National Clinical Guideline Centre

Final

Fractures (complex): assessment and management

Complex fractures: assessment and management of complex fractures

NICE Guideline NG37

Appendices I - P

February 2016

Final

Commissioned by the National Institute for Health and Care Excellence

Disclaimer
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Funding
National Institute for Health and Care Excellence

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Appendices

Appendix I: Forest plots

I.1 Open fractures

I.1.1 Limb salvage

Secondary upper limb amputation in adults

Figure 1: MESS in detecting the need for secondary upper limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Durham 1996	3	1	0	8	1.00 [0.29, 1.00]	0.89 [0.52, 1.00]

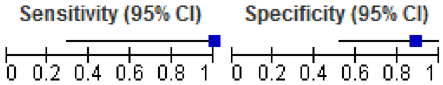
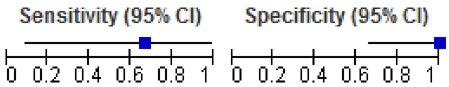


Figure 2: MESI in detecting need for secondary upper limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Durham 1996	2	0	1	9	0.67 [0.09, 0.99]	1.00 [0.66, 1.00]



Secondary lower limb amputation in adults

Figure 3: MESS in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bonanni 1993	4	19	14	21	0.22 [0.06, 0.48]	0.53 [0.36, 0.68]
Bosse 2001	12	19	43	238	0.22 [0.12, 0.35]	0.93 [0.89, 0.95]
Brown 2009	4	9	3	54	0.57 [0.18, 0.90]	0.86 [0.75, 0.93]
Dagum 1999	2	4	3	31	0.40 [0.05, 0.85]	0.89 [0.73, 0.97]
Doucet 2011	9	42	18	599	0.33 [0.17, 0.54]	0.93 [0.91, 0.95]
Durham 1996	5	5	1	19	0.83 [0.36, 1.00]	0.79 [0.58, 0.93]
El Sharawy 2005	4	42	0	16	1.00 [0.40, 1.00]	0.28 [0.17, 0.41]
Robertson 1991	16	0	49	43	0.25 [0.15, 0.37]	1.00 [0.92, 1.00]

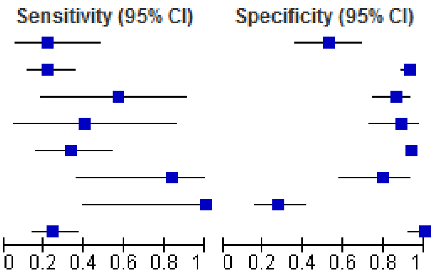


Figure 4: MESI in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bonanni 1993	1	4	17	36	0.06 [0.00, 0.27]	0.90 [0.76, 0.97]
Dagum 1999	0	2	5	33	0.00 [0.00, 0.52]	0.94 [0.81, 0.99]
Durham 1996	3	0	3	24	0.50 [0.12, 0.88]	1.00 [0.86, 1.00]
El Sharawy 2005	4	38	0	20	1.00 [0.40, 1.00]	0.34 [0.22, 0.48]

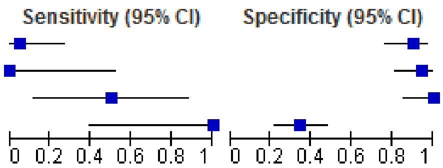


Figure 5: PSI in detecting need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bonanni 1993	6	12	12	28	0.33 [0.13, 0.59]	0.70 [0.53, 0.83]
Bosse 2001	20	42	35	215	0.36 [0.24, 0.50]	0.84 [0.79, 0.88]
Dagum 1999	3	2	2	33	0.60 [0.15, 0.95]	0.94 [0.81, 0.99]
Durham 1996	3	1	3	23	0.50 [0.12, 0.88]	0.96 [0.79, 1.00]

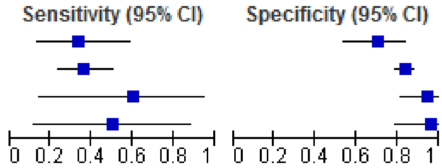


Figure 6: LSI in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bonanni 1993	11	23	7	17	0.61 [0.36, 0.83]	0.42 [0.27, 0.59]
Bosse 2001	16	7	39	250	0.29 [0.18, 0.43]	0.97 [0.94, 0.99]
Dagum 1999	3	6	2	29	0.60 [0.15, 0.95]	0.83 [0.66, 0.93]
Durham 1996	5	4	1	20	0.83 [0.36, 1.00]	0.83 [0.63, 0.95]

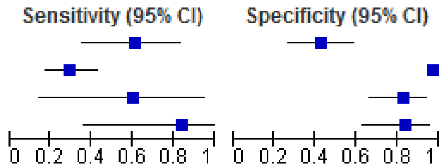


Figure 7: NISSSA in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	7	4	48	253	0.13 [0.05, 0.24]	0.98 [0.96, 1.00]

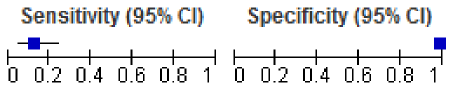


Figure 8: Ganga in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Madhuchandra 2015	1	0	0	39	1.00 [0.03, 1.00]	1.00 [0.91, 1.00]

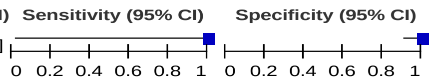
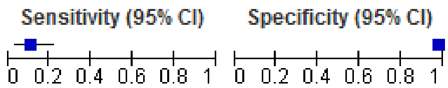


Figure 9: HFS '97 in detecting the need for secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	6	5	49	252	0.11 [0.04, 0.22]	0.98 [0.96, 0.99]



Primary/secondary upper limb amputation in children

Figure 10: MESS in detecting the need for primary/secondary upper limb amputation in children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Mommsen 2010	0	0	0	17	Not estimable	1.00 [0.80, 1.00]

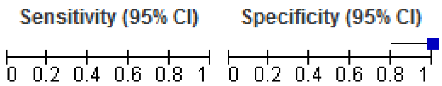


Figure 11: MESI in detecting need for primary/secondary lower limb amputation in children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Fagelman 2002	5	0	5	26	0.50 [0.19, 0.81]	1.00 [0.87, 1.00]
Mommsen 2010	8	4	0	15	1.00 [0.63, 1.00]	0.79 [0.54, 0.94]
Stewart 2012	2	3	1	18	0.67 [0.09, 0.99]	0.86 [0.64, 0.97]

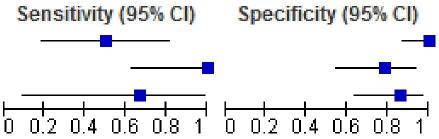


Figure 12: LSI in detecting need for primary/secondary lower limb amputation in children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Stewart 2012	2	4	1	17	0.67 [0.09, 0.99]	0.81 [0.58, 0.95]

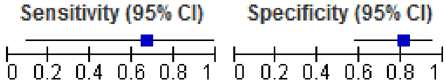


Figure 13: PSI in detecting need for primary/secondary lower limb amputation in CHILDREN

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Stewart 2012	3	2	0	19	1.00 [0.29, 1.00]	0.90 [0.70, 0.99]

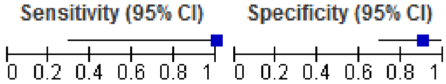


Figure 14: HFS '98 in detecting need for primary/secondary lower limb amputation in children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Stewart 2012	3	5	0	16	1.00 [0.29, 1.00]	0.76 [0.53, 0.92]

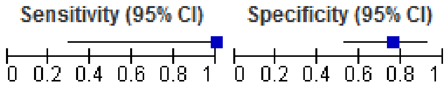
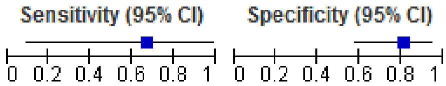


Figure 15: NISSSA in detecting need for primary/secondary lower limb amputation in children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Stewart 2012	2	4	1	17	0.67 [0.09, 0.99]	0.81 [0.58, 0.95]



