or unclear PICO
Mason 2010 <sup>344</sup>	No immediate unrestricted weight bearing
Partio 1990 <sup>408</sup>	Non-English language publication
Port 1996 <sup>426</sup>	Does not adjust for “fracture intervention” confounder
Siddique 2005 <sup>462</sup>	Post-surgery population
Sondenaa 1986 <sup>474</sup>	Post-surgery population
Van laarhoven 1996 <sup>516</sup>	Post-surgery population
Vioreanu 2007 <sup>526</sup>	Post-surgery population

## K.4.2 Timing of surgery – ankle fractures

**Table 16: Studies excluded from the clinical review**

Reference	Reason for exclusion
Bhandari 1999 <sup>57</sup>	Population does not match protocol (tibial fractures)
Carragee 1991 <sup>104</sup>	Reported insufficient data for analysis
Carragee 1993 <sup>103</sup>	Comparison does not match protocol (a comparison of transferred and non-transferred patients with ankle fractures)
Eventov 1978 <sup>167</sup>	Comparison does not match protocol (a comparison of surgical and conservative treatment for ankle fractures)
Fogel 1987 <sup>181</sup>	No relevant outcomes
Hulsker 2011 <sup>245</sup>	Not guideline condition (open fractures)
Miller 2012 <sup>358</sup>	Incorrect study design (non-comparative study)
Pietzik 2006 <sup>416</sup>	Reported insufficient data for analysis
Sharma 2006 <sup>457</sup>	Incorrect study design (non-comparative study)

## K.4.3 Timing of surgery – distal radius fractures

**Table 17: Studies excluded from the clinical review**

Reference	Reason for exclusion
Grewal 2007 <sup>208</sup>	No timing aspects included
Chung 2007 <sup>117</sup>	No timing aspects included, and population were people who had previously failed surgical treatment
Ward 2011 <sup>532</sup>	No timing aspects included
Lefevre 2012 <sup>306</sup>	Wrong population – people with malunion secondary to failed initial treatment
Kaufman 2014 <sup>265</sup>	Open fractures
Henry 2008 <sup>230</sup>	No timing aspects included
Handoll 2003 <sup>217</sup>	No timing aspects included
Handoll 2007 <sup>220</sup>	No timing aspects included

## K.4.4 Definitive treatment - distal radial fractures

**Table 18: Studies excluded from the clinical review**

Study	Reason for exclusion
Afekenstam 1989 <sup>5</sup>	Incorrect interventions
Anon 2011 <sup>3</sup>	Not published
Arora 2012 <sup>24</sup>	Incorrect study design
Atroshi 2006 <sup>25</sup>	Inappropriate comparison
Axelrod 1991 <sup>29</sup>	Incorrect study design
Bartl 2011 <sup>41</sup>	Protocol only
Bruijn 1987 <sup>90</sup>	Incorrect interventions
Chappuis 2011 <sup>109</sup>	Incorrect interventions



Study	Reason for exclusion
Chen 2010 <sup>111</sup>	Not English language
Chirpaz-Cerbat 2011 <sup>113</sup>	Incorrect study design
Chung 2013 <sup>116</sup>	Incorrect study design
Chung 2013 <sup>115</sup>	Incorrect study design
Cooper 2008 <sup>125</sup>	Incorrect study design
Costa 2011 <sup>126</sup>	Protocol only
Cui 2012 <sup>132</sup>	Inappropriate comparison
Diaz-Garcia 2011 <sup>149</sup>	Inappropriate comparison
Esposito 2013 <sup>164</sup>	Systematic review: study designs inappropriate
Faierman 1998 <sup>168</sup>	Systematic review: methods are not adequate/unclear
Falk 2012 <sup>169</sup>	Incorrect interventions
Ferris 1989 <sup>172</sup>	Inappropriate comparison
Franck 2000 <sup>185</sup>	Not English language
Freeman 2000 <sup>186</sup>	Abstract only
Fritz 1999 <sup>187</sup>	Incorrect study design
Gibbons 1994 <sup>196</sup>	Incorrect study design
Gomez-rice 2012 <sup>199</sup>	Incorrect study design
Gradl 2011 <sup>202</sup>	Incorrect interventions
Gradl 2014 <sup>203</sup>	Incorrect interventions
Gravier 2005 <sup>206</sup>	Incorrect interventions
Hahnloser 1999 <sup>213</sup>	Inappropriate comparison
Handoll 2003 <sup>217</sup>	Inappropriate comparison
Handoll 2007 <sup>220</sup>	Inappropriate comparison
Handoll 2008 <sup>216</sup>	Inappropriate comparison
Handoll 2009 <sup>218</sup>	Withdrawn
Handoll 2013 <sup>221</sup>	Protocol only
Horne 1991 <sup>240</sup>	Incorrect study design
Hossain 2006 <sup>241</sup>	Incorrect study design
Hove 2010 <sup>242</sup>	Inappropriate comparison
Hutchinson 2000 <sup>246</sup>	Inappropriate comparison
Jakubietz 2008 <sup>253</sup>	Inappropriate comparison
Jakubietz 2012 <sup>252</sup>	Inappropriate comparison
Jenkins 1989 <sup>257</sup>	Abstract only
Kasapinova 2014 <sup>264</sup>	Review
Kongsholm 1981 <sup>278</sup>	Inappropriate comparison
Kopylov 1999 <sup>281</sup>	Incorrect interventions
Kopylov 2001 <sup>280</sup>	Incorrect interventions
Koshimune 2005 <sup>282</sup>	Inappropriate comparison
Kreder 2005 <sup>284</sup>	Inappropriate comparison
Krishnan 2003 <sup>285</sup>	Inappropriate comparison
Krukhaug 2009 <sup>287</sup>	Inappropriate comparison
Kumbaraci 2014 <sup>292</sup>	Non RCT
Kulshrestha 2011 <sup>289</sup>	Inappropriate comparison

Study	Reason for exclusion
Laino 2012 <sup>296</sup>	Incorrect study design
Li 2010 <sup>313</sup>	Not English language
Lihai 2015 <sup>316</sup>	Review
Ludvigsen 1996 <sup>328</sup>	Not English language
Margaliot 2005 <sup>339</sup>	Systematic review: study designs inappropriate
Mccann 2012 <sup>347</sup>	Incorrect study design
Mcqueen 1998 <sup>351</sup>	Inappropriate comparison
Meier 2012 <sup>353</sup>	Not English language
Milutinovic 2013 <sup>360</sup>	Incorrect study design
Modi 2010 <sup>362</sup>	Systematic review is not relevant to review question or unclear PICO
Murray 2013 <sup>370</sup>	Incorrect study design
Nann 1994 <sup>379</sup>	Abstract only
Nazar 2009 <sup>382</sup>	Incorrect study design
Neumann 1996 <sup>385</sup>	Not English language
Osti 2012 <sup>402</sup>	Inappropriate comparison
Paksima 2004 <sup>403</sup>	Systematic review: study designs inappropriate
Pershad 2009 <sup>414</sup>	Incorrect study design
Pritchett 1995 <sup>428</sup>	Inappropriate comparison
Ring 1997 <sup>439</sup>	Incorrect study design
Safi 2013 <sup>446</sup>	Incorrect interventions
Schonnemann 2011 <sup>455</sup>	Incorrect interventions
Shyamalan 2009 <sup>461</sup>	Incorrect study design
Sommerkamp 1994 <sup>473</sup>	Inappropriate comparison
Strohm 2004 <sup>490</sup>	Inappropriate comparison
Trevisan 2013 <sup>508</sup>	Systematic review: methods are not adequate/unclear
Walenkamp 2013 <sup>527</sup>	Systematic review: study designs inappropriate
Walenkamp 2014 <sup>528</sup>	protocol
Wang 2013 <sup>530</sup>	Unable to gain access
Wei 2012 <sup>535</sup>	Systematic review: study designs inappropriate
Werber 2003 <sup>536</sup>	Inappropriate comparison
Xie 2013 <sup>545</sup>	Systematic review: study designs inappropriate
Xun 2011 <sup>546</sup>	Inappropriate comparison
Zettl 2009 <sup>558</sup>	Not English language
Zyluk 2007 <sup>561</sup>	Not English language

#### K.4.5 Definitive treatment - humerus fractures

**Table 19: Studies excluded from the clinical review**

Study	Reason for exclusion
Afridi 2002 <sup>6</sup>	Unable to obtain study; incorrect age group
Agarwal 2004 <sup>7</sup>	Incorrect age group; abstract only
Altay 2011 <sup>17</sup>	Supracondylar humerus fracture

Anakwenze 2014 <sup>21</sup>	Systematic review; no applicable outcome
Bastian 2009 <sup>42</sup>	Non-randomised case series
Bauer 1999 <sup>44</sup>	Not in English
Benegas 2014 <sup>53</sup>	Humeral shaft fracture
Biberthaler 2009 <sup>59</sup>	Abstract only
Bigorre 2009 <sup>60</sup>	Non comparative study
Bing 2002 <sup>61</sup>	A5 poster; not manuscript
Blonna 2014 <sup>65</sup>	Non-comparative study
Boons 2013 <sup>67</sup>	Abstract only
Boudard 2014 <sup>70</sup>	Non-randomised study; comparisons not matched for age
Boyle 2013 <sup>74</sup>	Non-randomised study; comparisons not matched for age
Brorson 2009 <sup>88</sup>	Exclude; study protocol
Brorson 2009 <sup>86</sup>	Narrative review
Brorson 2011 <sup>87</sup>	Systematic review; no reported outcomes
Brorson 2011 <sup>85</sup>	Narrative review
Brorson 2013 <sup>89</sup>	Narrative review
Buecking 2014 <sup>92</sup>	Compares operative approach; Deltoid split versus deltopectoral approach
Burkhart 2013 <sup>96</sup>	Narrative review
Chalmers 2014 <sup>107</sup>	Patients not matched for severity of fracture
Cuff 2013 <sup>131</sup>	Patients not matched confounders
Dai 2014 <sup>136</sup>	Systematic review is not relevant to review question or unclear PICO
Den hartog 2010 <sup>140</sup>	Systematic review; no analysis
Den hartog 2010 <sup>141</sup>	Study protocol
Edelmann 2011 <sup>162</sup>	Non- English Study
Ellwein 2015 <sup>163</sup>	Non-randomised study; distal humerus fractures
Fialka 2008 <sup>173</sup>	Compares 2 Hemiarthroplasty techniques
Fjalestad 2010 <sup>178</sup>	Included in economic analysis
Fjalestad 2014 <sup>179</sup>	Study protocol
Fuchtmeier 2007 <sup>188</sup>	Exclude; non-human biomechanical study
Gomberawalla 2013 <sup>198</sup>	Systematic review is not relevant to review question or unclear PICO
Handoll 2009 <sup>222</sup>	Study protocol
Hoellen 1997 <sup>233</sup>	Not in English
Hoellen 1997 <sup>234</sup>	Not in English
Holbein 1999 <sup>235</sup>	Not in English
Ilchmann 1998 <sup>248</sup>	Non-randomised study of Open reduction versus. Conservative
Kim 2012 <sup>272</sup>	Non-comparative study
Kontakis 2008 <sup>279</sup>	Review; no comparative studies
Kristiansen 1988 <sup>286</sup>	Exclude; no outcomes specific to protocol
Laflamme 2008 <sup>295</sup>	Non-comparative Study
Launonen 2012 <sup>300</sup>	Study protocol; fits protocol, but will not be published until 2017
Lefevre-Colau 2007 <sup>307</sup>	Compares 2 immobilisation techniques
Li 2011 <sup>314</sup>	Shaft fracture; incorrect Population.
Li 2013 <sup>315</sup>	Humeral shaft fractures

Lill 2012 <sup>319</sup>	Compares novel technique for IM nailing
Liu 2011 <sup>321</sup>	Compares separate techniques for open reduction and plating.
Lopiz 2014 <sup>323</sup>	Compares 2 separate IM nail models
Mao 2014 <sup>338</sup>	Systematic review; study designs inappropriate
Martetschlager 2012 <sup>343</sup>	Study compares surgical type
Namdari 2013 <sup>378</sup>	Systematic review is not relevant to review question or unclear PICO
Norris 2002 <sup>390</sup>	Non-trauma population
Nouraei 2014 <sup>393</sup>	Non-randomised study; no additional outcomes
Ockert 2010 <sup>397</sup>	Study compared the position of mechanical screws when using plating
Ockert 2014 <sup>398</sup>	Study compared the position of screw
Pijls 2010 <sup>418</sup>	Compares 2 techniques of open reduction
Rangan 2006 <sup>434</sup>	Abstract of RCT
Roderer 2011 <sup>440</sup>	Non comparative study
Smejkal 2008 <sup>468</sup>	Abstract only
Smejkal 2011 <sup>469</sup>	Non-English Review
Thorsness 2014 <sup>502</sup>	Non-randomised study; comparisons not matched for age
Trepat 2012 <sup>507</sup>	Non-randomised study does not report confounders.
Wali 2014 <sup>529</sup>	Humeral shaft fractures
Wild 2011 <sup>538</sup>	Non-randomised study comparing open reduction with Hemiarthroplasty
Zuckerman 2012 <sup>560</sup>	Abstract only

#### K.4.6 Definitive treatment - paediatric femoral fractures

**Table 20: Studies excluded from the clinical review**

Reference	Reason for exclusion
Abbott 2013 <sup>1</sup>	Cohort study – not well matched for key confounder (fracture type) and no MVA
Agarwal 2004 <sup>7</sup>	Most patients had forearm fractures
Akinyoola <sup>13</sup>	Interventions not compared in results section
Ali 2005 <sup>14</sup>	Thomas splint not on protocol
Allison 2011 <sup>16</sup>	Cohort study - comparisons covered by RCTs
Altay 2011 <sup>18</sup>	Interventions not on protocol
Baldwin 2011 <sup>36</sup>	Review- references checked
Bali 2011 <sup>37</sup>	Femoral neck fractures
Basumallick 2002 <sup>43</sup>	Comparison not on protocol
Buechsenschuetz 2002 <sup>91</sup>	Non RCT, and comparison already covered by an RCT
Cameron 1992 <sup>99</sup>	Not on children
Clinkscales 1997 <sup>120</sup>	Cohort studies - covered some of the comparators not covered by RCTs but excluded as there was no MVA. Ages appeared different between groups.
Coyte 1997 <sup>127</sup>	Non RCT, and comparison already covered by an RCT
Craig 2005 <sup>128</sup>	Review. References checked
Curtis 1995 <sup>133</sup>	Non protocol treatments.