Primary/secondary lower limb amputation in adults

Figure 16: MESS in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	45	19	55	238	0.45 [0.35, 0.55]	0.93 [0.89, 0.95]
Brown 2009	19	9	3	54	0.86 [0.65, 0.97]	0.86 [0.75, 0.93]
Doucet 2011	16	42	29	599	0.36 [0.22, 0.51]	0.93 [0.91, 0.95]
Johansen 1990 and Helfet 1990	12	0	0	14	1.00 [0.74, 1.00]	1.00 [0.77, 1.00]
Kjorstad 2007	6	1	2	49	0.75 [0.35, 0.97]	0.98 [0.89, 1.00]
Krettek 2001	14	1	3	69	0.82 [0.57, 0.96]	0.99 [0.92, 1.00]
Kumar 2007	10	1	1	49	0.91 [0.59, 1.00]	0.98 [0.89, 1.00]
Rajasekeran 2006	3	1	4	101	0.43 [0.10, 0.82]	0.99 [0.95, 1.00]
Robertson 1991	41	0	54	43	0.43 [0.33, 0.54]	1.00 [0.92, 1.00]
Sheehan 2014	14	14	26	101	0.35 [0.21, 0.52]	0.88 [0.80, 0.93]
Slauterbeck 1994	9	0	0	34	1.00 [0.66, 1.00]	1.00 [0.90, 1.00]

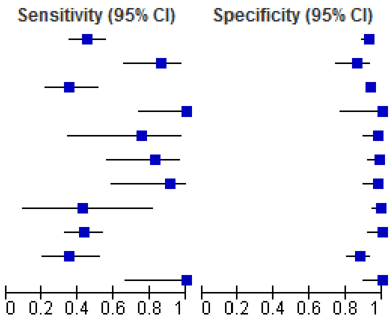


Figure 17: Ganga in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Rajasekeran 2006	7	3	0	99	1.00 [0.59, 1.00]	0.97 [0.92, 0.99]

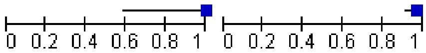


Figure 18: PSI in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	47	42	53	215	0.47 [0.37, 0.57]	0.84 [0.79, 0.88]

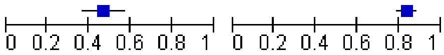


Figure 19: NISSSA in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	33	4	67	253	0.33 [0.24, 0.43]	0.98 [0.96, 1.00]
Krettek 2001	12	1	5	69	0.71 [0.44, 0.90]	0.99 [0.92, 1.00]

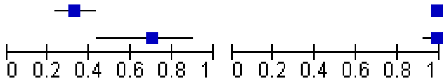


Figure 20: LSI in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	51	7	49	250	0.51 [0.41, 0.61]	0.97 [0.94, 0.99]

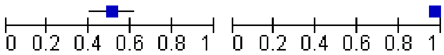


Figure 21: HFS '98 in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Krettek 2001	14	1	3	69	0.82 [0.57, 0.96]	0.99 [0.92, 1.00]

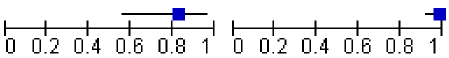
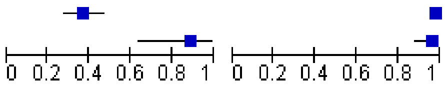


Figure 22: HFS/HFS '97 in detecting need for primary/secondary lower limb amputation in adults

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bosse 2001	37	5	63	252	0.37 [0.28, 0.47]	0.98 [0.96, 0.99]
Krettek 2001	15	3	2	67	0.88 [0.64, 0.99]	0.96 [0.88, 0.99]



I.1.2 Arterial shunts

Shunt versus definitive vascular repair

Figure 23: Mortality

Study or Subgroup	shunt Events	shunt Total	immediate def repair Events	immediate def repair Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Desai 2012	0	5	1	17	100.0%	0.27 [0.00, 29.45]
Total (95% CI)		**5**		**17**	**100.0%**	**0.27 [0.00, 29.45]**
Total events	0		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.54 (P = 0.59)						

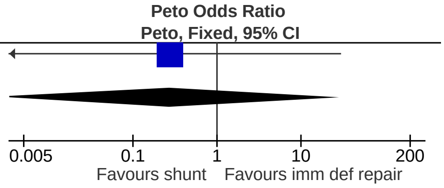


Figure 24: Amputation

Study or Subgroup	shunt Events	shunt Total	immediate def repair Events	immediate def repair Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Desai 2012	1	5	5	17	100.0%	0.68 [0.10, 4.55]
Total (95% CI)		**5**		**17**	**100.0%**	**0.68 [0.10, 4.55]**
Total events	1		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.40 (P = 0.69)						

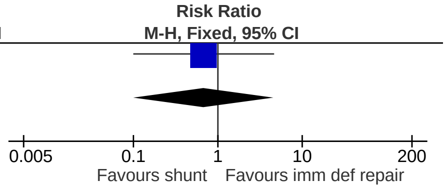


Figure 25: Compartment syndrome

Study or Subgroup	shunt Events	shunt Total	immediate def repair Events	immediate def repair Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Desai 2012	0	5	2	17	100.0%	0.26 [0.01, 7.61]
Total (95% CI)		**5**		**17**	**100.0%**	**0.26 [0.01, 7.61]**
Total events	0		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.79 (P = 0.43)						

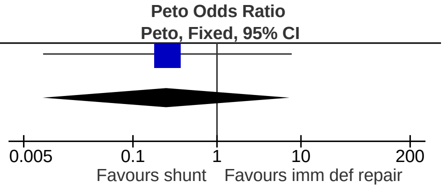
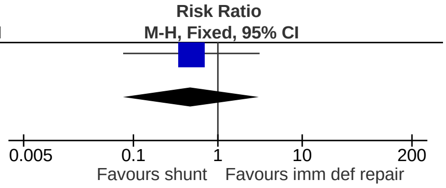


Figure 26: Other vascular surgery

Study or Subgroup	shunt Events	shunt Total	immediate def repair Events	immediate def repair Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Desai 2012	1	5	7	17	100.0%	0.49 [0.08, 3.07]
Total (95% CI)		**5**		**17**	**100.0%**	**0.49 [0.08, 3.07]**
Total events	1		7			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.77 (P = 0.44)						



I.1.3 MDT

Combined orthoplastic approach versus non-combined approach

Figure 27: Amputation

Study or Subgroup	Combined Events	Combined Total	Not combined Events	Not combined Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Naique 2006	1	25	2	47	100.0%	0.94 [0.09, 9.87]
Total (95% CI)		**25**		**47**	**100.0%**	**0.94 [0.09, 9.87]**
Total events	1		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						

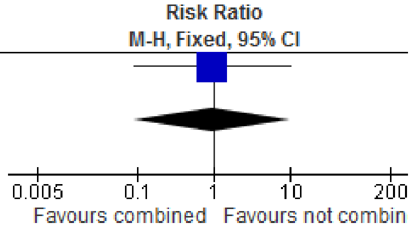


Figure 28: flap failure

Study or Subgroup	Combined Events	Combined Total	Not combined Events	Not combined Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Naique 2006	0	25	6	47	100.0%	0.19 [0.03, 1.10]
Total (95% CI)		**25**		**47**	**100.0%**	**0.19 [0.03, 1.10]**
Total events	0		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.85 (P = 0.06)						

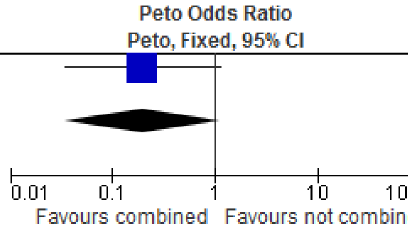


Figure 29: Deep infection

Study or Subgroup	Combined Events	Combined Total	Not combined Events	Not combined Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Naique 2006	1	25	5	47	100.0%	0.38 [0.05, 3.04]
Total (95% CI)		**25**		**47**	**100.0%**	**0.38 [0.05, 3.04]**
Total events	1		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.92 (P = 0.36)						

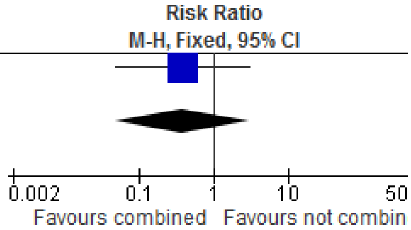
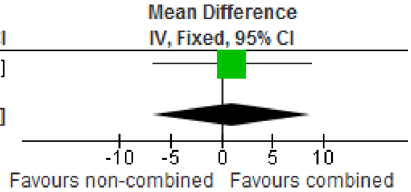


Figure 30: Enneking limb score (higher better)

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Naique 2006	75	15.9	25	74	15.9	47	100.0%	1.00 [-6.71, 8.71]
Total (95% CI)			**25**			**47**	**100.0%**	**1.00 [-6.71, 8.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.25 (P = 0.80)								

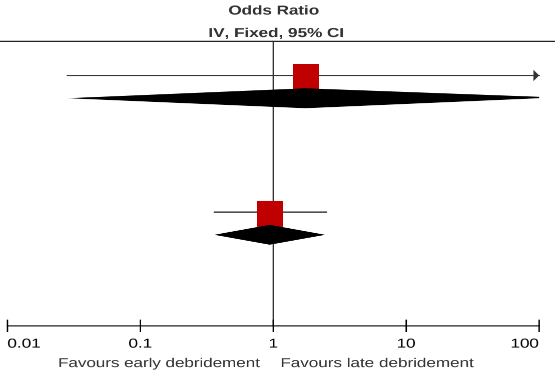


I.1.4 Optimal timing of debridement

Deep surgical site infection

Figure 31: Early versus delayed/late debridement multivariate analysis results (odds ratio)

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
1.1.1 ≤6 hours versus > 6 hours				
Noumi 2005	0.5639	2.1071	100.0%	1.76 [0.03, 109.26]
Subtotal (95% CI)			**100.0%**	**1.76 [0.03, 109.26]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 0.27 (P = 0.79)				
1.1.2 ≤ 8 hours versus >8 hours				
Harley 2002	-0.05	0.4951	100.0%	0.95 [0.36, 2.51]
Subtotal (95% CI)			**100.0%**	**0.95 [0.36, 2.51]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 0.10 (P = 0.92)				

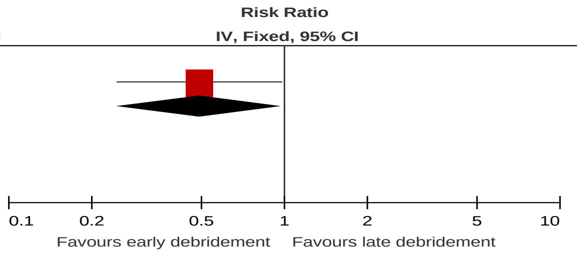


Test for subgroup differences: Chi² = 0.08, df = 1 (P = 0.78), I² = 0%

Noumi 2005 is adjusted for: age, sex, Gustilo type, fracture grade by AO type, fracture site, reamed versus undreamed nailing, existence of multiple trauma and existence of floating knee injury. Harley 2002 is adjusted for: male gender, age and Gustilo grade.

Figure 32: Early versus delayed/late debridement multivariate analysis results (relative risk)

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Fixed, 95% CI
1.2.2 < 8 hours versus > 8 hours				
Malhotra 2014	-0.7105	0.35	100.0%	0.49 [0.25, 0.98]
Subtotal (95% CI)			**100.0%**	**0.49 [0.25, 0.98]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 2.03 (P = 0.04)				

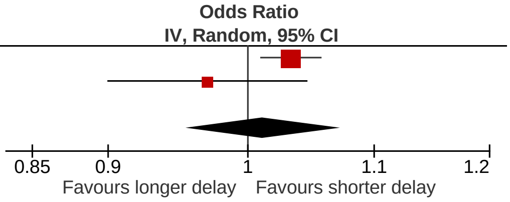


Test for subgroup differences: Not applicable

Adjusted for: The entire data set was used. This was assumed to be the content of the baseline characteristics table; age, ISS, RTS, SBP, lactate and Gustilo grade.

Figure 33: Delayed versus earlier debridement multivariate analysis results (adjusted OR)

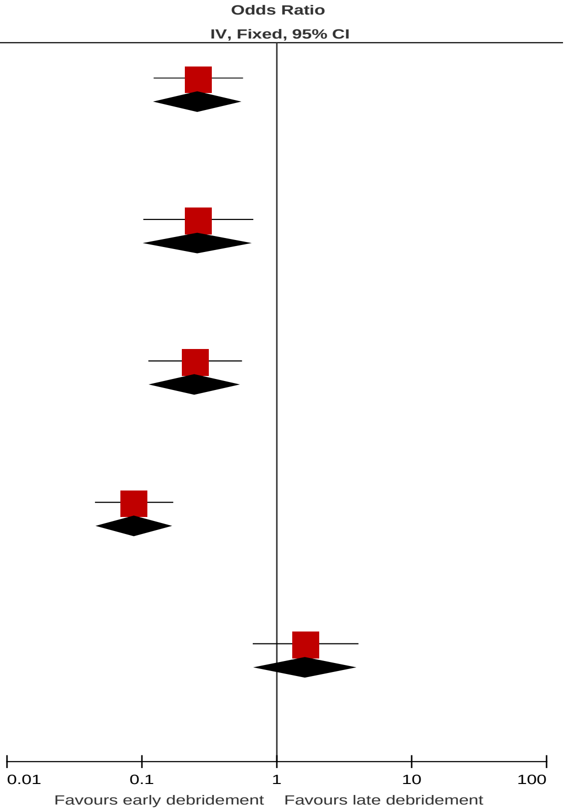
Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Hull 2014	0.0325	0.0115	66.7%	1.03 [1.01, 1.06]
Weber 2014	-0.0305	0.0382	33.3%	0.97 [0.90, 1.05]
Total (95% CI)			**100.0%**	**1.01 [0.95, 1.07]**
Heterogeneity: Tau² = 0.00; Chi² = 2.49, df = 1 (P = 0.11); I² = 60%				
Test for overall effect: Z = 0.39 (P = 0.70)				



Amputation

Figure 34: Debridement on hospital day 0 versus other timings in open tibial fractures, multivariate analysis results

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
2.1.1 Day 0 versus Day 1				
Davissears 2012	-1.3387	0.3828	100.0%	0.26 [0.12, 0.56]
Subtotal (95% CI)			**100.0%**	**0.26 [0.12, 0.56]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 3.50 (P = 0.0005)				
2.1.2 Day 0 versus Day 2				
Davissears 2012	-1.3392	0.4727	100.0%	0.26 [0.10, 0.66]
Subtotal (95% CI)			**100.0%**	**0.26 [0.10, 0.66]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 2.83 (P = 0.005)				
2.1.3 Day 0 versus Days 3 & 4				
Davissears 2012	-1.392	0.4013	100.0%	0.25 [0.11, 0.55]
Subtotal (95% CI)			**100.0%**	**0.25 [0.11, 0.55]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 3.47 (P = 0.0005)				
2.1.4 Day 0 versus Day 5 or greater				
Davissears 2012	-2.4351	0.3344	100.0%	0.09 [0.05, 0.17]
Subtotal (95% CI)			**100.0%**	**0.09 [0.05, 0.17]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 7.28 (P < 0.00001)				
2.1.5 Day 0 versus timing not specified				
Davissears 2012	0.4927	0.4539	100.0%	1.64 [0.67, 3.98]
Subtotal (95% CI)			**100.0%**	**1.64 [0.67, 3.98]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 1.09 (P = 0.28)				



Test for subgroup differences: Chi² = 27.00, df = 4 (P < 0.0001), I² = 85.2%

Adjusted for: age, sex, race, economic characteristics, injury severity scale score, comorbidities, associated injuries/procedure (arterial injury, tibial nerve injury, complicated open wound, fasciotomy, dislocation (knee or ankle)), admission type, location, bed size, hospital teaching status, hospital volume open tibial fractures per year, median household income and mechanism of injury.