Reference	Reason for exclusion
Daglar 2009 <sup>135</sup>	Not on children
Domb 2002 <sup>154</sup>	Not as per protocol – this is comparing different types of external fixation.
Even 2012 <sup>166</sup>	Not in children
Gaid 2006 <sup>193</sup>	Cohort study - Poor reporting of potential key confounders across groups (for example age of each group not given).
Gregory 1995 <sup>207</sup>	This cohort study covered some of the comparators that were not covered by RCTs but there was no MVA. Groups very different at baseline for comminution and open/closed fractures.
Gupta 2007 <sup>210</sup>	Non RCT, and comparison already covered by an RCT
Hedin 2004 <sup>226</sup>	This cohort study covered some of the comparators not covered by RCTs but there was no MVA. Groups very different at baseline for age.
Heffernan 2015 <sup>228</sup>	Non RCT and comparison already covered by an RCT
Hull 1997 <sup>244</sup>	Review. References checked.
Jarvis 2006 <sup>254</sup>	Cohort study – not well matched for key confounder (age) and no MVA. Also extremely small groups of 2-4.
Kaiser 2014 <sup>262</sup>	Used Buck's traction as comparator – not on protocol
Kumar 2014 <sup>290</sup>	Did not consider key confounder. Comparator not on protocol
Jencikova-Celerin 2008 <sup>256</sup>	Comparator was 'other fixation types'.
Lee 2007 <sup>305</sup>	Non comparative study
Li 2013 <sup>312</sup>	Subtrochanteric fracture
Lozman 1986 <sup>326</sup>	Exclude – not in children
McLaren 1990 <sup>349</sup>	Interventions not on protocol
Mehdinasab 2008 <sup>352</sup>	Non RCT. Comparisons in this study already covered by included RCTs
Nascimento 2013 <sup>380</sup>	Cohort study – comparisons covered by RCTs
Nork 1998 <sup>389</sup>	Non RCT and comparison covered by an RCT
Parsch 1997 <sup>407</sup>	Review – references checked
Podeszwa 2004 <sup>422</sup>	Cohort study – potentially confounding differences in a key confounder (age) with no adjustment
Poolman 2006 <sup>424</sup>	Review – references checked
Reis 1980 <sup>435</sup>	Exclude – not in children
Sahu 2012 <sup>448</sup>	Covered some of the comparators not covered by RCTs but excluded as there was no MVA. Ages unclear in the different groups.
Scheerder 2008 <sup>452</sup>	Comparing two types of Bryant traction – not as protocol
Schonk 1978 <sup>454</sup>	Cohort study – poor reporting of key confounders and no MVA. Interventions poorly described.
Shaikh 2012 <sup>456</sup>	Not available from any source
Siddiqui 2008 <sup>463</sup>	Treatments not on protocol
Soleimanpour 2013 <sup>472</sup>	Not available from any source
Song 2004 <sup>475</sup>	Cohort study - comparison covered by RCTs
Thomas 1981 <sup>500</sup>	Not in children
Ucar 2013 <sup>513</sup>	Interventions not on protocol
van Niekerk 1992 <sup>518</sup>	Adult study
Wright 2000 <sup>543</sup>	Review- references checked

Reference	Reason for exclusion
Zlowodzki 2007 <sup>559</sup>	Adult study

#### K.4.7 Post operative mobilisation - Distal femoral fractures

**Table 21: Studies excluded from the clinical review**

Reference	Reason for exclusion
Borgen 1975 <sup>68</sup>	Non comparative study
Kubiak 2013 <sup>288</sup>	Non-systematic review. All references checked for relevance

#### K.4.8 Post operative mobilisation – ankle fractures

**Table 22: Studies excluded from the clinical review**

Reference	Reason for exclusion
Black 2013 <sup>62</sup>	Systematic review is not relevant to review question or unclear PICO. Incorrect interventions
Cimino 1991 <sup>118</sup>	Incorrect study design. Incorrect interventions
Distasio 1994 <sup>152</sup>	Unable to obtain paper from BL
Dogra 1999 <sup>153</sup>	Incorrect interventions
Finsen 1989 <sup>175</sup>	No relevant outcomes
Hedstrom 1994 <sup>227</sup>	Incorrect interventions. No immediate unrestricted weight bearing
Kimmel 2012 <sup>273</sup>	No delayed unrestricted weight bearing. Incorrect interventions
Lee 2012 <sup>304</sup>	Not review population
Lehtonen 2003 <sup>308</sup>	Incorrect interventions. No immediate unrestricted weight bearing
Lin 2012 <sup>320</sup>	Systematic review is not relevant to review question or unclear PICO
Partio 1990 <sup>408</sup>	Non-English language publication
Siddique 2005 <sup>462</sup>	Incorrect study design. No immediate unrestricted weight bearing
Sondenaa 1986 <sup>474</sup>	Incorrect interventions. No immediate unrestricted weight bearing
Tropp 1995 <sup>510</sup>	Incorrect interventions. No immediate unrestricted weight bearing
Vioreanu 2007 <sup>526</sup>	Incorrect interventions. No immediate unrestricted weight bearing

## Appendix L: Excluded economic studies

### L.1 Acute stage assessment and diagnostic imaging

#### L.1.1 Imaging of scaphoid

**Table 23: Studies excluded from the economic review**

Reference	Reason for exclusion
Brooks 2005 <sup>83</sup>	This study was assessed as partially applicable with potentially serious limitations. However, the GDG judged that other available evidence was of greater applicability, methodological quality or both, and therefore this study was selectively excluded. This non-UK study has been included in the clinical review however the included study is from a UK perspective and is therefore more applicable.
Dorsay 2001 <sup>156</sup>	This study was assessed as partially applicable with potentially serious limitations. However, the GDG judged that other available evidence was of greater applicability, methodological quality or both, and therefore this study was selectively excluded.
Gooding 2004 <sup>201</sup>	This study was assessed as partially applicable with potentially serious limitations. However, the GDG judged that other available evidence was of greater applicability, methodological quality or both, and therefore this study was selectively excluded.
Hansen 2009 <sup>224</sup>	This study was assessed as partially applicable with potentially serious limitations. However, the GDG judged that other available evidence was of greater applicability, methodological quality or both, and therefore this study was selectively excluded.
Jenkins 2008 <sup>258</sup>	This study was assessed as partially applicable with potentially serious limitations. This study was excluded in the clinical review and so was also excluded here.
Murthy 2013 <sup>372</sup>	This study was assessed as partially applicable with potentially serious limitations. However, the GDG judged that other available evidence was of greater applicability, methodological quality or both, and therefore this study was selectively excluded.

### L.2 On-going management

#### L.2.1 Definitive treatment of distal radial fractures

**Table 24: Studies excluded from the economic review**

Reference	Reason for exclusion
Shauver 2011 <sup>458</sup>	This study was assessed as partially applicable with very serious limitations. Not all adverse events were considered and quality of life estimates conflicted with those in the clinical review. Complication rates were also different.

## L.2.2 Definitive treatment of humerus fractures

**Table 25: Studies excluded from the economic review**

Reference	Reason for exclusion
Fjalestad 2010 <sup>178</sup>	This study was assessed as partially applicable with very serious limitations. This study has also been excluded from the clinical review. There are large baseline differences in quality of life and there are inaccuracies in the reporting of some of the data.

## L.2.3 Definitive treatment - paediatric femoral fractures

**Table 26: Studies excluded from the economic review**

Reference	Reason for exclusion
Buechsenschuetz 2002 <sup>91</sup>	This study was assessed as partially applicable with potentially serious limitations. This study was excluded in the clinical review and so was also excluded here.
Hedin 2004 <sup>226</sup>	This study was assessed as partially applicable with potentially serious limitations. This study was excluded in the clinical review and so was also excluded here.
Scheerder 2008 <sup>452</sup>	This study was assessed as not applicable as the comparators were not relevant. It was therefore excluded.



# Appendix M: Cost-effectiveness analysis: Imaging of suspected scaphoid fractures

## M.1 Introduction

Many patients present to an Emergency Department (ED) with a wrist injury whose symptoms indicate a possible fracture to the scaphoid. The majority of these patients, however, are not expected to have a fracture. Accurate diagnosis of this type of fracture is important, as the consequence of a missed fracture that results in non-union, can lead to arthritic changes that cause a detrimental effect to the quality of life of the patient. The most frequent method of diagnosis currently is to use plain film X-ray images; the sensitivity of which is not regarded to be high enough for an ED clinician to confidently discharge a patient when a fracture is not clearly identified. Therefore, a patient with normal findings on X-ray images will be brought back to hospital for an appointment at the fracture clinic to assess the injury further. More accurate imaging could allow many of these patients to be discharged, therefore reducing the burden of excessive hospital attendances. There is, of course, an increased cost to performing more accurate diagnostic imaging such as CT and MRI and so the trade-off between the initial cost of imaging and the downstream costs of further clinic attendances needs to be assessed. More accurate imaging could also prevent reduced health outcomes due to delayed treatment following incorrect diagnosis.

An original economic analysis was prioritised to answer the following question: What is the clinically and cost effective imaging strategy for patients presenting at ED with a clinically suspected scaphoid fracture?

(Please see appendix C for related review protocol).

Published economic evidence in evaluating these trade-offs is limited. The evidence found in the economic literature search assessed MRI after an indeterminate X-ray compared to follow-up X-rays and did not consider any health effects<sup>409</sup>. One study<sup>258</sup> also looked at CT scans but also did not include any health effects and the reference standard used to inform the diagnostic accuracy data was delayed X-rays and not MRI as stated in our protocol.

This question was prioritised for original economic analysis due to the lack of applicable economic evidence of sufficient quality for all strategies in this question. The outcome of the question could have a large economic impact on current practice due to the difference in cost of the imaging modalities, as well as the high incidence of suspected scaphoid fractures but low prevalence of true fractures. Here we present a cost-utility analysis on the optimal imaging strategy for patients with a suspected scaphoid fracture.

## M.2 Methods

### M.2.1 Model overview

#### M.2.1.1 Comparators

The strategies assessed in the model are:

1. X-ray then follow-up

A plain film X-ray examination is performed on the day of presentation at ED and if the results are indeterminate, the patient's wrist will be immobilised and they are sent home. An

appointment at the fracture clinic is arranged around 10 days later for further assessment and X-rays. Further appointments may be required if a fracture still cannot be identified but symptoms remain.

2. X-ray then CT

A plain film X-ray examination is performed on the day of presentation at ED and if the results are indeterminate, the wrist is immobilised and the patient sent home. The patient returns to hospital shortly after for a CT scan, and a definitive diagnosis is then made.

3. X-ray then MRI

A plain film X-ray examination is performed on the day of presentation at ED and if the results are indeterminate, the wrist will be immobilised and the patient sent home. The patient returns to hospital shortly after for a MRI scan, and a definitive diagnosis is then made.

4. Immediate CT

A CT scan is performed on the day of presentation at ED and a definitive diagnosis is made.

5. Immediate MRI

An MRI scan is performed on the day of presentation at ED and a definitive diagnosis is made.

#### **M.2.1.2 Population**

Adults and children who attend ED with an injury suspected to be an isolated scaphoid fracture.

#### **M.2.1.3 Time horizon, perspective and discount rates**

A lifetime horizon was used and a UK NHS and PSS perspective. The analysis followed the standard assumptions of the reference case including discounting at 3.5% for health effects, and an incremental analysis conducted. No costs were modelled beyond the first year and therefore discounting was only applicable to health effects.

### **M.2.2 Approach to modelling**

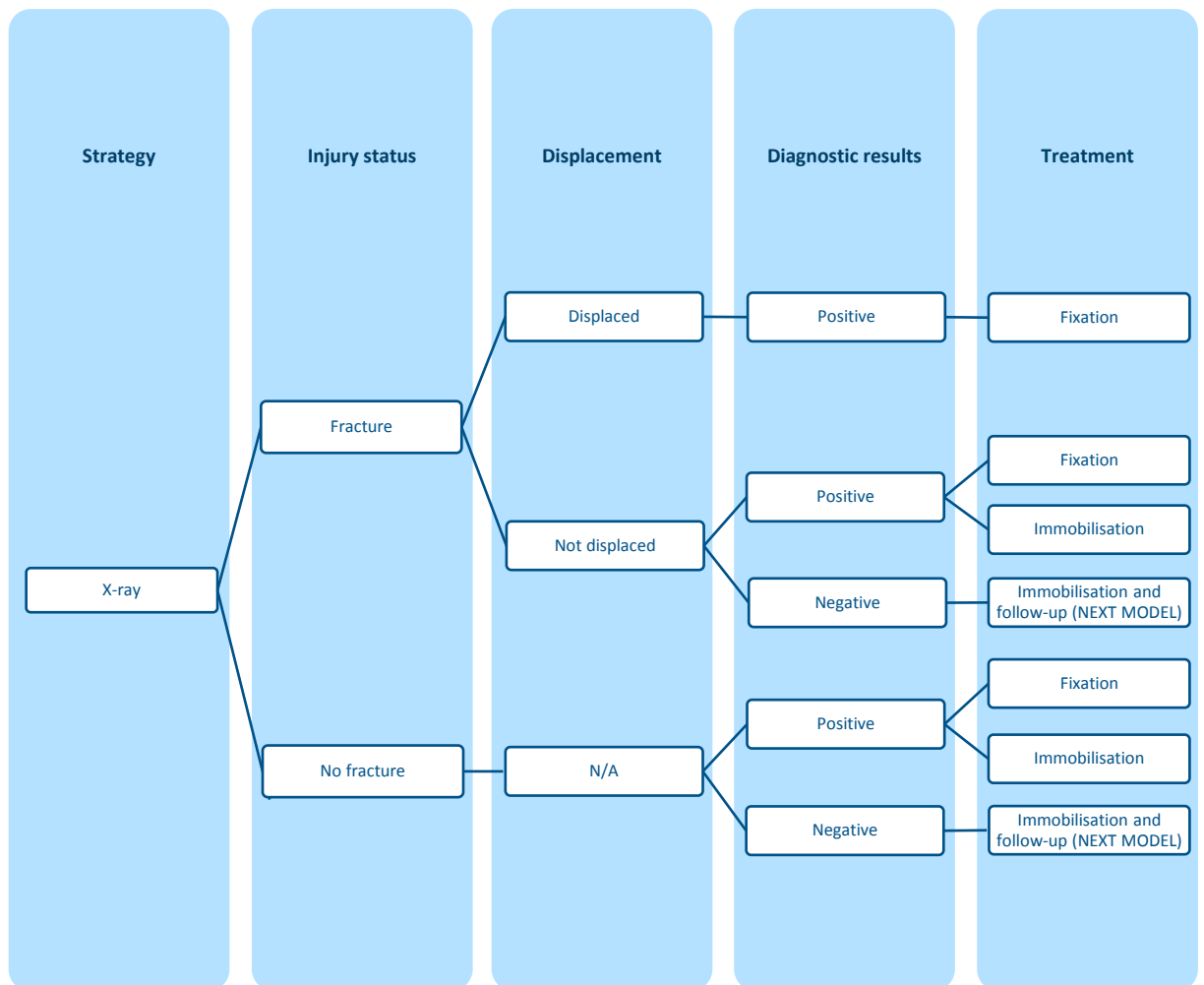
The model was developed using Microsoft Excel 2010. It assesses the impact of the different diagnostic accuracies of each imaging modality on both healthcare costs and health effects (QALYs). It looks at treatments following correct diagnoses and incorrect diagnoses, for patients who have fractures and for those who do not. Health effects were incorporated into the model by means of a long term reduction in quality of life due to delayed treatment following an incorrect diagnosis of a fracture.

#### **M.2.2.1 Model structure**

The model is a decision tree with four stages: true fracture status; displacement status; diagnostic result; treatment. The model structures for the different strategies are shown below.