I.1.5 Fixation

Definitive fixation and immediate cover versus definitive fixation and staged cover

Figure 35: Deep infection – RCT results

Study or Subgroup	Primary closure Events	Primary closure Total	Delayed closure Events	Delayed closure Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Benson 1983	0	40	2	36	100.0%	0.12 [0.01, 1.92]
Total (95% CI)		**40**		**36**	**100.0%**	**0.12 [0.01, 1.92]**
Total events	0		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.50 (P = 0.13)						

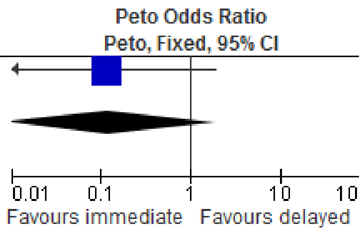


Figure 36: Deep infection - cohorts

Study or Subgroup	Immediate cover Events	Immediate cover Total	Delayed cover Events	Delayed cover Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gopal 2004	0	12	2	18	9.4%	0.29 [0.02, 5.60]
Jenkinson 2014	3	73	13	73	60.1%	0.23 [0.07, 0.78]
Wei 2014	5	27	6	22	30.6%	0.68 [0.24, 1.93]
Total (95% CI)		**112**		**113**	**100.0%**	**0.37 [0.18, 0.80]**
Total events	8		21			

Heterogeneity: Chi² = 1.89, df = 2 (P = 0.39); I² = 0%
Test for overall effect: Z = 2.55 (P = 0.01)

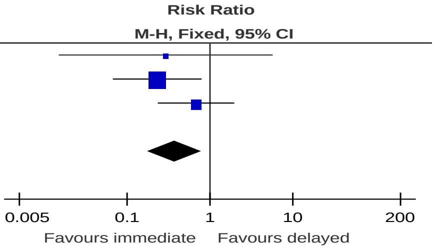


Figure 37: Amputation - cohorts

Study or Subgroup	Immediate cover Events	Immediate cover Total	Delayed cover Events	Delayed cover Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Wei 2014	1	27	3	22	100.0%	0.27 [0.03, 2.43]
Total (95% CI)		**27**		**22**	**100.0%**	**0.27 [0.03, 2.43]**
Total events	1		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.17 (P = 0.24)

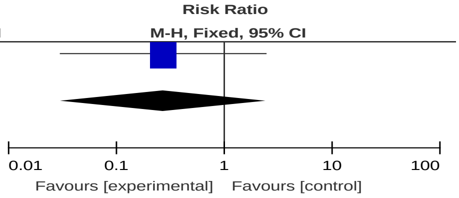
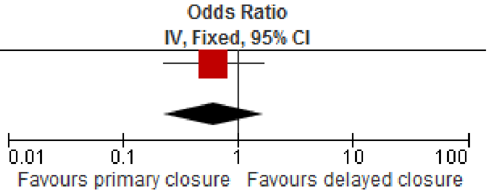


Figure 38: Further unplanned surgery

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Schemitsch 2012	-0.4769	0.513017	100.0%	0.62 [0.23, 1.70]
Total (95% CI)			**100.0%**	**0.62 [0.23, 1.70]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.93 (P = 0.35)



Definitive fixation and immediate cover versus staged fixation and staged cover

Figure 39: Flap failure (total or partial) -cohort

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Liu 2012	-2.3795	0.9464	100.0%	0.09 [0.01, 0.59]
Total (95% CI)			**100.0%**	**0.09 [0.01, 0.59]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.51 (P = 0.01)

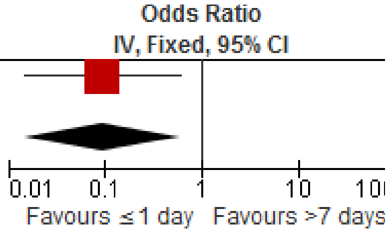
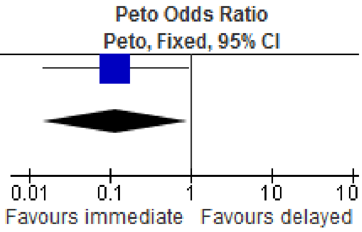


Figure 40: Deep infection – cohort

Study or Subgroup	Immediate cover Events	Immediate cover Total	Delayed cover Events	Delayed cover Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Hertel 1999	0	14	4	15	100.0%	0.11 [0.01, 0.91]
Total (95% CI)		**14**		**15**	**100.0%**	**0.11 [0.01, 0.91]**
Total events	0		4			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.04 (P = 0.04)						

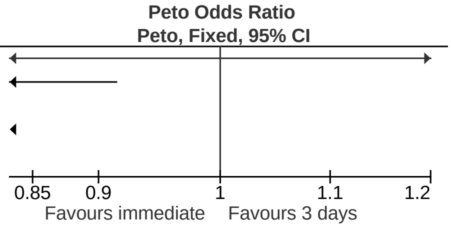


I.1.6 Cover

Immediate versus 3 days

Figure 41: Deep infection

Study or Subgroup	Immediate Events	Immediate Total	3 days Events	3 days Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Gopal 2004	0	12	1	10	21.8%	0.11 [0.00, 5.68]
Hertel 1999	0	14	4	15	78.2%	0.11 [0.01, 0.91]
Total (95% CI)		**26**		**25**	**100.0%**	**0.11 [0.02, 0.71]**
Total events	0		5			
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.99); I² = 0%						
Test for overall effect: Z = 2.32 (P = 0.02)						



Immediate versus 7 days

Figure 42: Deep infection (RCT)

Study or Subgroup	immediate Events	immediate Total	7 days Events	7 days Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Benson 1983	0	40	2	36	100.0%	0.12 [0.01, 1.92]
Total (95% CI)		**40**		**36**	**100.0%**	**0.12 [0.01, 1.92]**
Total events	0		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.50 (P = 0.13)						

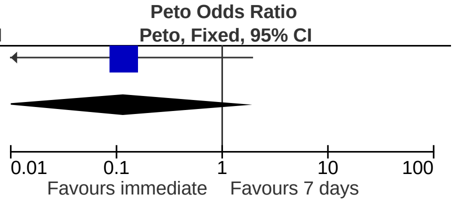


Figure 43: Deep infection (cohorts)

Study or Subgroup	Immediate cover Events	Immediate cover Total	Delayed cover Events	Delayed cover Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Wei 2014	5	27	6	22	100.0%	0.68 [0.24, 1.93]
Total (95% CI)		**27**		**22**	**100.0%**	**0.68 [0.24, 1.93]**
Total events	5		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.73 (P = 0.47)						

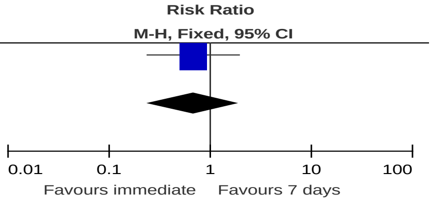
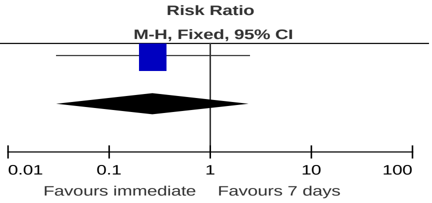


Figure 44: Amputation (cohorts)

Study or Subgroup	Immediate cover Events	Immediate cover Total	Delayed cover Events	Delayed cover Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Wei 2014	1	27	3	22	100.0%	0.27 [0.03, 2.43]
Total (95% CI)		**27**		**22**	**100.0%**	**0.27 [0.03, 2.43]**
Total events	1		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.17 (P = 0.24)						

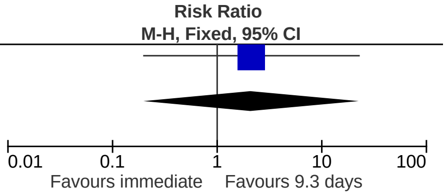


Immediate versus more than 7 days

Figure 45: Infection (not specified if deep)

Study or Subgroup	immediate cover Events	immediate cover Total	9 days cover Events	9 days cover Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hohmann 2007	2	46	1	49	100.0%	2.13 [0.20, 22.71]
Total (95% CI)		**46**		**49**	**100.0%**	**2.13 [0.20, 22.71]**
Total events	2		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.63 (P = 0.53)



More than 14 days versus less than 3 days

Figure 46: Deep infection

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Liu 2012	2.0028	0.795	100.0%	7.41 [1.56, 35.20]
Total (95% CI)			**100.0%**	**7.41 [1.56, 35.20]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.52 (P = 0.01)

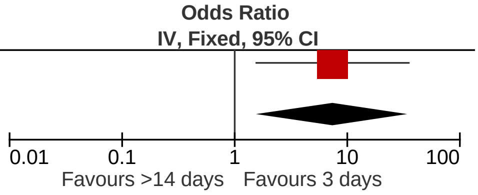


Figure 47: Osteomyelitis

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Liu 2012	2.3542	1.1479	100.0%	10.53 [1.11, 99.89]
Total (95% CI)			**100.0%**	**10.53 [1.11, 99.89]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.05 (P = 0.04)

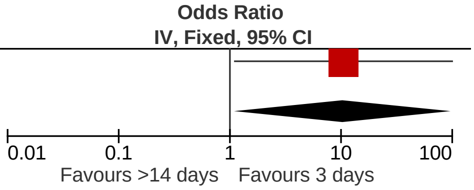
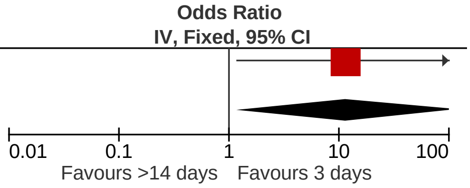


Figure 48: Flap take backs

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Liu 2012	2.4423	1.1574	100.0%	11.50 [1.19, 111.14]
Total (95% CI)			**100.0%**	**11.50 [1.19, 111.14]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.11 (P = 0.03)

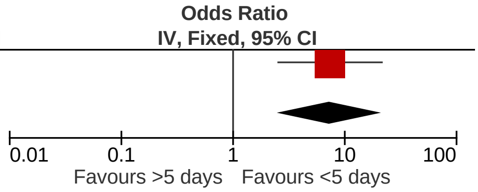


More than 5 days versus less than 5 days

Figure 49: Deep infection

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
Lack 2015	2.0001	0.5449	100.0%	7.39 [2.54, 21.50]
Total (95% CI)			**100.0%**	**7.39 [2.54, 21.50]**

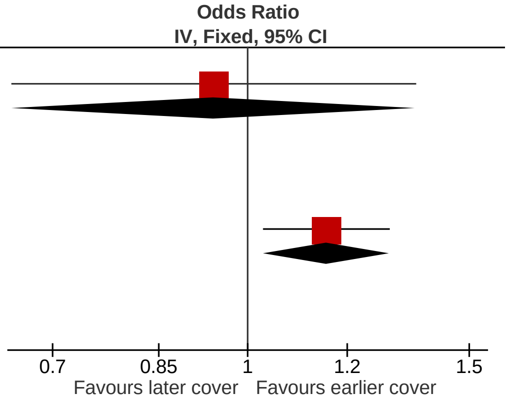
Heterogeneity: Not applicable
Test for overall effect: Z = 3.67 (P = 0.0002)



Timing as a continuous variable

Figure 50: Odds of deep infection per day delay in cover

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
5.1.1 cover at 1-7 days				
D'Alleyrand 2014	-0.0619	0.1882	100.0%	0.94 [0.65, 1.36]
Subtotal (95% CI)			**100.0%**	**0.94 [0.65, 1.36]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 0.33 (P = 0.74)				
5.1.2 cover at >7 days				
D'Alleyrand 2014	0.1441	0.0584	100.0%	1.15 [1.03, 1.30]
Subtotal (95% CI)			**100.0%**	**1.15 [1.03, 1.30]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 2.47 (P = 0.01)				



I.1.7 Definitive dressings after debridement

NPWT versus standard dressing

Figure 51: Deep infection

	NPWT		Standard dressing		Risk Ratio
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI
Stannard 2009	2	35	7	23	0.19 [0.04, 0.83]

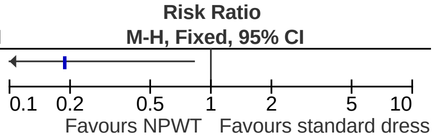
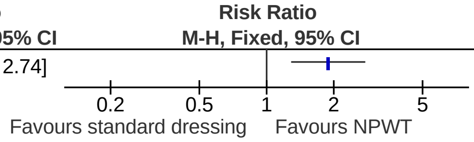


Figure 52: Wound healed at 30 days

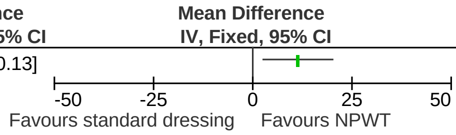
	NPWT		Standard dressing		Risk Ratio
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI
Rasool 2013	25	25	13	25	1.89 [1.30, 2.74]



Appearance of 100% granulation tissue over the wound

Figure 53: Quality of life at 3 months (SF36 physical component)

	NPWT			Standard dressing			Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI
Stannard 2009	43.8	16.6	35	32.4	16.6	23	11.40 [2.67, 20.13]



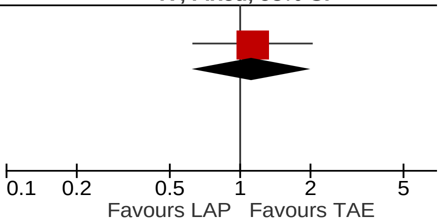
I.2 Pelvic fractures

I.2.1 Pelvic haemorrhage control

LAP versus TAE

Figure 54: In-hospital mortality

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Fixed, 95% CI
2.1.2 Mortality-Odds Ratio				
Katsura 2013	0.1222	0.2981	100.0%	1.13 [0.63, 2.03]
Subtotal (95% CI)			**100.0%**	**1.13 [0.63, 2.03]**
Heterogeneity: Not applicable				
Test for overall effect: Z = 0.41 (P = 0.68)				



I.3 Pilon fractures

I.3.1 Pilon early fixation

MIXED OPEN/CLOSED

Definitive fixation within 24 hours versus temp fixation and definitive fixation at more than 7 days

Figure 55: Number of surgeries

Study or Subgroup	<24 hours Mean	<24 hours SD	<24 hours Total	>7 days Mean	>7 days SD	>7 days Total	Weight	Mean Difference IV, Fixed, 95% CI
Davidovitch 2011	1.5	0.738	20	2.1	0.738	26	100.0%	-0.60 [-1.03, -0.17]
Total (95% CI)			**20**			**26**	**100.0%**	**-0.60 [-1.03, -0.17]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.73 (P = 0.006)								

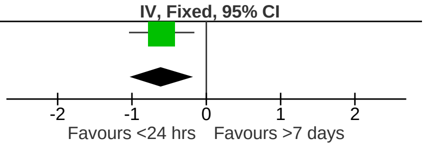


Figure 56: Function - AOFAS

Study or Subgroup	<24 hours Mean	<24 hours SD	<24 hours Total	>7 days Mean	>7 days SD	>7 days Total	Weight	Mean Difference IV, Fixed, 95% CI
Davidovitch 2011	77.1	14.4	20	72.4	21	26	100.0%	4.70 [-5.55, 14.95]
Total (95% CI)			**20**			**26**	**100.0%**	**4.70 [-5.55, 14.95]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.90 (P = 0.37)								

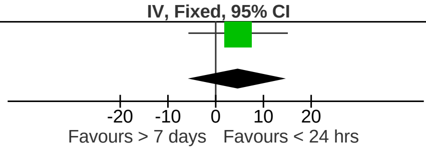


Figure 57: Function - SMFA

Study or Subgroup	<24 hours Mean	<24 hours SD	<24 hours Total	>7 days Mean	>7 days SD	>7 days Total	Weight	Mean Difference IV, Fixed, 95% CI
Davidovitch 2011	25.8	15.2	20	34.3	19.1	26	100.0%	-8.50 [-18.41, 1.41]
Total (95% CI)			**20**			**26**	**100.0%**	**-8.50 [-18.41, 1.41]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.68 (P = 0.09)								

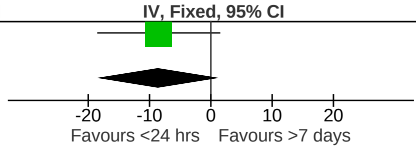


Figure 58: People with unplanned surgery

Study or Subgroup	<24 hours Events	<24 hours Total	>7 days Events	>7 days Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Koulouvaris 2007	0	42	1	13	100.0%	0.01 [0.00, 1.47]
Total (95% CI)		**42**		**13**	**100.0%**	**0.01 [0.00, 1.47]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.80 (P = 0.07)

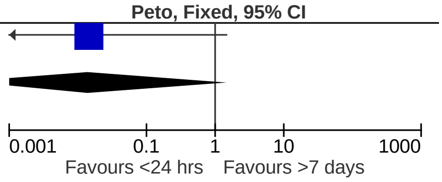
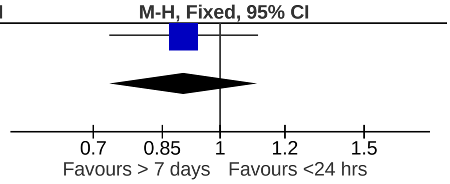


Figure 59: Return to normal activities

Study or Subgroup	<24 hours Events	<24 hours Total	>7 days Events	>7 days Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Koulouvaris 2007	35	42	12	13	100.0%	0.90 [0.73, 1.11]
Total (95% CI)		**42**		**13**	**100.0%**	**0.90 [0.73, 1.11]**
Total events	35		12			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.97 (P = 0.33)