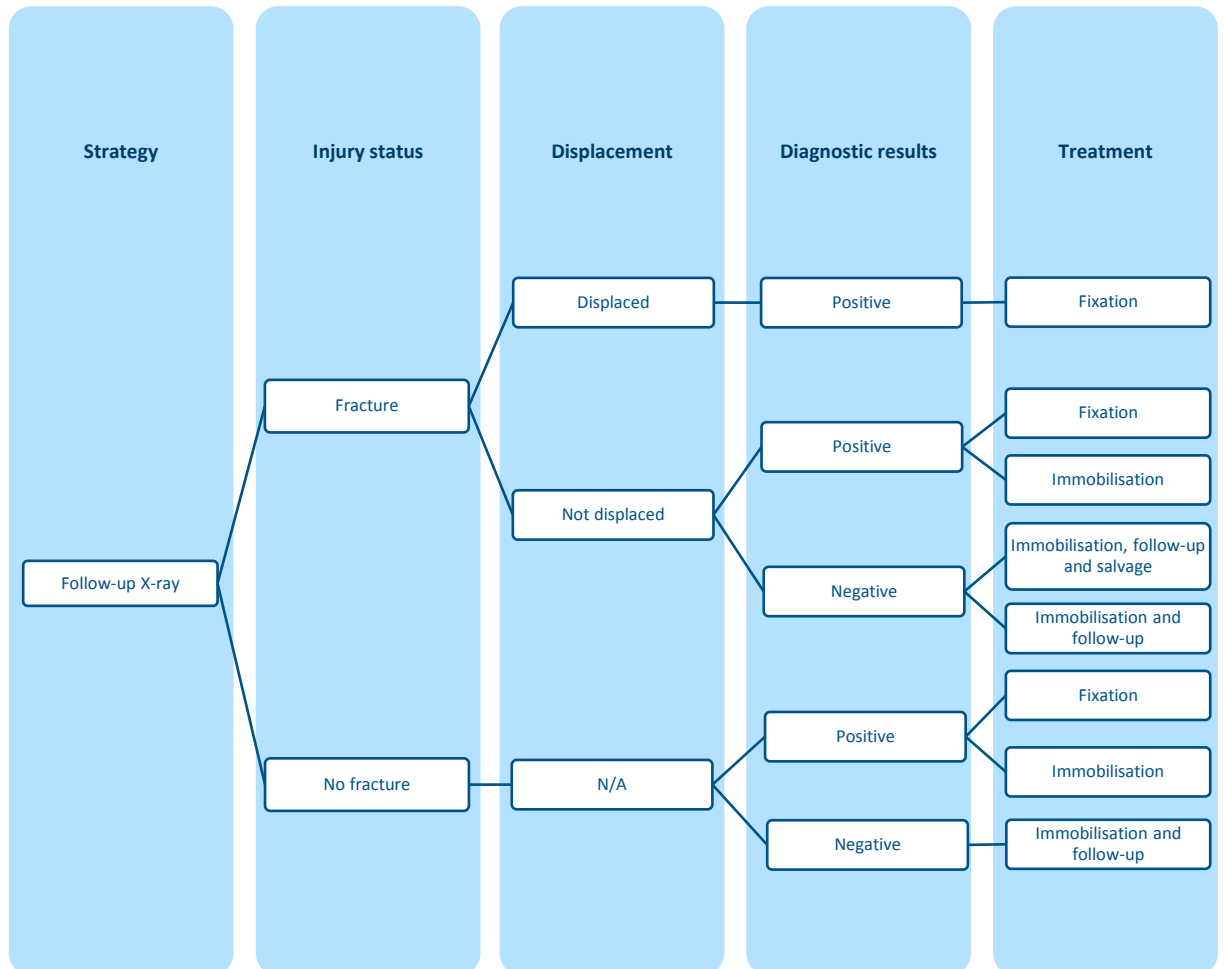
**Figure 217: Initial X-ray model structure**

This part of the model is relevant only to the strategies where people who attend the ED with a suspected scaphoid fracture are given an initial X-ray (strategies 1, 2 and 3). People who have a positive X-ray image will be immobilised in plaster cast or will have surgical fixation performed. Those who have a negative X-ray in this initial stage will then go through the next stage of the strategy. The next stages are outlined in Figure 218 and Figure 219 below. The results of each stage are combined to give the results of the overall strategy.



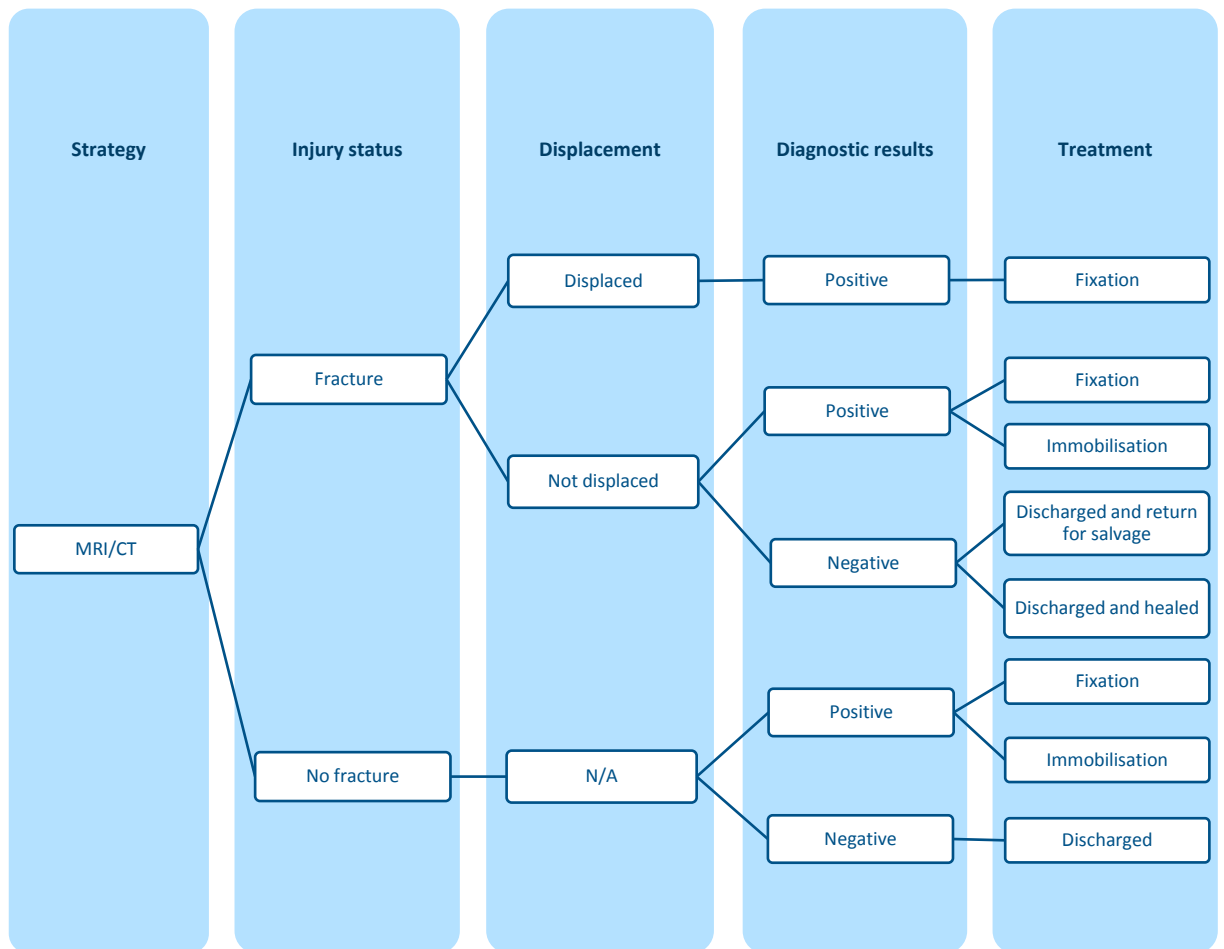
**Figure 218: X-ray follow-up model structure**

This is the second stage of the follow-up X-ray strategy, so the population entering this model are those who have had a negative or 'indeterminate' X-ray. The key differences between these are in the treatment stages as after a false negative follow-up X-ray the patient is assumed to have been missed but may present later and require salvage surgery. Also, the prevalence of fracture is reduced as the majority of them will be identified at the initial X-ray stage.



**Figure 219: MRI/CT model structure**

This structure is for the immediate MRI or CT strategies as well as the strategies where these modalities are used as a follow-up to an initial negative X-ray.



The population is divided at each step in the tree to apply the relevant costs and health effects to different subsets of the population. The first step splits the population by the presence or absence of a fracture. This is the expected proportional split of the population, based on prevalence study data, before any diagnostic examination has been performed.

The second step only applies to those with a fracture, as it separates those with a displaced fracture from those with a non-displaced. This step is included to allow for different diagnostic accuracies to be applied and different treatment strategies after diagnosis. In the base case analysis, all patients with a displaced fracture were assumed to be identified on all imaging modalities and were also assumed to require fixation.

The third step splits each branch by the results of the image, i.e. positive or negative. For the strategies that have an initial X-ray, a negative result is considered to be 'indeterminate' due to its low sensitivity. These patients will go through the steps of the tree again and a mean number of follow up attendances will be applied to those whose image is still negative. Note that the prevalence of fracture will have changed in those patients with an initial negative or 'indeterminate' X-ray. The prevalence in this group of patients is determined by the initial prevalence as well as the results of imaging. All fractures in this group are assumed to be non-displaced due to the assumption that all displaced fractures will be identified on the initial images.

At the final step, each branch is split by treatment type. This is described below, by imaging modality and diagnosis:

#### **Initial X-ray**

- True positive diagnosis: Surgical fixation or cast immobilisation.
- False negative diagnosis: Patients are immobilised and go through the decision tree of the next imaging modality.
- True negative diagnosis: Patients are immobilised and go through the decision tree of the next imaging modality.
- False positive diagnosis: Patients are immobilised (a sensitivity analysis explores the potential for surgery as a management plan).

#### **Follow-up X-ray**

- True positive diagnosis: As for initial X-ray.
- False negative diagnosis: Patients are followed up but some fractures heal naturally and others require a return to hospital for surgery. This surgery is 'salvage surgery'; a more expensive procedure than fixation that is required due to the arthritic changes that occur from delayed treatment of non-union.
- True negative diagnosis: Patients are followed up a fixed number of times and immobilised as a precaution.
- False positive diagnosis: As for initial X-ray.

#### **MRI/CT (immediate or after initial X-ray)**

- True positive diagnosis: Surgical fixation or cast immobilisation.
- False negative diagnosis: Patients are discharged. Some patients, whose fracture does not heal naturally, return for re-imaging and surgery. This surgery is 'salvage surgery'; a more expensive procedure than fixation that is required due to the arthritic changes that occur from delayed treatment of non-union.
- True negative diagnosis: Patients are discharged.
- False positive diagnosis: Patients are immobilised (a sensitivity analysis explores the potential for surgery as a management plan). The model allows for false positive diagnoses to potentially have surgery or immobilisation but the probability of this is zero for the base case analysis.

#### **M.2.2.2 Key assumptions**

- People indicated for surgery will have a CT scan for planning purposes. This cost is included in the model because an additional CT will not be required if CT is used as the diagnostic modality.
- People whose fracture was missed after a CT and returned to hospital with an indication for salvage surgery received an MRI scan to assess the injury further. People whose injury was

missed after an MRI and returned to hospital with an indication for salvage surgery received a CT scan to assess the injury further.

- A fracture that is still not identified on a follow-up X-ray is assumed to remain unidentified at any subsequent follow-up visits.
- Those with an identified fracture are assumed to return to full health after one year, due to a lack of quality of life data showing the progression beyond this time point. For patients whose fracture is not identified, the quality of life detriment was assumed to be sustained for life, in order to account for the detrimental effect of delayed treatment.
- A fracture that is not identified on X-ray but is immobilised as a precaution is not considered to be a missed fracture unless it is a fracture that requires surgery. Therefore, the false negatives that are followed up in the fracture clinic and don't represent with an indication for surgery are assumed to have been treated appropriately in a plaster cast. These patients will therefore return to normal health after the first year.

### M.2.2.3 Uncertainty

The model was built probabilistically to take account of the uncertainty around input parameter point estimates. A probability distribution was defined for each model input parameter where data was available or reliable assumptions could be made. When the model was run, a value for each input was randomly selected simultaneously from its respective probability distribution; mean costs and mean QALYs were calculated using these values. The model was run 10,000 times for the base case analysis and results were summarised.

The way in which distributions are defined reflects the nature of the data, so for example utilities were given a beta distribution, which is bounded by 0 and 1, reflecting that a quality of life weighting will not be outside this range. A description of the different types of distributions used for each type of input is given in Table 27. All of the variables that were made probabilistic in the model and their distributional parameters are detailed in Table 29 and in the relevant input summary tables in Section M.2.3. Probability distributions in the analysis were parameterised using error estimates from data sources or assumptions were where data sources did not exist.

Various deterministic sensitivity analyses were also undertaken to test the robustness of model assumptions. In these analyses, one or more inputs were changed and the analysis rerun to evaluate the impact on results and whether conclusions on which intervention should be recommended would change.

**Table 27: Description of the type and properties of distributions used in the probabilistic sensitivity analysis**

Parameter	Type of distribution	Properties of distribution
Probabilities (epidemiology, imaging accuracy estimates)	Beta	Bounded between 0 and 1.  For the sensitivity and specificity, as the sample size and the number of events were specified, alpha and beta values were calculated as follows: Alpha = (number of patients ruled in if sensitivity or out if specificity) Beta = (Number of patients) – (number of patients ruled in/out)

Parameter	Type of distribution	Properties of distribution
		<p>For epidemiology data where the number of cases was available, alpha and beta values were calculated as follows:            Alpha = (number of patients with condition)            Beta = (Number of patients without condition)</p> <p>Where data were provided only as a probability, assumptions were made about the sample size.</p>
Costs  Utilities	Gamma	<p>Bounded at 0, positively skewed. Derived from mean and its standard error.</p> <p>For the costs and utilities;            Alpha and Beta values were calculated as follows:            Alpha = <math>(\text{mean}/\text{SE})^2</math>            Beta = <math>\text{SE}^2/\text{Mean}</math></p>

The following variables were left deterministic (that is, they were not varied in the probabilistic analysis):

- cost-effectiveness threshold (which was deemed to be fixed by NICE)
- probability that fixation surgery is performed on displaced fractures
- probability of surgery following a false positive diagnosis
- sensitivity of all tests on displaced fractures
- sensitivity of follow up X-ray
- sensitivity of MRI
- specificity of follow-up X-ray
- specificity of CT
- specificity of MRI
- mean number of follow-up visits
- general population quality of life
- duration of reduced quality of life for identified fractures
- duration of reduced quality of life for missed fractures
- mean age at time of injury
- mean age at death
- PRWE score (predicted EQ-5D score was made probabilistic)

## M.2.3 Model inputs

### M.2.3.1 Summary table of model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case (primary) analysis is provided in Table 28 below. More details about sources, calculations and rationale for selection can be found in the sections following this summary table.