Temp fixation and definitive fixation at more than 24 hours to 7 days versus temp fixation and definitive fixation at more than 7 days

Figure 60: Deep infection

Study or Subgroup	Favours 24hrs to 7 days Events	Favours 24hrs to 7 days Total	>7 days Events	>7 days Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Harris 2006	1	16	0	63	100.0%	139.42 [1.06, 18295.53]
Total (95% CI)		**16**		**63**	**100.0%**	**139.42 [1.06, 18295.53]**
Total events	1		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.98 (P = 0.05)

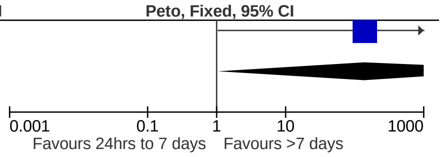


Figure 61: Unplanned surgery

Study or Subgroup	>24hrs to 7 days Events	>24hrs to 7 days Total	>7 days Events	>7 days Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Harris 2006	4	16	4	63	100.0%	3.94 [1.10, 14.06]
Total (95% CI)		**16**		**63**	**100.0%**	**3.94 [1.10, 14.06]**
Total events	4		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.11 (P = 0.03)

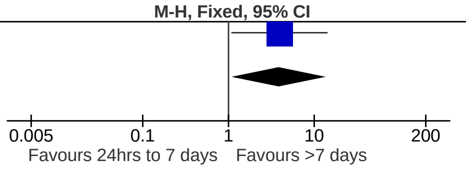


Figure 62: Function - foot function index

Study or Subgroup	>24hrs to 7 days Mean	>24hrs to 7 days SD	>24hrs to 7 days Total	>7 days Mean	>7 days SD	>7 days Total	Weight	Mean Difference IV, Fixed, 95% CI
Harris 2006	0.4	0.305	16	0.23	0.305	63	100.0%	0.17 [0.00, 0.34]
Total (95% CI)			**16**			**63**	**100.0%**	**0.17 [0.00, 0.34]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.99 (P = 0.05)

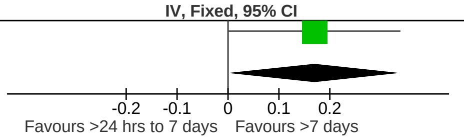
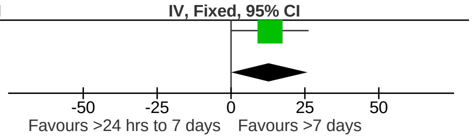


Figure 63: Function – musculoskeletal function assessment score

	>24hrs to 7 days			>7 days				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Harris 2006	34	23.5	16	20.9	23.5	63	100.0%	13.10 [0.21, 25.99]
Total (95% CI)			**16**			**63**	**100.0%**	**13.10 [0.21, 25.99]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.99 (P = 0.05)								



CLOSED only

Temp fixation and definitive fixation at more than 24 hours to 7 days versus temp fixation and definitive fixation at more than 7 days

Figure 64: Deep infection

	>24 hours to 7 days		>7 days			Peto Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	Peto, Fixed, 95% CI
Tang 2014	0	23	1	23	100.0%	0.14 [0.00, 6.82]
Total (95% CI)		**23**		**23**	**100.0%**	**0.14 [0.00, 6.82]**
Total events	0		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.00 (P = 0.32)						

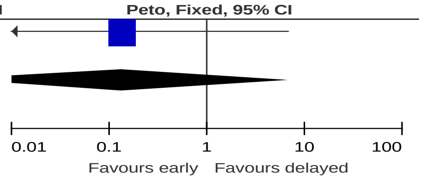


Figure 65: Function (poor/fair)n

	>24 hours to 7 days		>7 days			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Tang 2014	0	23	0	23		Not estimable
Total (95% CI)		**23**		**23**		**Not estimable**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						

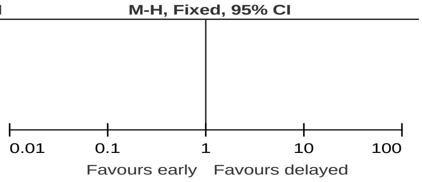
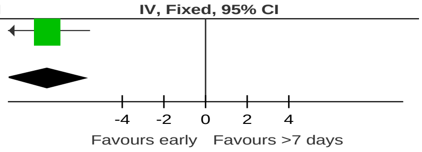


Figure 66: Hospital stay (days)

	>24 hours to 7 days			>7 days				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Tang 2014	7.6	2.6	23	15.2	4.2	23	100.0%	-7.60 [-9.62, -5.58]
Total (95% CI)			**23**			**23**	**100.0%**	**-7.60 [-9.62, -5.58]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 7.38 (P < 0.00001)								



I.3.2 Pilon fixation

RCT data

Figure 67: Surgical site infection

	Staged ORIF		External fixation			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Wang2010	2	27	0	29	33.1%	5.36 [0.27, 106.78]
Wyrsch 1996	5	19	1	20	66.9%	5.26 [0.68, 41.01]
Total (95% CI)		**46**		**49**	**100.0%**	**5.29 [0.97, 28.80]**
Total events	7		1			
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.99); I² = 0%						
Test for overall effect: Z = 1.93 (P = 0.05)						

Risk Ratio
M-H, Fixed, 95% CI

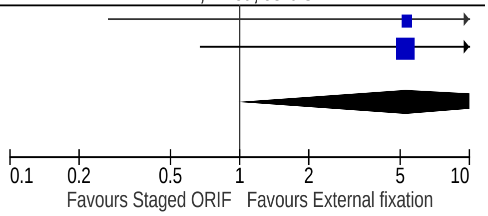


Figure 68: Osteomyelitis

	Staged ORIF		External fixation			Peto Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	Peto, Fixed, 95% CI
Wang2010	1	27	0	29	26.0%	7.96 [0.16, 402.02]
Wyrsch 1996	3	19	0	20	74.0%	8.73 [0.85, 89.36]
Total (95% CI)		**46**		**49**	**100.0%**	**8.52 [1.15, 63.01]**
Total events	4		0			
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.97); I² = 0%						
Test for overall effect: Z = 2.10 (P = 0.04)						

Peto Odds Ratio
Peto, Fixed, 95% CI

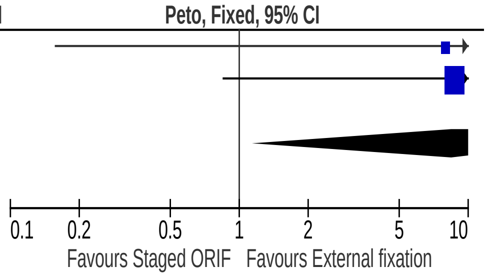


Figure 69: Ankle Fusion

	Staged ORIF		External fixation			Peto Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	Peto, Fixed, 95% CI
Wyrsch 1996	0	19	1	20	100.0%	0.14 [0.00, 7.18]
Total (95% CI)		**19**		**20**	**100.0%**	**0.14 [0.00, 7.18]**
Total events	0		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.97 (P = 0.33)						

Peto Odds Ratio
Peto, Fixed, 95% CI

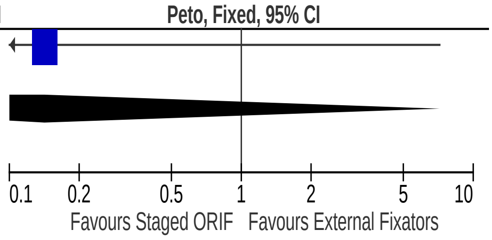


Figure 70: Unplanned further surgery (continuous)

	Staged ORIF			External fixation				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Wyrsch 1996	1.47	2.12	19	0.3	0.57	20	100.0%	1.17 [0.18, 2.16]
Total (95% CI)			**19**			**20**	**100.0%**	**1.17 [0.18, 2.16]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.33 (P = 0.02)								

Mean Difference
IV, Fixed, 95% CI

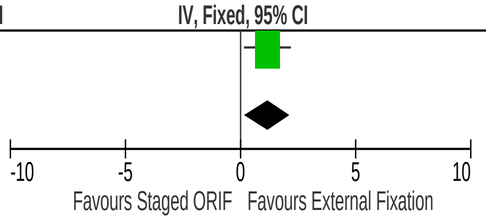


Figure 71: Unplanned further surgery (dichotomous)