**Table 28: Summary of base-case model inputs**

Input	Data	Source
<b>Baseline risk</b>		
Prevalence of scaphoid fracture among those where a fracture is suspected.	16%	Geijer et al. 2013 <sup>194</sup>
Probability that the fracture is displaced.	20%	Dias et al. 2011 <sup>147</sup>
Probability that fixation is performed on a displaced fracture as opposed to immobilisation.	100%	GDG assumption
Probability that fixation is performed on a non-displaced fracture as opposed to immobilisation.	5%	GDG assumption
Probability of surgery for a false positive diagnosis	0%	GDG assumption
<b>Test accuracy</b>		
Sensitivity of all tests for displaced fractures	100%	GDG assumption
Sensitivity of initial X-ray	70%	Jørgsholm et al. 2013 <sup>261</sup>
Sensitivity of follow-up X-ray	70%	GDG assumption guided by Jørgsholm et al. 2013 <sup>261</sup>
Sensitivity of CT (immediate)	95%	Jørgsholm et al. 2013 <sup>261</sup>
Sensitivity of CT (after indeterminate X-ray)	88%	Ilica et al. 2011 <sup>249</sup>
Sensitivity of MRI	100%	Reference standard
Specificity of initial X-ray	98%	Jørgsholm et al. 2013 <sup>261</sup>
Specificity of follow-up X-ray	95%	GDG assumption guided by Jørgsholm et al. 2013 <sup>261</sup>
Specificity of CT	100%	Ilica et al. 2011 <sup>249</sup>
Specificity of MRI	100%	Reference standard
<b>Costs</b>		
Cost of plain film X-ray	£28	Direct access plain film, NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of CT	£85	Diagnostic imaging – outpatients (Trauma and orthopaedics), NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of MRI	£143	Diagnostic imaging – outpatients (Trauma and orthopaedics), NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of immobilisation	£10	GDG assumption. Estimated cost of plaster cast materials required.
Cost of surgical fixation	£1,373	HRG: HA54Z (Day case), NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of salvage surgery	£1,549	HRG: HA52Z (Day case), NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of initial fracture clinic attendance	£128	HRG: WF01B (Trauma and Orthopaedics), NHS Reference Costs 2012-2013 <sup>142</sup>
Cost of follow-up fracture clinic attendance	£102	HRG: WF01A (Trauma and Orthopaedics), NHS Reference Costs 2012-2013 <sup>142</sup>

Input	Data	Source
Cost of ED attendance	£120	HRG: WF01B (Accident and Emergency), NHS Reference Costs 2012-2013 <sup>142</sup>
Mean number of follow-up visits	2.5	GDG assumption
Quality of life		
PRWE 1-year post scaphoid fracture	22 (Pain = 15; Function = 7)	MacDermid et al. 1998 <sup>329</sup>
EQ-5D index at 1-year post scaphoid fracture	0.819	Mapped from PRWE score from MacDermid et al. 1998 <sup>329</sup>
General population QoL for 30 year old	0.93	Kind et. al. 1999 <sup>274</sup>
Duration of reduced QoL for identified fractures	1 year	GDG assumption based on restriction of available data to one year from MacDermid et al. 1998 <sup>329</sup>
Duration of reduced QoL for missed fractures	Lifetime	GDG assumption
Others		
Mean age at time of injury	30 years	GDG assumption
Mean age at death	80 years	Interim life tables, England and Wales, 2010-2012. <sup>399</sup>

### M.2.3.2 Summary of distributions for probabilistic analysis

**Table 29: Summary of distributions and parameters**

Input	Point estimate	Probability distribution	Distribution parameters
Baseline risk			
Prevalence of scaphoid fracture among those where a fracture is suspected.	0.16	Beta	$\alpha=32, \beta=168$
Probability that the fracture is displaced. <sup>a</sup>	0.20	Beta	$\alpha=40, \beta=160$
Probability that fixation is performed on a non-displaced fracture as opposed to immobilisation. <sup>a</sup>	0.05	Beta	$\alpha=10, \beta=190$
Test accuracy			
Sensitivity of initial X-ray	0.70	Beta	$\alpha=87, \beta=38$
Sensitivity of CT (immediate)	0.95	Beta	$\alpha=116, \beta=6$
Sensitivity of CT (after indeterminate X-ray)	0.88	Beta	$\alpha=14, \beta=2$
Specificity of initial X-ray	0.98	Beta	$\alpha=172, \beta=3$
Costs			
Cost of plain film X-ray	£28	Gamma	$\alpha=12.5, \beta=2.3$
Cost of CT	£85	Gamma	$\alpha=6.3, \beta=13.6$
Cost of MRI	£143	Gamma	$\alpha=5.0, \beta=28.6$
Cost of immobilisation	£10	Gamma	$\alpha=59.2, \beta=0.2$
Cost of surgical fixation	£1,373	Gamma	$\alpha=11.0, \beta=124.3$
Cost of salvage surgery	£1,549	Gamma	$\alpha=12.8, \beta=120.8$

Input	Point estimate	Probability distribution	Distribution parameters
Cost of initial fracture clinic attendance	£128	Gamma	$\alpha=18.1, \beta=7.0$
Cost of follow-up fracture clinic attendance	£102	Gamma	$\alpha=9.5, \beta=10.7$
Cost of ED attendance	£120	Gamma	$\alpha=3.1, \beta=38.7$
Quality of life			
EQ-5D index at 1-year post scaphoid fracture	0.819	Beta	$\alpha=290, \beta=64$
General population EQ5D	0.930	Beta	$\alpha=700, \beta=53$

(a) Parameters for this input were based on the same sample size as the study used for the prevalence of scaphoid fracture as only the point estimate was provided in the study.

### M.2.3.3 Prevalence of scaphoid fracture and displacement of fracture

One study, Duckworth et al. 2011<sup>159</sup>, on the assessment of suspected scaphoid fractures, reported that previous studies found the prevalence of scaphoid fractures among those who attend ED with a suspected fracture to be between 5% and 20%. Another study, Geijer et al. 2013<sup>194</sup>, reported an average of 16% from a meta-analysis, and a range from 5% to 19%. The GDG agreed to use the value of 16% in the base case and a range of 5% to 20% in the sensitivity analysis.

The prevalence of displacement, as reported by Dias et al. 2011<sup>147</sup>, is 20% in mid waist scaphoid fractures. This was assumed to be the prevalence among all scaphoid fractures.

### M.2.3.4 Diagnostic accuracy

The clinical review assessed diagnostic studies that used MRI as the reference standard. The GDG considered this to be the most reliable reference standard due to its high sensitivity for diagnosing scaphoid fractures in comparison to X-ray and CT. They acknowledged that the specificity of MRI may be imperfect as it is likely to identify other injuries that are indistinguishable from fractures, which would cause the sensitivity of the index tests to be underestimated and the specificity overestimated. As MRI was chosen as the reference standard, the estimates of sensitivity and specificity for the other modalities are relative to this modality. Therefore, the model used values of 100% for both sensitivity and specificity of MRI, but these values along with the sensitivity and specificity for the other imaging modalities were varied in sensitivity analyses to assess the potential impact of the uncertainty.

This data was found from the clinical review but it was assumed that all displaced fractures would be identified on any imaging modality. The diagnostic accuracy data was therefore assumed to apply to those with non-displaced fractures. These values were tested in sensitivity analyses.

The diagnostic accuracy of follow-up X-rays was not found in the clinical review and so the GDG assumed that it was the same as for the initial X-ray. A sensitivity analysis was performed to account for a potential improvement in diagnostic accuracy.

### M.2.3.5 Age and life expectancy

The mean age of the population of people with scaphoid fractures was assumed by the GDG to be 30 years. This was based on the mean ages given by the included clinical studies, which ranged from 22 to 39 years.

Life expectancy was estimated from the Office for National Statistics Life Tables<sup>399</sup>, and was estimated for a 30 year old as 49.87 remaining years. This gives an average age at death of 80 years.

### **M.2.3.6 Costs and resource use**

The cost of cast immobilisation was taken from the expert opinion of the GDG. All other costs are from NHS reference costs 2012-2013. The number of fracture clinic visits was assumed based on the expert opinion of the GDG.

The cost of a first ED visit is not included in any strategy as this is assumed to apply to all patients.

Those who have surgical fixation performed have the cost of a CT scan applied, as this is required for surgery planning. This is not applied where a CT scan was already used as part of the diagnostic strategy. The cost of immobilisation is also applied as the patient is sent home for a later planned surgery attendance.

A patient who returns to hospital following a false negative diagnosis on CT is given an MRI to assess the injury before surgery is planned. Those who return after a false negative diagnosis from MRI will have a CT scan to assess the injury before surgery is planned.

People whose fracture is identified on first imaging and immobilised in plaster have the cost of a follow-up fracture clinic attendance applied, which is required to have the cast removed.

Those who are discharged following a false negative diagnosis from CT or MRI have the cost of an ED visit, additional immobilisation as well as the cost of the salvage procedure, which is planned on a later surgery list.

### **M.2.3.7 Quality of life**

A systematic search, incorporated as part of the literature economic search in the guideline, was undertaken to identify relevant quality of life estimates. One relevant study was found, MacDermid et al. 1998<sup>329</sup>, which was a validation study of the Patient Rated Wrist Evaluation (PRWE) from Canada. The PRWE is a questionnaire made up of two components: a pain component and a function component. Each component consists of questions about the person's pain and functional ability in different situations and asks them to rate each question on a scale from 0 to 10, where 0 means no problems or pain and 10 means unable to function or worst pain. In this study, 35 people with a scaphoid fracture provided a score at 1-year post scaphoid fracture. These people also had a distal radial fracture but the GDG thought that the mean score of 22 was a good enough estimate. This quality of life score was translated into a utility value as described in M.2.4.1.

## **M.2.4 Computations**

### **M.2.4.1 Mapping**

To derive a utility from the PRWE score, we predicted the EQ-5D index for the PRWE score using a mapping function. There were no published mapping studies for these two outcome measures so we developed our own mapping function using data from a population with distal radial fractures.<sup>126</sup> These patients were asked to complete both the PRWE and EQ-5D questionnaires at 3 months, 6 months and 12 months post injury; as well as a retrospective one to assess the patient's quality of life pre-injury.

The mapping function was derived using linear regression performed with SPSS version 22. The dependent variables used to predict the EQ5D score were: the pre-injury EQ5D score, the pain component of the PRWE, the function component of the EQ5D and the product of the components. The mapping function was validated using the 6 month dataset as a validation set to test for stability in the performance of the mapping function.

The mapping function developed is given by:

$$EQ5D_S = 0.344 \times EQ5D_B - 0.0059 \times PRWE_P - 0.0062 \times PRWE_F + 0.00013 \times PRWE_{P \times F} + 0.623$$

Where:

$EQ5D_S$  is the EQ5D estimate for a person with a scaphoid fracture.

$EQ5D_B$  is the baseline EQ5D of the person before they had a fracture.

$PRWE_P$  is the PRWE pain component score out of 50.

$PRWE_F$  is the PRWE function component score out of 100

$PRWE_{P \times F}$  is the product of  $PRWE_F$  and  $PRWE_P$ .

#### M.2.4.2 QALYs

The model applies the utility score calculated from the mapping, as described in section M.2.4.1 above, to each person with a scaphoid fracture. Those without a fracture are given a utility for the general population.<sup>274</sup> If the fracture is identified on initial imaging (or by the first follow-up image in the follow-up strategies) then the patient will return to the general population utility for each of the remaining life years. If they are not identified, they will remain in the initial reduced health state for the remaining years of life. The utilities are summed across the lifetime for all patients along each diagnostic pathway to calculate the total QALYs accrued for a particular diagnostic strategy. This will be done for each strategy in order to calculate the net monetary benefit as described in section M.2.7 below.

#### M.2.4.3 Discounting

Costs were not discounted as they were all incurred in the first year. QALYs were discounted to reflect time preference (discount rate 3.5%) using the following formula:

Discount formula:

$$\text{Discounted total} = \frac{\text{Total}}{(1+r)^n}$$

Where:

$r$ =discount rate per annum

$n$ =time (years)

In the analysis, the total number of QALYs and resource costs accrued by each branch of the tree was recorded. These subtotals were summed across all branches to ascertain the total number of patients in the population and the total QALYs and resource costs accrued for the population. The total cost and QALYs accrued by the cohort was divided by the number of patients in the population to calculate the mean cost per patient and mean QALYs per patient. The net benefit of each strategy was calculated in order to find the optimal strategy. This is explained in section M.2.7 below.

#### M.2.5 Sensitivity analyses

One-way sensitivity analyses were performed on the parameters shown in Table 30 below. The upper and lower values are given as well as any additional values. All values were provided by the GDG.

**Table 30: Parameter values used in sensitivity analyses**

Input	Lower	Upper	Additional analyses.
Baseline risk			
Prevalence of scaphoid fracture among those where a fracture is suspected.	5%	20%	
Probability that the fracture is displaced.	10%	30%	

Input	Lower	Upper	Additional analyses.
Probability that surgery is performed on a non-displaced fracture.	1%	10%	50%
<b>Test accuracy</b>			
Sensitivity of initial X-ray	65%	75%	
Sensitivity of follow-up X-ray	65%	75%	5% higher than initial
Sensitivity of CT	Immediate	90%	100%
	After indeterminate X-ray	80%	100%
Sensitivity of MRI	98%	N/A	
Specificity of initial X-ray	95%	100%	
Specificity of follow-up X-ray	95%	100%	
Specificity of CT	95%	N/A	
Specificity of MRI	95%	N/A	
<b>Costs</b>			
Cost of X-ray	£0		
Cost of CT	£70	£100	
Cost of MRI	£100	£200	
Cost of immobilisation	£5	£15	
Cost of surgical fixation	£1000	£2000	
Cost of salvage surgery	N/A	£5000	
Cost of initial fracture clinic attendance	£100	£150	
Cost of follow-up fracture clinic attendance	£75	£125	
Mean number of follow-up visits	1	5	
<b>Quality of life</b>			
PRWE 1-year post scaphoid	10	30	
EQ-5D mapped from PRWE scores above	0.89	0.78	

### M.2.6 Model validation

The model was developed in consultation with the GDG; model structure, inputs and results were presented to and discussed with the GDG for clinical validation and interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was peer reviewed by a second experienced health economist from the NCGC; this included systematic checking of many of the model calculations.

### M.2.7 Estimation of cost effectiveness

The widely used cost-effectiveness metric is the incremental cost-effectiveness ratio (ICER). This is calculated by dividing the difference in costs associated with 2 alternatives by the difference in QALYs. The decision rule then applied is that if the ICER falls below a given cost per QALY threshold the result is considered to be cost effective. If both costs are lower and QALYs are higher the option is said to dominate and an ICER is not calculated.

$$ICER = \frac{Costs(B) - Costs(A)}{QALYs(B) - QALYs(A)}$$

Cost-effective if:

- ICER < Threshold

Where:  $Costs(A)$  = total costs for option A;  $QALYs(A)$  = total QALYs for option A

When there are more than 2 comparators, as in this analysis, options must be ranked in order of increasing cost then options ruled out by dominance or extended dominance before calculating ICERs excluding these options. An option is said to be dominated, and ruled out, if another intervention is less costly and more effective. An option is said to be extendedly dominated if a combination of 2 other options would prove to be less costly and more effective.

It is also possible, for a particular cost-effectiveness threshold, to re-express cost-effectiveness results in terms of net monetary benefit (NMB). This is calculated by multiplying the total QALYs for a comparator by the threshold cost per QALY value (for example, £20,000) and then subtracting the total costs (formula below). The decision rule then applied is that the comparator with the highest NMB is the most cost-effective option at the specified threshold. That is the option that provides the highest number of QALYs at an acceptable cost. For clarity in presenting the results, the incremental NMB was calculated in reference to a single strategy to easily identify the differences in NMB.

$$Net\ Monetary\ Benefit\ (X) = (QALYs(X) \times \lambda) - Costs(X)$$

Where:  $\lambda$  = threshold (£20,000 per QALY gained)

Cost-effective if:

- Highest net benefit

Both methods of determining cost effectiveness will identify exactly the same optimal strategy. For ease of computation NMB is used in this analysis to identify the optimal strategy.

Results are also presented graphically where total costs and total QALYs for each diagnostic strategy are shown. Comparisons not ruled out by dominance or extended dominance are joined by a line on the graph where the slope represents the incremental cost-effectiveness ratio.

### M.2.8 Interpreting Results

NICE's report, 'Social value judgements: principles for the development of NICE guidance'<sup>381</sup>, sets out the principles that GDGs should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- The intervention costs less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

As we have several interventions, we use the NMB to rank the strategies on the basis of their relative cost-effectiveness. The highest NMB identifies the optimal strategy at a willingness to pay of £20,000 per QALY gained.