Study or Subgroup	Staged ORIF Events	Staged ORIF Total	External fixation Events	External fixation Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Wyrsch 1996	9	19	4	20	100.0%	2.37 [0.87, 6.42]
Total (95% CI)		**19**		**20**	**100.0%**	**2.37 [0.87, 6.42]**
Total events	9		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.70 (P = 0.09)

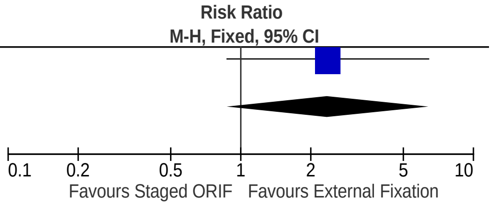


Figure 72: Wound breakdown

Study or Subgroup	Staged ORIF Events	Staged ORIF Total	External fixation Events	External fixation Total	Weight	Risk Difference M-H, Fixed, 95% CI
Wyrsch 1996	6	19	0	20	100.0%	0.32 [0.10, 0.53]
Total (95% CI)		**19**		**20**	**100.0%**	**0.32 [0.10, 0.53]**
Total events	6		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.87 (P = 0.004)

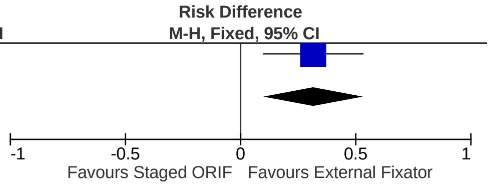
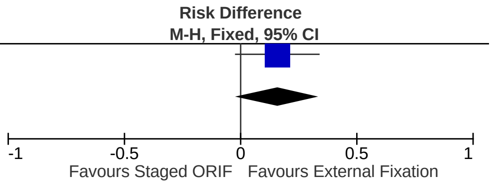


Figure 73: Amputation

Study or Subgroup	Staged ORIF Events	Staged ORIF Total	External fixation Events	External fixation Total	Weight	Risk Difference M-H, Fixed, 95% CI
Wyrsch 1996	3	19	0	20	100.0%	0.16 [-0.02, 0.34]
Total (95% CI)		**19**		**20**	**100.0%**	**0.16 [-0.02, 0.34]**
Total events	3		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.73 (P = 0.08)

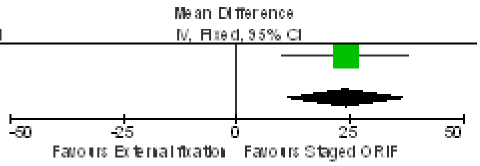


Cohort Data

Figure 74: Health-related quality of life (SF-36 functional Score)

Study or Subgroup	Staged ORIF Mean	Staged ORIF SD	Staged ORIF Total	External fixation Mean	External fixation SD	External fixation Total	Weight	Mean Difference IV, Fixed, 95% CI
Richards 2012	49.7	30.1	27	25.5	18	18	100.0%	24.20 [10.13, 38.27]
Total (95% CI)			27			18	100.0%	24.20 [10.13, 38.27]

Heterogeneity: Not applicable
Test for overall effect: Z = 3.37 (P = 0.0008)



I.4 Other

I.4.1 Detecting compartment syndrome

Diagnostic RCT review

Continuous compartment pressure monitoring versus no compartment pressure monitoring

Figure 75: Sensory loss

Study or Subgroup	Monitored Events	Monitored Total	Unmonitored Events	Unmonitored Total	Risk Ratio M-H, Fixed, 95% CI
Harris 2006	5	71	5	84	1.18 [0.36, 3.92]

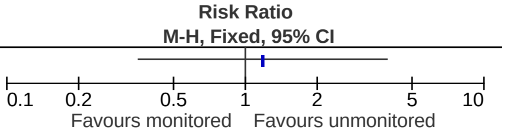
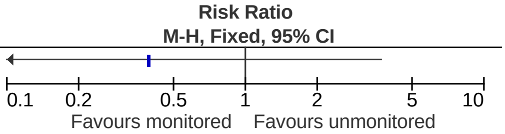


Figure 76: Contracture

Study or Subgroup	Monitored Events	Monitored Total	Unmonitored Events	Unmonitored Total	Risk Ratio M-H, Fixed, 95% CI
Harris 2006	1	71	3	84	0.39 [0.04, 3.71]



Appendix J: Excluded clinical studies

J.1 Open fractures

J.1.1 Limb salvage

Table 1: Studies excluded from the clinical review

Reference	Reason for exclusion
Adegbehingbe, 2006[4]	No usable accuracy data
Agel, 2014[5]	No accuracy data
Bevevino, 2014[42]	Modelling study
Bosse, 2002[50]	No accuracy data
Clement, 2014[69]	No accuracy data
Dua, 2014A[96]	No accuracy data
Dua, 2014[95]	Not assessing accuracy of prediction tools
Fochtmann, 2014[116]	No accuracy data
Fodor, 2012[117]	Review – reference list examined
Gregory, 1985[134]	Developmental study
Guraya, 2004[140]	No accuracy data for salvage group
Hierner, 1995[163]	No accuracy data
Higgins, 2010[164]	Review –references examined
Hoogendoorn, 2002[172]	Review –references examined
Howe, 1987[178]	Developmental study
Krettek, 2001a[223]	Erratum – related to author names
Ly, 2008[242]	Not predicting amputation
Mackenzie, 2006[244]	Not assessing accuracy of prediction tools
Osullivan, 1997[293]	No accuracy data
Poole, 1994[322]	Not assessing accuracy of prediction tools
Shanmuganathan, 2008[365]	Review –references examined
Sharma, 2003	Amputations appeared to be made on the basis of the MESS score
Swionkowski, 2002[387]	Developmental study
Zaraca, 2011[433]	Not an accuracy study

J.1.2 Antibiotics

Table 2: Studies excluded from the clinical review

Reference	Reason for exclusion
Alarabi 2007[7]	Inadequate adjustment for confounders
Alarabi 2008[8]	Corrigendum for ALARABI2007
Bremmer 2012[52]	Abstract
Gonzalez 2014[128]	Did not look at time of antibiotic administration
Grote 2012[136]	Not in English and was not ordered
Hatfield 2012[153]	Conference abstract
Hauser 2006[154]	Review, not systematic

Reference	Reason for exclusion
Hughes 1993[180]	Review, not systematic
Leonidou 2014[234]	No adjustment for key confounders; age and contamination data given but not for each group
Malik 2004[248]	Study does not report outcomes by timing of antibiotics
Mccaul 2013[259]	Conference abstract
Patzakis 1983[311]	Study does not report outcomes by timing of antibiotics
Rojczyk 1979[346]	Not in English
Thomas 2013[392]	Study does not report outcomes by timing of antibiotics
Zumsteg 2014[440]	Unclear MVA inputs. No baseline characteristics provided.

J.1.3 Dressings before debridement

Table 3: Studies excluded from the clinical review

Study	Reason for exclusion
Back 2013[23]	Systematic review is not relevant to review question or unclear PICO
Blum 2012[49]	Incorrect interventions. Post-debridement treatments
Calhoun 1993[60]	Not review population. Chronic osteomyelitis
Contractor 2008[71]	Systematic review is not relevant to review question or unclear PICO
Halvorson 2011[144]	Incorrect study design. Non-comparative study
Kazakos 2009[206]	Incorrect interventions. Plasma rich platelet gel
Keating 1996[207]	Incorrect interventions. Post-debridement treatment
Keen 2012[210]	Incorrect study design
Liu 2012[237]	Incorrect interventions. After debridement
Moehring 2000[276]	Incorrect interventions. Took place after debridement
Moues 2004[281]	Not guideline condition
Ogbemudia 2010[297]	Not review population
Rasool 2013[332]	Dressings applied after debridement
Rinker 2008[342]	Incorrect study design
Runkel 2011[354]	Systematic review is not relevant to review question or unclear PICO
Stannard 2009[380]	Incorrect interventions. After debridement
Stannard 2010[379]	Study design not relevant to review. Review
Tang 2010[389]	Incorrect interventions. Post-debridement treatment
Wright 2007[423]	Incorrect study design
Yuenyongviwat 2011[430]	Incorrect interventions. Only standard dressings

J.1.4 Arterial shunts

Table 4: Studies excluded from the clinical review

Study	Reason for exclusion
Al-salman 1997[10]	Incorrect interventions
Asensio 2006[17]	Incorrect interventions
Ball 2009[28]	Incorrect interventions
Ball 2009[27]	Incorrect interventions
Barros d'sa 2006[33]	Failed to adjust for time to initial vascular repair