## M.3 Results

Table 31 below shows the results of the probabilistic analysis. This consists of the mean costs and QALYs per patient from which the NMB was calculated. Below this shows the difference in NMB in reference to the follow-up X-ray strategy. The final row shows the ranking of the strategies in terms of cost effectiveness i.e. the immediate MRI strategy is cost effective in comparison to all other strategies. Table 32 shows the number of people with a true positive diagnosis (TP), a true negative diagnosis (TN), a false positive diagnosis (FP) and a false negative diagnosis (FN) in each imaging strategy.

**Table 31: Probabilistic analysis**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Mean cost per patient	£416	£292	£343	£151	£214
Mean QALYs per patient	22.560	22.549	22.561	22.545	22.561
Net monetary benefit at £20,000 per QALY threshold	£450,780	£450,685	£450,884	£450,751	£451,013
Incremental net monetary benefit	Reference	−£95	£104	−£29	£234
Ranking	3rd	5th	2nd	4th	1st

**Table 32: Event rates per 1000 individuals with suspected scaphoid fracture**

	TP	TN	FP	FN
Follow up X-rays	148	811	29	12
X-ray then CT	155	826	14	5
X-ray then MRI	160	826	14	0
Immediate CT	154	840	0	6
Immediate MRI	160	840	0	0

Table 33 below shows the non-dominated strategies ranked from lowest cost to highest. The ICERs reported are compared to the strategy in the previous row.

**Table 33: ICERs of non-dominated strategies**

Strategy (a)	Cost per patient	QALY per patient	ICER
Immediate CT	£151	22.545	
Immediate MRI	£214	22.561	£3,854

(a) Follow up x-rays and X-ray followed by CT were dominated by immediate MRI which is less costly and more effective. X-ray followed by MRI is also dominated as immediate MRI produces the same number of QALYs at a lower cost.

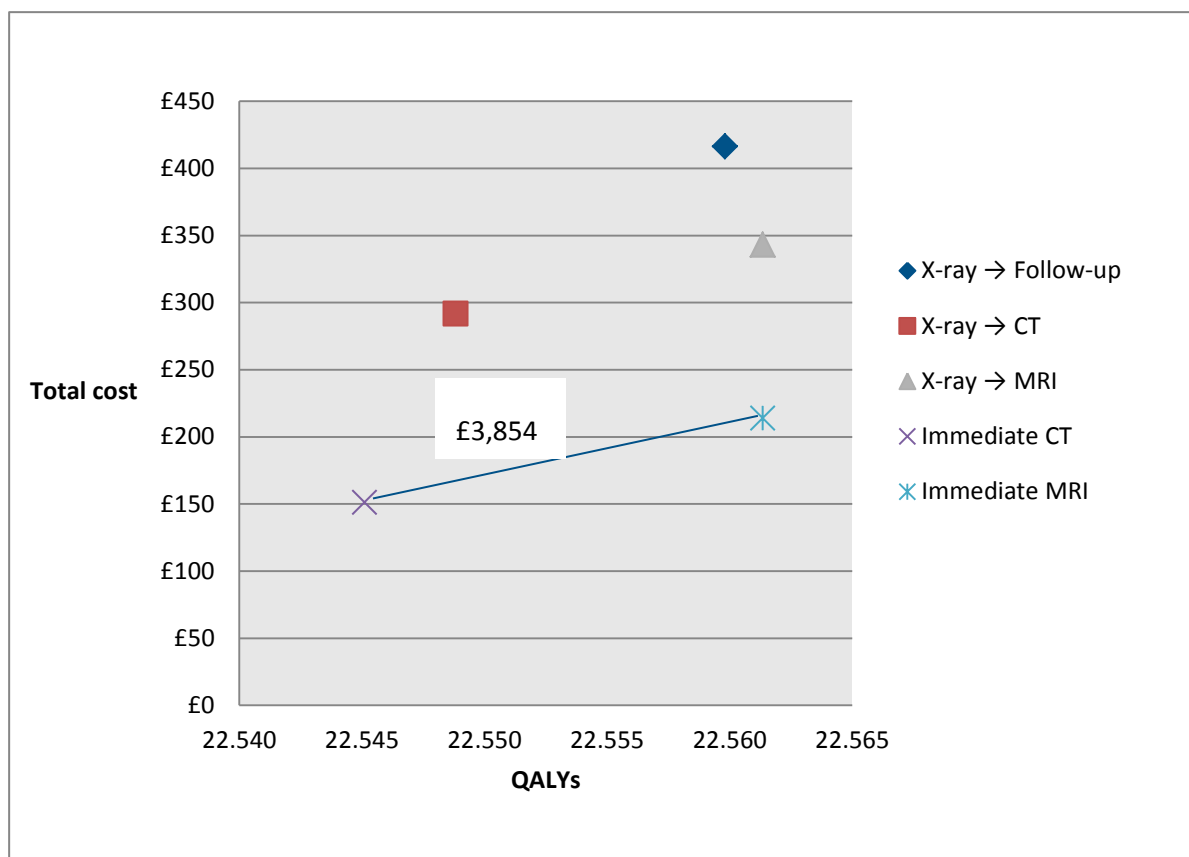
Using the ICER decision rule, we can see that the most cost effective option is Immediate MRI, as immediate MRI compared to immediate CT has an ICER below the NICE threshold of £20,000 and all other options are dominated. Immediate MRI is confirmed as being the most cost effective strategy using the net benefit decision rule as shown in Table 31.

The cost effectiveness plane in Figure 220 below is a graphical representation of the costs and utilities per patient from each strategy.

The slope of the line between two strategies represents the ICER, this can be seen for immediate MRI compared to immediate CT.

**Figure 220: Cost effectiveness plane**





A key driver in the overall cost is the number of extra visits required for those who have an initial X-ray, especially those who go on to have follow-up X-rays after this. This makes the immediate strategies the cheapest and then the key driver separating CT and MRI is health related quality of life detriment from the missed fractures on CT. This makes the additional cost for the MRI strategy cost effective.

## M.4 Sensitivity Analysis Results

The tables below show the results of the sensitivity analyses for which the overall conclusion of the model changed, i.e. immediate MRI was no longer the optimal strategy. Table 37 is included to show the point at which the analysis in Table 36 changes back to the same conclusion as the base case analysis. The complete set of results from all sensitivity analyses can be seen in section M.6.

**Table 34: Sensitivity of CT = 100%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.558	22.539	22.560	22.527	22.560
Net monetary benefit	£450,743	£450,498	£450,847	£450,381	£450,977
Incremental net monetary benefit	Reference	−£245	£104	−£363	£234

**Table 35: PRWE at 1 year post fracture = 0**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total QALYs per patient	22.577	22.577	22.577	22.577	22.577
Net monetary benefit	£451,127	£451,252	£451,201	£451,393	£451,331
Incremental net monetary benefit	Reference	£125	£74	£265	£203

**Table 36: Reduced HRQoL following missed fracture sustained for only four additional years**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.559	22.558	22.560	22.557	22.560
Net monetary benefit	£450,769	£450,859	£450,847	£450,988	£450,977
Incremental net monetary benefit	Reference	£90	£79	£219	£208

**Table 37: Reduced HRQoL following missed fracture sustained for five additional years**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.559	22.557	22.560	22.556	22.560
Net monetary benefit	£450,768	£450,850	£450,847	£450,976	£450,977
Incremental net monetary benefit	Reference	£82	£80	£208	£209

## M.5 Discussion

### M.5.1 Summary of results

In the probabilistic analysis, the most expensive strategy was the follow-up X-rays. The two immediate strategies were the cheapest even though they used more expensive imaging modalities. This was due to a reduction in number of return visits to the fracture clinic by discharging patients at the initial imaging stage. The cheapest strategy of the two immediate strategies was CT due to cheaper imaging costs than MRI. When considering the health effects alongside costs, however, the net benefit was in favour of the immediate MRI strategy due to the higher sensitivity and therefore reduction in the number of missed fractures. This was based on extrapolated health effects of missed fractures over a lifetime and for all patients with missed fractures.

The sensitivity analysis where the extrapolation is only extended to four additional years, the optimal strategy changes to immediate CT, as the difference in QALYs becomes much smaller and the cost effectiveness tends towards the cheaper strategy. When this value is five additional years, immediate MRI is the optimal strategy.

Reducing the PRWE score to 0 means there is no difference in quality of life between the strategies and so it is purely driven by costs. The optimal strategy in this analysis is therefore immediate CT.

Due to a suspected lower specificity of the reference standard, MRI, it was thought that the sensitivity of CT could be underestimated in the studies included and it could in fact be as sensitive as MRI. For this reason, a sensitivity analysis was performed with a sensitivity of 100% for CT. This makes immediate CT the optimal strategy as it becomes as effective as MRI but with a lower cost.

### **M.5.2 Limitations and interpretation**

A key limitation of this analysis is that HRQoL data was only available from a short term study<sup>329</sup> over a 12 month period. This meant that an assumption was made that the long term quality of life for patients with missed fractures was sustained for a lifetime due to patients developing arthritis after delayed treatment. This limitation was explored through a sensitivity analysis.

For missed fractures, when reduced HRQoL is sustained for only four additional years then the optimal strategy changes from immediate MRI to immediate CT. Since the model assumes, in this sensitivity analysis, that the whole group of missed fractures sustains the reduced health for the four additional years out of remaining 49 (the lifetime), it can also be interpreted, when not considering discounting, as 8% (4/49) of the group sustaining this health effect for the lifetime. The optimal strategy changes between four and five additional years. We can therefore say that the change would occur when the proportion of people with missed fractures who are affected by a lifelong health detriment is at some point between 8% and 10%. Taking into account discounting, this proportion rises to between 16% and 19%.

Radiation risk has not been included in the analysis due to a lack of data. However, the GDG considered the risk of cancer from radiation to the wrist and although they acknowledged that children are more susceptible to radiation, they believed it to be too small a risk to have an effect on the results of this analysis. The model within the Spinal Injuries guideline considered radiation in a sensitivity analysis and found this did not change the conclusions.

The lack of data showing the accuracy of follow-up X-rays is also a limitation. There are two factors that may affect the accuracy of follow-up X-rays: firstly that the likelihood of the follow-up X-ray result is in some way conditional on the initial results; secondly the reduction in swelling at the follow-up stage allowing a fracture to be more visible on the image. The GDG thought that the follow-up X-ray is likely to have equal sensitivity and specificity to the initial X-ray and maybe even slightly higher sensitivity. This was taken into account in a sensitivity analysis but showed no effect on the overall conclusions.

MRI was chosen as the reference standard in the diagnostic accuracy review as it was thought to be the most sensitive. However, it may not be 100% specific and could therefore over diagnose injuries. This means that the sensitivity of the index tests would be underestimated when compared to MRI as a reference standard so the sensitivity of CT could be closer to MRI. This could mean that CT is cost effective.

There is a large service delivery change in providing immediate MRI to people with suspected scaphoid fractures, which has a large cost. However, there are newly developed extremity scanners that have lower operating costs according to the GDG and they believed that these could provide benefit to other populations, for example, people with suspected ligamentous injuries.

### **M.5.3 Generalisability to other populations or settings**

The analysis considered both adults and children and these were considered to be similar in terms of prevalence of the injury.

It is uncertain whether the model will be applicable to other types of fracture. It is not normally the case that MRI is seen as the gold standard for bony injuries. The GDG considered the results were robust for adults and children with a suspected scaphoid fracture.

### **M.5.4 Comparisons with published studies**

Patel et al. 2013<sup>409</sup> conducted an economic analysis within an RCT, which showed that using MRI after an indeterminate X-ray was cost saving when compared to follow-up X-rays. This study did not

compare CT after an indeterminate X-ray nor did it compare immediate imaging strategies. Health related quality of life was also not included in this study. The results showed that MRI was cost saving in comparison to follow-up X-rays.

### **M.5.5 Conclusions**

Immediate MRI is likely to be the most cost effective imaging strategy for patients with a suspected scaphoid fracture.

An initial X-ray may be cost effective if there are likely to be fractures that are missed on MRI but captured on X-ray. If this is the case, a screening X-ray followed by MRI in the same attendance may be cost effective as the additional cost of an attendance would not be required.

Immediate CT may be cost effective if the effects of missing a scaphoid fracture either last no longer than four years or only occur in a small proportion of patients with missed fractures. This may also be optimal if the sensitivity of CT is greater than the evidence suggests.

This analysis is assessed as directly applicable with potentially serious limitations.

### **M.5.6 Implications for future research**

Future research would be useful to assess the quality of life of patients with scaphoid fractures in the long term, following a particular imaging strategy. A way in which this could be done is with a test and treat randomised controlled trial, comparing the strategies outlined in this report and subsequent treatment. With an accompanying economic evaluation, this would allow the assessment of cost effectiveness without the need for diagnostic accuracy data and hence remove the limitation of having MRI as a reference standard, which may underestimate the sensitivity of comparator modalities due to having a suspected specificity of less than 100%.

## M.6 Results of Sensitivity Analyses

**Table 38: Prevalence of scaphoid fracture = 5%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£404	£263	£318	£106	£165
Total QALYs per patient	22.571	22.568	22.572	22.567	22.572
Net monetary benefit	£451,020	£451,093	£451,116	£451,226	£451,268
Incremental net monetary benefit	Reference	£73	£96	£206	£248

**Table 39: Prevalence of scaphoid fracture = 20%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£421	£303	£352	£168	£231
Total QALYs per patient	22.553	22.539	22.555	22.535	22.555
Net monetary benefit	£450,642	£450,486	£450,750	£450,529	£450,871
Incremental net monetary benefit	Reference	-£156	£108	-£114	£229

**Table 40: Prevalence of displacement = 10%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£397	£272	£324	£132	£193
Total QALYs per patient	22.558	22.545	22.560	22.541	22.560
Net monetary benefit	£450,759	£450,636	£450,867	£450,694	£450,998
Incremental net monetary benefit	Reference	-£123	£108	-£65	£239

**Table 41: Prevalence of displacement = 30%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£436	£312	£362	£171	£234
Total QALYs per patient	22.558	22.549	22.560	22.545	22.560
Net monetary benefit	£450,727	£450,660	£450,828	£450,736	£450,956
Incremental net monetary benefit	Reference	-£68	£101	£9	£229

**Table 42: Probability of surgery = 1%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£410	£285	£336	£145	£206
Total QALYs per patient	22.559	22.547	22.560	22.543	22.560
Net monetary benefit	£450,775	£450,655	£450,854	£450,721	£450,984
Incremental net monetary benefit	Reference	-£120	£80	-£53	£209

**Table 43: Probability of surgery = 10%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£426	£301	£351	£160	£222

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total QALYs per patient	22.556	22.547	22.560	22.543	22.560
Net monetary benefit	£450,704	£450,639	£450,839	£450,706	£450,968
Incremental net monetary benefit	Reference	-£65	£135	£3	£265

**Table 44: Probability of surgery = 50%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£496	£370	£421	£226	£291
Total QALYs per patient	22.544	22.547	22.560	22.543	22.560
Net monetary benefit	£450,390	£450,570	£450,769	£450,640	£450,899
Incremental net monetary benefit	Reference	£181	£380	£251	£509

**Table 45: Probability of surgery following false positive diagnosis = 0.1%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,648	£450,847	£450,715	£450,977
Incremental net monetary benefit	Reference	-£95	£104	-£28	£234

**Table 46: Sensitivity of X-ray = 65%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£418	£293	£344	£151	£213
Total QALYs per patient	22.557	22.545	22.560	22.543	22.560
Net monetary benefit	£450,732	£450,609	£450,846	£450,715	£450,977
Incremental net monetary benefit	Reference	-£123	£114	-£17	£245

**Table 47: Sensitivity of X-ray = 75%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£415	£291	£341	£151	£213
Total QALYs per patient	22.558	22.549	22.560	22.543	22.560
Net monetary benefit	£450,755	£450,694	£450,849	£450,715	£450,977
Incremental net monetary benefit	Reference	-£61	£95	-£40	£222

**Table 48: Sensitivity of delayed X-ray + 5%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,748	£450,648	£450,847	£450,715	£450,977
Incremental net monetary benefit	Reference	-£100	£99	-£34	£229

**Table 49: Specificity of X-ray = 95%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£407	£289	£338	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,753	£450,651	£450,852	£450,715	£450,977
Incremental net monetary benefit	Reference	-£102	£99	-£38	£224

**Table 50: Specificity of X-ray = 100%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£422	£294	£345	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,738	£450,646	£450,845	£450,715	£450,977
Incremental net monetary benefit	Reference	-£92	£107	-£23	£239

**Table 51: Sensitivity of CT = 80% (after indeterminate X-ray), 90% (immediate CT)**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.558	22.539	22.560	22.527	22.560
Net monetary benefit	£450,743	£450,498	£450,847	£450,381	£450,977
Incremental net monetary benefit	Reference	-£245	£104	-£363	£234

**Table 52: Sensitivity of CT = 100%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£152	£213
Total QALYs per patient	22.558	22.560	22.560	22.560	22.560
Net monetary benefit	£450,743	£450,898	£450,847	£451,038	£450,977
Incremental net monetary benefit	Reference	£155	£104	£295	£234

**Table 53: Specificity of CT = 95%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£297	£343	£156	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,643	£450,847	£450,710	£450,977
Incremental net monetary benefit	Reference	-£100	£104	-£33	£234

**Table 54: Sensitivity of MRI = 98%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.558	22.547	22.558	22.543	22.553
Net monetary benefit	£450,743	£450,648	£450,807	£450,715	£450,845
Incremental net monetary benefit	Reference	-£95	£64	-£28	£102

**Table 55: Specificity of MRI = 95%**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£347	£151	£218
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,648	£450,843	£450,715	£450,972
Incremental net monetary benefit	Reference	-£95	£100	-£28	£229

**Table 56: PRWE at 1 year post fracture = 10**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.571	22.568	22.572	22.566	22.572
Net monetary benefit	£451,004	£451,058	£451,088	£451,175	£451,217
Incremental net monetary benefit	Reference	£54	£84	£171	£213

**Table 57: PRWE at 1 year post fracture = 30**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.551	22.535	22.553	22.530	22.553
Net monetary benefit	£450,597	£450,417	£450,713	£450,456	£450,842
Incremental net monetary benefit	Reference	-£179	£116	-£140	£246

**Table 58: PRWE at 1 year post fracture = 0**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.577	22.577	22.577	22.577	22.577
Net monetary benefit	£451,127	£451,252	£451,201	£451,393	£451,331
Incremental net monetary benefit	Reference	£125	£74	£265	£203

**Table 59: X-ray cost =£0**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£329	£264	£315	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,831	£450,676	£450,876	£450,715	£450,977
Incremental net monetary benefit	Reference	-£155	£45	-£116	£146

**Table 60: MRI cost =£100**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£305	£151	£170
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,648	£450,885	£450,715	£451,020
Incremental net monetary benefit	Reference	-£95	£142	-£28	£277



**Table 61: MRI cost = £200**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£392	£151	£270
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,648	£450,798	£450,715	£450,920
Incremental net monetary benefit	Reference	-£95	£55	-£28	£177

**Table 62: CT cost = £70**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£416	£278	£342	£136	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,744	£450,662	£450,848	£450,730	£450,978
Incremental net monetary benefit	Reference	-£82	£104	-£14	£234

**Table 63: CT cost = £100**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£305	£343	£166	£214
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,743	£450,635	£450,847	£450,700	£450,976
Incremental net monetary benefit	Reference	-£108	£104	-£42	£234

**Table 64: Cast cost = £5**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£405	£287	£338	£151	£212
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,754	£450,653	£450,853	£450,716	£450,978
Incremental net monetary benefit	Reference	-£101	£98	-£39	£223

**Table 65: Cast cost = £15**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£428	£297	£348	£152	£214
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,732	£450,643	£450,842	£450,714	£450,976
Incremental net monetary benefit	Reference	-£89	£111	-£18	£244

**Table 66: Initial fracture clinic cost = £100**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£393	£268	£319	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,767	£450,672	£450,871	£450,715	£450,977
Incremental net monetary benefit	Reference	-£95	£104	-£52	£210

**Table 67: Initial fracture clinic cost = £150**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£436	£311	£362	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,724	£450,629	£450,828	£450,715	£450,977
Incremental net monetary benefit	Reference	-£95	£104	-£9	£253

**Table 68: Follow-up fracture clinic cost = £75**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£380	£289	£339	£148	£210
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,780	£450,651	£450,851	£450,718	£450,980
Incremental net monetary benefit	Reference	-£128	£71	-£62	£200

**Table 69: Follow-up fracture clinic cost = £125**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£449	£295	£346	£154	£216
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,711	£450,645	£450,844	£450,712	£450,974
Incremental net monetary benefit	Reference	-£66	£133	£1	£263

**Table 70: Fixation cost = £1000**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£403	£278	£328	£137	£199
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,757	£450,662	£450,862	£450,729	£450,991
Incremental net monetary benefit	Reference	-£95	£105	-£28	£234

**Table 71: Fixation cost = £2000**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£440	£316	£367	£175	£237
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,719	£450,624	£450,823	£450,691	£450,953
Incremental net monetary benefit	Reference	-£95	£104	-£28	£234

**Table 72: Salvage surgery = £5000**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£419	£293	£343	£153	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,741	£450,647	£450,847	£450,714	£450,977
Incremental net monetary benefit	Reference	-£94	£106	-£27	£236

**Table 73: Reduced HRQoL following missed fracture sustained for only four additional years**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.559	22.558	22.560	22.557	22.560
Net monetary benefit	£450,769	£450,859	£450,847	£450,988	£450,977
Incremental net monetary benefit	Reference	£90	£79	£219	£208

**Table 74: Reduced HRQoL following missed fracture sustained for five additional years**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£417	£292	£343	£151	£213
Total QALYs per patient	22.559	22.557	22.560	22.556	22.560
Net monetary benefit	£450,768	£450,850	£450,847	£450,976	£450,977
Incremental net monetary benefit	Reference	£82	£80	£208	£209

**Table 75: Only one additional fracture clinic visit**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£359	£292	£343	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,801	£450,648	£450,847	£450,715	£450,977
Incremental net monetary benefit	Reference	-£153	£47	-£86	£176

**Table 76: Five additional fracture clinic visits**

Strategy	X-ray → X-ray	X-ray → CT	X-ray → MRI	CT	MRI
Total cost per patient	£820	£292	£343	£151	£213
Total QALYs per patient	22.558	22.547	22.560	22.543	22.560
Net monetary benefit	£450,339	£450,648	£450,847	£450,715	£450,977
Incremental net monetary benefit	Reference	£308	£508	£375	£638

# Appendix N: Mapping of DRAFFT trial data to predict an EQ5D index score from a PRWE score

## N.1 Objective

To estimate the EQ5D index score from a Patient Reported Wrist Evaluation (PRWE) score in patients with a scaphoid fracture. This estimate would be used for all patients with a fracture in the non-complex fractures imaging of scaphoid economic model, with assumptions applied as to the duration of disability following timely or delayed treatment.

## N.2 Method

To derive a mapping function using data from a surgical intervention trial (DRAFFT) with a population of patients who had a distal radial fracture and reported outcomes from both the PRWE and the EQ5D.

The PRWE is a patient reported outcome measure that can be used for a variety of injuries that involve the wrist. It has two components: a pain component and a functional component. Each component consists of a number of questions that are answered using a scale from 0 to 10 to assess the patient's level of ability or pain in different situations. A high score represents a higher level of pain and a lower level of function. The pain component has five of these questions to give an overall component score out of 50. The functional component has two sub sections, each of five questions, to give an overall component score of 100. The overall PRWE score is given as the pain score plus half of the functional score to give an overall score out of 100.

To derive the mapping function, ordinary least squares regression was performed using SPSS version 22. The dependent variable used in the regression was EQ5D at 12 months. This was used because the published PRWE score for scaphoid fractures was obtained at 12 months. The independent variables used were:

- baseline EQ5D score
- age
- the pain component score
- the functional component score
- the product of the PRWE pain and function component scores
- square terms

All SPSS input methods for entering variables into the model were used to find the most appropriate mapping function. Each function was assessed by comparing the R-squared as well as statistical significance of the coefficient for each of the included variables.

The regression model was validated by assessing the performance across intervals of EQ5D and of PRWE scores. For EQ5D, the model was assessed in increments of 0.25 up to 0.5 and then increments of 0.1 beyond that. For PRWE, the model was assessed in increments of 25. The mean error, mean absolute error, and mean squared error were compared within each range as well as the mean EQ5D and mean predicted EQ5D. The model coefficients were also applied to the 6 month PRWE data to calculate predictions and the same methods were used to assess performance on this external data set.

### N.3 Results

The best fitting model included baseline EQ5D score, the two PRWE component scores as well as the product of these. Other variables were excluded as they did not have a statistically significant coefficient when included. The best fitting model showed a goodness of fit R-squared value of 0.453.

The mean predicted EQ5D was fairly similar to the actual mean at 0.8497 and 0.8412 respectively. The mean error was 0.0000, the mean absolute error was 0.0944 and the mean squared error was 0.0167. When the coefficients were applied to the 6 month data, the mean predicted EQ5D and mean actual EQ5D were 0.8090 and 0.7907. The mean error was 0.0135, the mean absolute error was 0.1033 and the mean squared error was 0.0230.

When the model dataset was assessed on intervals of the actual EQ5D at 12 months, the performance of the model was shown to be much better for higher EQ5D values than for lower values. However, this is not surprising given the low numbers of people with a low EQ5D score. A more useful assessment is to show how well the model predicts over intervals of PRWE score, given that this is the known value to be mapped from. The mean predicted EQ5D and actual EQ5D were very similar for the ranges 0-25 and 25-50. For the range 0-25, the predicted and actual EQ5D scores were 0.8951 and 0.8967 respectively, and for the PRWE range 25-50, the predicted and actual EQ5D scores were 0.7015 and 0.6973 respectively.

Applying the same splits to the 6 month data showed a similar trend with better predictions among those with a higher EQ5D, but again this is to be expected with reduced numbers of people. When split by PRWE score the results were similar to the 12 month data. For the PRWE range 0-25 the mean predicted EQ5D and mean actual EQ5D were 0.8774 and 0.8629 respectively.

For a full SPSS output, see section **Error! Reference source not found.** below.

### N.4 Conclusion

Given that the R-squared is relatively low, this means that only about half of the variability in the data can be explained by the predicted regression. This means there would be a lot of uncertainty if used on patient level data. However, for predicting a mean EQ5D from a PRWE score in the range 0-25, it appears to produce an accurate prediction. Therefore, for the purposes of the imaging of scaphoid economic model, it is expected to provide a reasonable estimate of EQ5D for patients who have a scaphoid fracture with a PRWE score of 22.

### N.5 Full SPSS output

The goodness of fit results of the DRAFFT utility mapping analysis are summarised in Table 77 below. This table shows the R, R-squared and adjusted R-squared statistics as well as the standard error.

**Table 77: Model Summary<sup>(b)</sup>**

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.673 <sup>a</sup>	.453	.447	.13017

(a) Predictors: (Constant), PRWE\_12\_PxF, EQ5D\_0, PRWE\_12\_P, PRWE\_12\_F

(b) Dependent Variable: EQ5D\_12

Table 78 below shows the ANOVA results, in which the F-statistic is used to test the hypothesis that all the coefficients are equal to zero.

**Table 78: ANOVA<sup>(a)</sup>**

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	4.877	4	1.219	71.949	.000 <sup>(b)</sup>
	Residual	5.880	347	.017		
	Total	10.756	351			

(a) *Dependent Variable: EQ5D\_12*(b) *Predictors: (Constant), EQ5D\_0, PRWE\_12\_P, PRWE\_12\_F, PRWE\_12\_PxF*

Table 79 below shows the coefficients computed from the analysis. The baseline EQ5D score is denoted EQ5D\_0, the pain component of the PRWE score at 12 months is denoted PRWE\_12\_P, the function component of the PRWE score at 12 months is denoted PRWE\_12\_F and the product of the two is denoted PRWE\_12\_PxF.

**Table 79: Coefficients<sup>(a)</sup>**

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
1 (Constant)	.623	.044		14.206	.000	.537	.710
EQ5D_0	.344	.045	.319	7.619	.000	.255	.433
PRWE_12_P	-.006	.002	-.286	-3.817	.000	-.009	-.003
PRWE_12_F	-.006	.001	-.568	-5.748	.000	-.008	-.004
PRWE_12_PxF	.000	.000	.332	3.209	.001	.000	.000

(a) *Dependent Variable: EQ5D\_12*

The descriptive statistics in Table 80 below show the range, mean, standard deviation and variance of the actual EQ5D score, the predicted EQ5D score, the error in the prediction, the squared error and the absolute error, for the development dataset collected at 12 months.

**Table 80: Descriptive Statistics – 12 months**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
EQ5D_12	398	-.09	1.00	.8412	.00968	.19304	.037
EQ5D_12_PRED	409	.33	.97	.8497	.00600	.12133	.015
EQ5D_12_RES	352	-.75	.36	.0000	.00690	.12943	.017

EQ5D_12_RES_SQ	352	.00	.56	.0167	.00244	.04572	.002
EQ5D_12_RES_ABS	352	.00	.75	.0944	.00471	.08840	.008
Valid N (listwise)	352						

The descriptive statistics in Table 81 below show the same as Table 80 above but for the validation dataset collected at 6 months.

**Table 81: Descriptive Statistics – 6 months**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
EQ5D_6	394	-.18	1.00	.7907	.01009	.20020	.040
EQ5D_6_PRED	406	.31	.97	.8090	.00628	.12651	.016
EQ5D_6_RES	348	-.32	.86	.0135	.00810	.15116	.023
EQ5D_6_RES_SQ	348	.00	.74	.0230	.00370	.06911	.005
EQ5D_6_RES_ABS	348	.00	.86	.1033	.00595	.11105	.012
Valid N (listwise)	348						

Table 82 to Table 85 below show the same descriptive statistics as tables Table 80 and Table 81 above across difference intervals of EQ5D score and PRWE score. These are denoted with the suffix 'level' and the value given in the first column is the upper limit of the interval.

**Table 82: Descriptive Statistics**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
EQ5D_12_level							
. EQ5D_12	0						
EQ5D_12_PRED	57	.36	.97	.8227	.01841	.13896	.019
EQ5D_12_RES	0						
EQ5D_12_RES_SQ	0						
EQ5D_12_RES_ABS	0						
Valid N (listwise)	0						
.25 EQ5D_12	10	-.09	.19	.1020	.02577	.08149	.007
EQ5D_12_PRED	6	.35	.84	.5664	.08235	.20172	.041
EQ5D_12_RES	6	-.75	-.17	-.4530	.08687	.21280	.045
EQ5D_12_RES_SQ	6	.03	.56	.2430	.07997	.19589	.038

	EQ5D_12_RES_ABS	6	.17	.75	.4530	.08687	.21280	.045
	Valid N (listwise)	6						
.50	EQ5D_12	7	.26	.49	.3557	.03184	.08423	.007
	EQ5D_12_PRED	4	.61	.97	.7428	.07807	.15615	.024
	EQ5D_12_RES	4	-.56	-.12	-.3753	.09251	.18503	.034
	EQ5D_12_RES_SQ	4	.01	.31	.1665	.06078	.12156	.015
	EQ5D_12_RES_ABS	4	.12	.56	.3753	.09251	.18503	.034
	Valid N (listwise)	4						
.60	EQ5D_12	13	.52	.59	.5523	.01007	.03632	.001
	EQ5D_12_PRED	10	.33	.81	.6415	.04345	.13739	.019
	EQ5D_12_RES	10	-.22	.19	-.0935	.03876	.12257	.015
	EQ5D_12_RES_SQ	10	.00	.05	.0223	.00528	.01669	.000
	EQ5D_12_RES_ABS	10	.01	.22	.1311	.02373	.07504	.006
	Valid N (listwise)	10						
.70	EQ5D_12	47	.62	.69	.6713	.00370	.02533	.001
	EQ5D_12_PRED	40	.47	.97	.7452	.01796	.11361	.013
	EQ5D_12_RES	40	-.28	.15	-.0739	.01748	.11058	.012
	EQ5D_12_RES_SQ	40	.00	.08	.0174	.00338	.02136	.000
	EQ5D_12_RES_ABS	40	.00	.28	.1012	.01354	.08566	.007
	Valid N (listwise)	40						
.80	EQ5D_12	108	.71	.80	.7782	.00259	.02692	.001
	EQ5D_12_PRED	98	.59	.97	.8289	.00942	.09325	.009
	EQ5D_12_RES	98	-.24	.18	-.0511	.00897	.08882	.008
	EQ5D_12_RES_SQ	98	.00	.06	.0104	.00108	.01072	.000
	EQ5D_12_RES_ABS	98	.00	.24	.0877	.00529	.05241	.003
	Valid N (listwise)	98						
.90	EQ5D_12	32	.81	.88	.8591	.00328	.01855	.000



	EQ5D_12_PRED	29	.55	.97	.8483	.01804	.09717	.009
	EQ5D_12_RES	29	-.13	.33	.0106	.01938	.10434	.011
	EQ5D_12_RES_SQ	29	.00	.11	.0106	.00386	.02079	.000
	EQ5D_12_RES_ABS	29	.00	.33	.0774	.01286	.06927	.005
	Valid N (listwise)	29						
1.00	EQ5D_12	181	1.00	1.00	1.0000	.00000	.00000	.000
	EQ5D_12_PRED	165	.64	.97	.9224	.00436	.05600	.003
	EQ5D_12_RES	165	.03	.36	.0776	.00436	.05600	.003
	EQ5D_12_RES_SQ	165	.00	.13	.0091	.00125	.01609	.000
	EQ5D_12_RES_ABS	165	.03	.36	.0776	.00436	.05600	.003
	Valid N (listwise)	165						

**Table 83: Descriptive Statistics**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
					Std.		
PRWE_12_level	Statistic	Statistic	Statistic	Statistic	Error	Statistic	Statistic
. EQ5D_12	44	-.09	1.00	.7364	.04279	.28386	.081
EQ5D_12_PRED	0						
EQ5D_12_RES	0						
EQ5D_12_RES_SQ	0						
EQ5D_12_RES_ABS	0						
Valid N (listwise)	0						
25.0 EQ5D_12	287	.09	1.00	.8967	.00823	.13939	.019
0 EQ5D_12_PRED	325	.47	.97	.8951	.00427	.07696	.006
EQ5D_12_RES	285	-.75	.33	.0018	.00727	.12268	.015
EQ5D_12_RES_SQ	285	.00	.56	.0150	.00264	.04463	.002
EQ5D_12_RES_ABS	285	.00	.75	.0924	.00477	.08055	.006

	Valid N (listwise)	285						
50.0	EQ5D_12	49	.08	1.00	.6973	.02757	.19297	.037
0	EQ5D_12_PRED	60	.36	.81	.7015	.01050	.08133	.007
	EQ5D_12_RES	49	-.51	.36	-.0167	.02426	.16980	.029
	EQ5D_12_RES_SQ	49	.00	.26	.0285	.00808	.05657	.003
	EQ5D_12_RES_ABS	49	.00	.51	.1144	.01794	.12556	.016
	Valid N (listwise)	49						
75.0	EQ5D_12	15	.52	.80	.6713	.01756	.06802	.005
0	EQ5D_12_PRED	20	.53	.70	.6407	.01030	.04606	.002
	EQ5D_12_RES	15	-.02	.16	.0376	.01535	.05945	.004
	EQ5D_12_RES_SQ	15	.00	.03	.0047	.00221	.00857	.000
	EQ5D_12_RES_ABS	15	.00	.16	.0448	.01391	.05387	.003
	Valid N (listwise)	15						
100.	EQ5D_12	3	.08	.52	.2633	.13220	.22898	.052
00	EQ5D_12_PRED	4	.33	.66	.4255	.07924	.15847	.025
	EQ5D_12_RES	3	-.27	.19	-.0831	.13896	.24068	.058
	EQ5D_12_RES_SQ	3	.03	.07	.0455	.01419	.02458	.001
	EQ5D_12_RES_ABS	3	.17	.27	.2085	.03198	.05538	.003
	Valid N (listwise)	3						

**Table 84: Descriptive Statistics**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
EQ5D_6_level							
EQ5D_6	0						
EQ5D_6_PRED	58	.31	.97	.8077	.01838	.13998	.020
EQ5D_6_RES	0						

	EQ5D_6_RES_SQ	0						
	EQ5D_6_RES_ABS	0						
	Valid N (listwise)	0						
.25	EQ5D_6	15	-.18	.23	.0733	.03580	.13865	.019
	EQ5D_6_PRED	14	.34	.75	.6157	.03716	.13906	.019
	EQ5D_6_RES	14	.26	.86	.5249	.04508	.16868	.028
	EQ5D_6_RES_SQ	14	.07	.74	.3020	.04826	.18058	.033
	EQ5D_6_RES_ABS	14	.26	.86	.5249	.04508	.16868	.028
	Valid N (listwise)	14						
.50	EQ5D_6	2	.26	.33	.2950	.03500	.04950	.002
	EQ5D_6_PRED	1	.66	.66	.6592	.	.	.
	EQ5D_6_RES	1	.33	.33	.3292	.	.	.
	EQ5D_6_RES_SQ	1	.11	.11	.1084	.	.	.
	EQ5D_6_RES_ABS	1	.33	.33	.3292	.	.	.
	Valid N (listwise)	1						
.60	EQ5D_6	17	.52	.59	.5612	.00861	.03551	.001
	EQ5D_6_PRED	15	.48	.97	.6875	.03588	.13898	.019
	EQ5D_6_RES	15	-.11	.38	.1209	.03420	.13245	.018
	EQ5D_6_RES_SQ	15	.00	.14	.0310	.00999	.03869	.001
	EQ5D_6_RES_ABS	15	.02	.38	.1454	.02649	.10260	.011
	Valid N (listwise)	15						
.70	EQ5D_6	69	.62	.69	.6675	.00284	.02360	.001
	EQ5D_6_PRED	56	.33	.93	.7122	.01562	.11687	.014
	EQ5D_6_RES	56	-.29	.24	.0454	.01481	.11086	.012
	EQ5D_6_RES_SQ	56	.00	.08	.0141	.00229	.01714	.000
	EQ5D_6_RES_ABS	56	.00	.29	.0969	.00929	.06950	.005
	Valid N (listwise)	56						

.80	EQ5D_6	143	.73	.80	.7773	.00208	.02484	.001
	EQ5D_6_PRED	125	.54	.97	.7973	.00841	.09400	.009
	EQ5D_6_RES	125	-.22	.18	.0192	.00794	.08879	.008
	EQ5D_6_RES_SQ	125	.00	.05	.0082	.00078	.00872	.000
	EQ5D_6_RES_ABS	125	.00	.22	.0761	.00440	.04918	.002
	Valid N (listwise)	125						
	.90	EQ5D_6	34	.81	.88	.8559	.00399	.02324
EQ5D_6_PRED		33	.62	.96	.8394	.01385	.07958	.006
EQ5D_6_RES		33	-.22	.11	-.0158	.01334	.07663	.006
EQ5D_6_RES_SQ		33	.00	.05	.0059	.00186	.01070	.000
EQ5D_6_RES_ABS		33	.00	.22	.0585	.00888	.05101	.003
Valid N (listwise)		33						
1.00		EQ5D_6	114	1.00	1.00	1.0000	.00000	.00000
	EQ5D_6_PRED	104	.68	.97	.9114	.00582	.05939	.004
	EQ5D_6_RES	104	-.32	-.03	-.0886	.00582	.05939	.004
	EQ5D_6_RES_SQ	104	.00	.10	.0113	.00167	.01701	.000
	EQ5D_6_RES_ABS	104	.03	.32	.0886	.00582	.05939	.004
	Valid N (listwise)	104						

**Table 85: Descriptive Statistics**

	N	Minimum	Maximum	Mean		Std. Deviation	Variance
				Statistic	Std. Error		
PRWE_6_level	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
EQ5D_6	44	-.17	1.00	.7459	.03149	.20891	.044
EQ5D_6_PRED	0						
EQ5D_6_RES	0						
EQ5D_6_RES_SQ	0						

	EQ5D_6_RES_ABS	0						
	Valid N (listwise)	0						
25.00	EQ5D_6	235	.08	1.00	.8629	.00970	.14872	.022
	EQ5D_6_PRED	272	.53	.97	.8774	.00432	.07124	.005
	EQ5D_6_RES	233	-.26	.65	.0142	.00788	.12031	.014
	EQ5D_6_RES_SQ	233	.00	.42	.0146	.00255	.03894	.002
	EQ5D_6_RES_ABS	233	.00	.65	.0917	.00517	.07889	.006
	Valid N (listwise)	233						
50.00	EQ5D_6	87	-.17	1.00	.7010	.01942	.18111	.033
	EQ5D_6_PRED	101	.46	.79	.7011	.00674	.06776	.005
	EQ5D_6_RES	87	-.32	.86	.0024	.01991	.18575	.035
	EQ5D_6_RES_SQ	87	.00	.74	.0341	.01123	.10475	.011
	EQ5D_6_RES_ABS	87	.00	.86	.1117	.01586	.14794	.022
	Valid N (listwise)	87						
75.00	EQ5D_6	26	-.18	.80	.5685	.04916	.25067	.063
	EQ5D_6_PRED	31	.31	.69	.5903	.01826	.10167	.010
	EQ5D_6_RES	26	-.29	.67	.0242	.04722	.24075	.058
	EQ5D_6_RES_SQ	26	.00	.44	.0563	.02148	.10951	.012
	EQ5D_6_RES_ABS	26	.00	.67	.1651	.03409	.17384	.030
	Valid N (listwise)	26						
100.00	EQ5D_6	2	.08	.08	.0800	.00000	.00000	.000
	EQ5D_6_PRED	2	.34	.37	.3581	.01378	.01949	.000
	EQ5D_6_RES	2	.26	.29	.2781	.01378	.01949	.000
	EQ5D_6_RES_SQ	2	.07	.09	.0776	.00767	.01084	.000
	EQ5D_6_RES_ABS	2	.26	.29	.2781	.01378	.01949	.000
	Valid N (listwise)	2						

# Appendix O: Qualitative study checklist

## O.1 Information and support

**Table 86: Qualitative study checklist: Information and support**

Link to GRADE criteria	Question	Forsberg 2014 <sup>182</sup>	Slaney 2014 <sup>467</sup>	Okonta 2011 <sup>400</sup>	O'Brien 2010 <sup>396</sup>
Limitations of evidence	Is a qualitative study/survey an appropriate approach?	✓	✓	✓	✓
Limitations of evidence	Is the study clear in what it seeks to do?	✓	✓	✓	✓
Limitations of evidence	How defensible/rigorous is the research design/methodology?	?	✓	✓	✓
Limitations of evidence	How well was the data collection carried out?	✓	✓	✓	✓
Limitations of evidence	Is the role of the researcher clearly described?	✗	✓	✗	✓
Limitations of evidence	Is the context clearly described?	✓	✓	✗	✓
Limitations of evidence	Were the methods reliable?	✓	✓	✓	✓
Limitations of evidence	Is the data analysis sufficiently rigorous?	?	✓	?	✓
Limitations of evidence	Are the data rich (for qualitative study and open ended survey questions)?	✓	✓	✓	✓
Limitations of evidence	Is the analysis reliable?	?	✓	?	✓
Limitations of evidence/ Applicability of evidence/ Sufficiency of evidence	Are the findings convincing?	✓	✓	✓	✓
Applicability of evidence	Are the findings relevant to the aims of the study?	✓	✓	✓	✓
Limitations of evidence/ Applicability of evidence/	Are the conclusions adequate?	✓	✓	✓	✓

Link to GRADE criteria	Question	Forsberg 2014 <sup>182</sup>	Slaney 2014 <sup>467</sup>	Okonta 2011 <sup>400</sup>	O'Brien 2010 <sup>396</sup>
Sufficiency of evidence					

## Appendix P: Research recommendations

### P.1 Ankle imaging

**Research question: Is CT scanning in addition to initial plain film X-ray clinically effective and cost effective for planning surgical treatment of unstable/displaced ankle fractures compared with plain film X ray alone?**

**Why this is important:** Ankle fractures are common and affect a significant number of people every year. Outcomes following surgery are important for patients' long-term function and quality of life, and may also be associated with additional cost if another operation is needed. It is important to know whether adding CT scanning to plain film X-ray improves outcomes following surgery and is cost effective.

#### Criteria for selecting high priority research recommendations:

PICO question	<p>Is the use of CT scanning in addition to initial plain film X-ray clinically and cost effective for planning surgical treatment of unstable/displaced ankle fractures compared to plain film X ray alone?</p> <p>Population - Adults and children with a suspected unstable/displaced ankle fracture</p> <p>I – CT scan plus X-ray</p> <p>C – X-ray alone</p> <p>O –Health-related quality of life, pain/discomfort, return to normal activities, psychological wellbeing, adverse effects (unnecessary imaging, need for revision surgery, functional outcomes), Radiological outcomes – satisfactory fracture reduction.</p>
Importance to patients or the population	<p>Ankle fracture affects 122 per 100,000 people per year. There is on-going debate as to the relative risks versus benefits of surgery for the treatment of displaced ankle fractures.<sup>155</sup> The decision to operate or not, and the type of surgery planned, is usually based upon the interpretation of plain radiographs (X-rays). However, it is not always easy to interpret these X-rays; with particular regard to the reduction of the syndesmosis (the joint between the two bones of the lower leg).<sup>330</sup> Pre-operative CT scanning may allow the surgeon to more accurately determine which patients would benefit and from what surgery. However, pre-operative CT scanning requires additional time and resources.</p>
Relevance to NICE guidance	<p>The production of high quality research in this area could inform clinical practice for patients and surgeons. It would identify the most effective imaging technique to use with this population.</p>
Relevance to the NHS	<p>The identification of the most clinical and cost-effective way to plan surgical treatment of unstable/displaced ankle fractures would prevent unnecessary operations and improve outcome for patients with this common injury.</p>
National priorities	<p>Ankle fractures affect all types of patients, from top athletes with high-energy injuries to elderly patients whose fracture is related to osteoporosis. Patients have both short and long-term restrictions in mobility which affect health-related quality of life.<sup>320</sup> Improving the diagnosis and treatment of patients with</p>



	this injury is a research priority for the National Institute for Health Research, Orthopaedic Trauma Society and Arthritis Research UK.
Current evidence base	There is increasing recognition that it is difficult to assess fractures involving syndesmosis of the ankle joint using X-rays alone. <sup>330</sup> However, it is not known if pre-operative CT scanning will improve the ability of surgeons to plan surgery and therefore improve outcomes for patients. There have been no trials at all in this area.
Equality	
Study design	Primary research using a randomised controlled design would be appropriate to investigate this question. This would ideally use the most reliable and valid patients-reported outcomes for ankle fracture and health-related quality of life..
Feasibility	The large numbers of people affected by this condition, and the increasing availability of CT scanning in Emergency Departments, means that such a trial is feasible
Other comments	There is no current research in this area
Importance	High priority: Ankle fractures affect a large proportion of the population, leading to significant short and long-term disability. The current evidence base does not allow NICE to make a clear recommendation regarding the most clinically effective and cost effective imaging technique for patients with ankle fracture. Specifically, is the use of CT scanning in addition to initial plain film X-ray clinically and cost effective for planning surgical treatment of unstable/displaced ankle fractures?

## P.2 Clinics

**Research question: What is the clinical and cost effectiveness of virtual new patient fracture systems versus next day consultant-led face-to-face new patient fracture clinics in people presenting with non complex fractures in the emergency department and thought to need an orthopaedic opinion?**

**Why this is important:** Currently many people with fractures are asked to attend a next-day clinic led by a consultant, although it is believed that a virtual clinic may be at least as effective. If this is the case, face-to-face clinics may be an unnecessary use of time and resources for both patients and the NHS. Firm evidence of clinical and cost effectiveness is needed before virtual clinics can be introduced as part of a change in service structure.

### Criteria for selecting high priority research recommendations:

PICO question	<p><b>Population:</b> patients with non-complex fractures seen in ED not for admission, thought to require an orthopaedic opinion</p> <p><b>Intervention:</b> Virtual (remotely managed) new patient fracture systems (with discharge direct from ED protocols, orthopaedic consultant virtual review, telephone follow up, and triage to specialist clinics). This will include consideration of MDT issues.</p> <p><b>Comparator:</b> Next day consultant-led face to face new patient fracture clinics</p> <p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• Patient satisfaction</li> </ul>
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	<ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Serious adverse incidents</li> <li>• Cost</li> <li>• Resource use</li> <li>• Time off work</li> <li>• Return to normal activities</li> </ul>
Importance to patients or the population	Currently most patients with fractures are required to attend for face to face clinics, although there is a belief that the virtual clinic system may be at least as effective. If so, having to travel to attend face to face clinics may be a drain on patients' time and resources, and any research indicating that such patients have equivalent or better outcomes if given a virtual clinic appointment will reduce the burden on patients.
Relevance to NICE guidance	This research question will allow NICE to provide more definitive guidance on referral for people with fractures.
Relevance to the NHS	Currently most patients with fractures are required to attend for face to face clinics, although there is a belief that the virtual clinic system may be at least as effective. If so, unnecessary face to face clinics may be a drain on NHS resources, and any research indicating that such patients have equivalent or better outcomes if given a virtual clinic appointment will reduce the burden on the NHS.
National priorities	None
Current evidence base	No good quality evidence in this area currently exists.
Equality	All groups may benefit
Study design	Randomised controlled trial? Cluster randomised controlled trial?
Feasibility	This should be highly feasible, with no technical or ethical issues.
Other comments	There is no current research in this area
Importance	<b>High</b>

### P.3 Distal radius fracture manipulation with image intensifier

**Research question:** For patients with displaced fractures of the distal radius, is manipulation with real time image guidance more clinically and cost effective than manipulation without real time image guidance?

**Why this is important:** In a large minority of patients with a distal radius fracture the bone fragments are displaced and need manipulation and reduction into an anatomical position. Currently in the NHS, most manipulations for distal radius fractures are performed in the emergency department without real time image guidance. It is believed that image guidance may be important, but despite hundreds of patients having manipulation of their displaced distal radius fracture in the ED each day, no high-quality research exists in this area.

**Criteria for selecting high priority research recommendations:**

PICO question	<b>Population:</b> Adults with closed, displaced distal radius fractures who are being considered for
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	<p>manipulation in the ED</p> <p>Sub-grouping criteria:</p> <ul style="list-style-type: none"> <li>• 16-50 and over 50 as surrogate for bone density</li> <li>• intra-articular/extra articular fracture of the radial carpal joint</li> </ul> <p><b>Intervention:</b></p> <ul style="list-style-type: none"> <li>• Manipulation with image intensifier at first presentation</li> </ul> <p><b>Comparator:</b></p> <ul style="list-style-type: none"> <li>• Manipulation without image intensifier at first presentation</li> </ul> <p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• Wrist function</li> <li>• Health related quality of life</li> <li>• Radiographic outcome</li> <li>• Resource use</li> <li>• Adverse events (Including second procedures)</li> </ul>
<p>Importance to patients or the population</p>	<p>Most distal radius fractures are ‘undisplaced’ i.e. the bones remain aligned in a normal anatomical position. However, in a large minority of patients the bone fragments are displaced and require manipulation and reduction into an anatomical position. Currently in the NHS, most manipulations for distal radius fractures are performed in the emergency department without real time image guidance.</p> <p>The GDG considered that manipulation without the use of real time image guidance could potentially lead to more inadequate reductions, more re-manipulations, and hence more interventions for the patient and potentially more damage to the soft-tissues around the wrist. ‘Failed’ reductions may also lead to more secondary surgical procedures for patients and greater cost for the NHS. Manipulations can be painful procedures and reducing this burden on patients is a high priority for this research.</p>
<p>Relevance to NICE guidance</p>	<p>This would answer the question of whether distal radius fractures should be reduced with the aid of real time image guidance or not. This would form an integral part of future NICE non-complex fracture guidelines.</p>
<p>Relevance to the NHS</p>	<p>The majority of people with displaced distal radius fractures will first present in the emergency department (ED) and, if required, that is where they will have their fracture manipulated. Currently, manipulations in the ED are carried out without the aid of real-time image guidance. Real-time image guidance may provide better outcomes for the patients. However, there would be a cost associated with installing the imaging equipment in the ED.</p> <p>If real time image guidance is clinically and cost effective for patients with a dorsally displaced distal radius fracture this would lead to a large change in ED services across the NHS.</p>
<p>National priorities</p>	<p>This question has been identified as a research priority by the Orthopaedic Trauma Society. Reducing demand for resource and costs in over-stretched Emergency Departments is a priority for the NHS.</p>
<p>Current evidence base</p>	<p>There are currently no published trials comparing closed manipulations of distal</p>

	radius fractures with and without real time image guidance.
Equality	This research recommendation would potentially benefit all adults, but particularly older people who frequently have manipulations in the ED for fragility fractures of the distal radius.
Study design	The GDG felt that a randomised study comparing manipulation with real time image guidance versus manipulation without real time image guidance would be the most rigorous approach. The study with subgroup by age (16-50 and over 50, as a surrogate for bone density) and intra-articular/extra articular fractures to provide information on the groups who may benefit more from one approach or the other.
Feasibility	This is a common injury and a common procedure in ED. There is likely to be equipoise among clinicians. There will be (NHS excess treatment) costs associated with providing real time image guidance in ED but these may be offset against potential cost savings in terms of reduced need for further interventions and reduced adverse events.
Other comments	Reducing the need for further interventions will improve flow of patients through ED, reducing waiting times for patients and potentially reducing costs.
Importance	<b>Hundreds of patients have manipulation of their displaced distal radius fracture in the ED each day, but there is no high-quality research in this area.</b>

## P.4 Post-operative ankle weight bearing strategy

**Research question:** What is the most clinically and cost effective strategy for weight in people who have had surgery for internal fixation of an ankle fracture?

**Why this is important:** In the NHS, open reduction and internal fixation of the ankle is often performed. Currently there is variation in the advice about mobilisation and weight-bearing given to people who have had this done. There is uncertainty as to whether people should be advised to immediately start unrestricted weight-bearing as tolerated or to wait a number of weeks.

### Criteria for selecting high priority research recommendations:

PICO question	<p>Population</p> <ul style="list-style-type: none"> <li>Skeletally mature people who have had internal fixation for an ankle fracture. All patterns of injury (including contralateral) and fixation will be included.</li> </ul> <p>Subgroup by cast type; i.e.:</p> <ul style="list-style-type: none"> <li>non-removable cast</li> <li>removable cast or splint</li> <li>no immobilisation device</li> </ul> <p>Intervention</p> <ul style="list-style-type: none"> <li>Advise unrestricted weight bearing immediately post-op (weight bearing as tolerated). Written and verbal advice.</li> </ul> <p>Comparison</p> <ul style="list-style-type: none"> <li>Advise restricted weight bearing for 6 weeks post-op (partial and non-weight bearing) with unrestricted weight-bearing thereafter. Written</li> </ul>
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	<p>and verbal advice.</p> <p>Outcomes</p> <ul style="list-style-type: none"> <li>• Ankle function (8 weeks, 3 months, 6 months)</li> <li>• Health related quality of life (8 weeks, 3 months, 6 months)</li> <li>• Return to normal activities</li> <li>• Resource use</li> <li>• Adverse events (incl. secondary interventions)</li> </ul> <p>Exclusions</p> <ul style="list-style-type: none"> <li>• People with neuropathy</li> </ul>
Importance to patients or the population	<p>The GDG considered the possible advantages of immediate unrestricted weight bearing to be facilitation of faster rehabilitation for people who have open reduction and internal fixation (ORIF) of the ankle. It could minimise inactivity osteopenia, reduce muscle atrophy, and result in fewer post-surgical pulmonary embolisms and deep vein thrombosis. This in turn should allow for a faster return to normal activities. Hence research definitively demonstrating this would improve the quality of life for patients.</p>
Relevance to NICE guidance	<p>It would answer the clinical question around weight bearing strategy in post-operative patients following open reduction and internal fixation of ankle fractures and be the basis for a clinical recommendation in the non-complex fractures guideline.</p>
Relevance to the NHS	<p>The population of people in the UK receiving ORIF for ankle fractures is large; there were 1000 procedures carried out by the NHS in 2014. At the moment health professionals are uncertain what weight bearing advice to give to people with concerns that early unrestricted weight bearing will lead to additional re-displacements while delaying weight bearing leads to slower recovery and other adverse events, for example post-surgical pulmonary embolisms. There would be significant cost and resource use gains for the NHS if this question were answered. These would be manifested through fewer secondary interventions and reduced length of stay for patients.</p>
National priorities	
Current evidence base	<p>All eight studies included in the clinical review were small, with fewer than 100 participants in each and an overall average of 59. All evidence identified in the systematic review was graded as very low quality due to risk of bias and imprecision. This led to inconclusive results for the critical outcomes of interest.</p>
Equality	<p>This research recommendation would potentially benefit all groups, particularly older people, who may be particularly affected by immobility.</p>
Study design	<p>A randomised controlled trial would be the most appropriate form of research methodology for this question.</p>
Feasibility	<p>The research would be very feasible, with low cost and no serious technical issues. One potential ethical issue may be randomising people to the immediate weight bearing group, where the possibility of re-displacement may exist. However this is offset by the likelihood that most patients would benefit from</p>

	such an intervention, based on the clinical experience of the GDG.
Other comments	<p>Potential funders of this study may be include Orthopaedic Research UK or the Chartered Society of Physiotherapy.</p> <p>The study should measure compliance with the advice given, to assess fidelity of the intervention; for example, by using pressure measurements.</p>
Importance	This research recommendation is of high importance: the research is essential to inform future updates of key recommendations in the guideline

## P.5 Torus fractures treatment

**Research question:** What is the clinical effectiveness and cost effectiveness of no treatment for torus fractures of the distal radius in children compared with soft splints, removable splints or bandages?

**Why this is important:** Torus fractures of the distal radius are among the most common fractures in children but management varies widely between immediate discharge from the emergency department to repeated outpatient reviews with casting and imaging. These fractures result from trauma to growing bones and account for an estimated 500,000 emergency department attendances a year in the UK. Current treatment often involves application of a bandage, or a removable cast or a soft cast, with review in outpatient clinics and repeated X-ray imaging. This is despite anecdotal evidence that treatment with simple analgesia and immediate discharge from the emergency department is safe and effective. There have been no studies comparing current treatments with no intervention in children with torus fractures. A randomised controlled trial is needed to evaluate the clinical and cost effectiveness of no treatment compared with soft splints, removable splints or bandages.

### Criteria for selecting high priority research recommendations:

<b>PICO question</b>	<p>Is no treatment more clinically and cost effective for treating buckle fractures of the distal radius in children than soft splints, removable splints or bandages?</p> <p>P: Children aged 1-9 years with an isolated buckle fracture of the distal radius</p> <p>I: No treatment</p> <p>C: soft splints, removable splints or bandages. Note that these will <u>not</u> be compared to each other.</p> <p>O: patient reported pain/discomfort, parent or carer satisfaction with treatment, return to normal activities, skin problems and re-fracture</p>
<b>Importance to patients or the population</b>	If no treatment with immediate discharge is found to be as effective as active treatments this will reduce the need for the child to wear, and the parents or carers to look after, what may be an inconvenient or uncomfortable cast. It will also reduce the need for patients to unnecessarily attending clinics.
<b>Relevance to NICE guidance</b>	In the current guidelines we have advised against rigid casts but have been unable to recommend that no treatment is given because of the lack of evidence, despite the feeling in the GDG that there would be no disadvantages to no treatment
<b>Relevance to the NHS</b>	If no treatment with immediate discharge is found to be as effective as active treatments this will reduce costs in terms of splint materials or bandages, as well as reducing time costs involved in instructing children and parents/carers in the use and care of the materials. It will also reduce the costs of the number of attendances to hospital.

<b>National priorities</b>	This study does not relate to any National priorities
<b>Current evidence base</b>	The current evidence shows that soft casts, bandages or removable casts may be more effective than rigid casts. No evidence exists regarding the relative effectiveness of no treatment.
<b>Equality</b>	This study will specifically relate to children.
<b>Study design</b>	<p>A stratified randomization design is important to ensure that each of the three strata (soft cast v no treatment; removable cast v no treatment; bandage v no treatment) are free from selection bias. The entire sample should first be randomized to the three strata and then allocation to the intervention and comparator should occur via independent randomization. The three strata may also be collapsed into one to give an overall result for no treatment versus active treatment.</p> <p>This should be a non-inferiority trial rather than one required to show greater efficacy, as if no treatment is equal to the other treatments it can be inferred it is more desirable because of inevitable reductions in costs. Thus it should be powered and analysed accordingly.</p>
<b>Feasibility</b>	With the large number of torus fracture cases per year there should be little problem recruiting enough patients for a valid trial. There are no ethical issues. Overall this should be a feasible project.
<b>Other comments</b>	None
<b>Importance</b>	The results of this study could significantly reduce costs in the NHS, given the common prevalence of this injury.

## Appendix Q: NICE technical team

Name	Role
Sharon Summers-Ma	Guideline Lead
Phil Alderson	Clinical Advisor
Steven Barnes	Clinical Lead
Ross Maconachie	Health Economist
Ben Doak	Guideline Commissioning Manager
Thomas Feist	Guideline Coordinator
Anne-Louise Clayton	Editor



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