Study	Reason for exclusion
Cavadas 2009[64]	Macroreplantations case series
Chambers 2006[65]	Incorrect interventions
Fox 2008[120]	Failed to adjust for time to initial vascular repair
Gifford 2009[123]	failed to adjust for time to initial vascular repair
Granchi 2000[132]	Incorrect interventions
Laohapensang 1994[229]	Incorrect interventions
Nichols 1986[286]	Failed to adjust for time to initial vascular repair
Reber 1999[333]	Incorrect interventions
Subramanian 2008[384]	Incorrect interventions. case series
Taller 2008[388]	Incorrect interventions

J.1.5 MDT

Table 5: Studies excluded from the clinical review

Reference	Reason for exclusion
British Orthopaedic Association, British Association of Plastic Surgeons. The Early Management of Severe Tibial Fractures: The Need for Combined Plastic and Orthopaedic Management : [a Report by the BOA/BAPS Working Party on Severe Tibial Injuries]. Associations; 1993. Available from: http://books.google.co.uk/books?id=swxDHQAACAAJ	Not available from any sources
Court-Brown, Cross AT, Hahn DM, Marsh DR, Willett K, Quaba AAWF et al. A report by the British Orthopaedic Association/British Association of Plastic Surgeons Working Party on the Management of Open Tibial Fractures September 1997. British Journal of Plastic Surgery. 1997; 50(8):570-583	Review article. References checked and one article ordered
Godina M. early microsurgical reconstruction of complex trauma of the extremities. Plast Reconst Surg 1986; 78:285-92	Mixed population containing people without open fractures
Green AR. The courage to co-operate: the team approach to open fractures of the lower limb. Annals of the Royal College of Surgeons of England. 1994; 76(6):365-366	Review. References checked and two articles ordered
Levin LS. The reconstructive ladder: An orthoplastic approach. Orthopedic Clinics of North America. 1993; 24(3):393-409	Review article. References checked and no articles ordered
Moda SK et al. The role of early flap coverage in the management of open fractures of both bones of the	Not relevant to the protocol

Reference	Reason for exclusion
leg. Injury 1994; 25: 83-5 (was in the search)	
Nayagam S, Graham K, Pearse M, Nanchahal J. Reconstructive surgery in limbs: the case for the orthoplastic approach. Annals of Plastic Surgery. 2011; 66(1):6-8	Review article. References checked and no articles ordered
Rahman S, Trickett R, Pallister I. From guidelines to standards of care: Increasing workload, but diminishing patient burden in open tibial fractures. International Journal of Surgery. 2013; 11(8):682	Abstract. Not relevant to protocol
Stammers J, Williams D, Hunter J, Vesely M, Nielsen D. The impact of trauma centre designation on open tibial fracture management. Annals of the Royal College of Surgeons of England. 2013; 95(3):184-187	Groups are not as on protocol. The 'tertiary' group contained 14/15 with a non-combined approach and the 'primary' group had 21/29 with a combined approach. There was sufficient departure from the protocol in these groups to exclude rather than downgrade for indirectness. For example, the 8 in the primary group that were not managed with a combined approach were very uncomplicated orthopaedic cases, and this may have contributed considerably to any advantage in the primary group. There was no sub-grouping of results within the study to allow us to extract only the results pertaining to the cases correlating with the protocol.

J.1.6 Optimal timing of debridement

Table 6: Studies excluded from the clinical review

Reference	Reason for exclusion
Ashford 2004[18]	Inadequate adjustment for confounders
Alarabi 2007[7]	Inadequate adjustment for confounders
Alhilli 2010[9]	Inadequate adjustment of confounders.
Arti 2012[16]	Systematic review does not meet protocol criteria.
Bednar 1993[39]	Inadequate adjustment for confounders.
Dellinger 1988[88]	Does not meet the protocol criteria.
Gougoulias 2009[131]	Systematic review does not look at debridement timing.
Ibrahim 2014[186]	Systematic review does not meet protocol criteria.
Ikem 2001[187]	No Surgical debridement timing comparisons
Ikem 2006[188]	No Surgical debridement timing comparisons
Jacob 1992[190]	No Surgical debridement timing comparisons
Khatod 2003[215]	Inadequate adjustment of confounders.
Kindsfater 1995[217]	Confounders are not compared between treatment groups
Kreder 1995[222]	Insufficient data reported by debridement time. Unclear reporting.
Kurylo 2011[225]	Inadequate adjustment of confounders.
Leonidou 2014[234]	No adjustment for key confounders; age and contamination data given but not for each group
Mclain 1991[262]	Inadequate adjustment of confounders.
Patzakis 1989[310]	Inadequate adjustment of confounders.
Pollak 2010[320]	Does not meet the protocol criteria.

Reference	Reason for exclusion
Reuss 2007[337]	Inadequate adjustment of confounders.
Schenker 2012[364]	Systematic Review. References checked for eligibility
Schenker 2012[364]	Inadequate adjustment of confounders.
Skaggs 2000[370]	Inadequate adjustment for confounders.
Skaggs 2005[371]	Inadequate adjustment for confounders.
Spencer 2004[375]	Inadequate adjustment of confounders.
Srour2015 [377]	No multivariable analysis for Gustillo grade in the light of large differences in proportions of people with each grade across groups
Sungaran 2007[385]	Inadequate adjustment of confounders.
Tripuraneni 2008[399]	Inadequate adjustment of confounders.
Wei 2014[416]	Inadequate adjustment of confounders across the debridement timing groups
Yusof 2013[432]	Inadequate adjustment of confounders.
Zumsteg 2014[440]	No baseline characteristics provided. Unclear what variables were in the logistic regression.

J.1.7 Fixation

Table 7: Studies excluded from the clinical review

Reference	Reason for exclusion
ALLISON2011[11]	No comparison between immediate (early) versus staged (delayed) closure
BALDWIN2009[26]	No comparison between immediate (early) versus staged (delayed) closure
BARTLETT1997[34]	No comparison between immediate (early) versus staged (delayed) closure
BERRY2004[41]	No comparison between immediate (early) versus staged (delayed) closure
BHANDARI2001[43]	No comparison between immediate (early) versus staged (delayed) closure
BLICK1989[48]	No comparison between immediate (early) versus staged (delayed) closure
BREUGEM2006[53]	SR does not meet our inclusion criteria
BUCKLEY1996[55]	Inadequate adjustment for confounders
BURGESS1987[57]	No comparison between immediate (early) versus staged (delayed) closure
BYRD1981[58]	No comparison between immediate (early) versus staged (delayed) closure
BYRD1985[59]	Inadequate adjustment for confounders
CAUDLE1987	Inadequate adjustment for confounders
CIERNY1983[67]	Inadequate adjustment for confounders
COX1970[74]	No comparison between immediate (early) versus staged (delayed) closure
CULLEN1996[78]	No comparison between immediate (early) versus staged (delayed) closure
DALLEYRAND 2014[81]	Unknown when the fracture fixation was carried out in relation to the cover timing

Reference	Reason for exclusion
DAVISSEARS2012[83]	No comparison between immediate (early) versus staged (delayed) closure
DELONG1999[89]	Inadequate adjustment for confounders
DONG2011[93]	No comparison between immediate (early) versus staged (delayed) closure
EDWARDS1983[101]	Not a systematic review
EDWARDS1988[102]	No comparison between immediate (early) versus staged (delayed) closure
ERDMANN1997[108]	No comparison between immediate (early) versus staged (delayed) closure
FERRERA1999[113]	No comparison between immediate (early) versus staged (delayed) closure
FISCHER1991[114]	No comparison between immediate (early) versus staged (delayed) closure
FRANCEL1992[121]	Inadequate adjustment for confounders
GLASS2009A[124]	No comparison between immediate (early) versus staged (delayed) closure
GODINA1986[126]	Inadequate adjustment for confounders
GOPAL2000[129]	Inadequate adjustment for confounders
GOUGOULIAS2009A[130]	No comparison between immediate (early) versus staged (delayed) closure
GREENBAUM2001[133]	No comparison between immediate (early) versus staged (delayed) closure
GRIMARD1996[135]	Inadequate adjustment for confounders
GUSTILO1976[141]	No comparison between immediate (early) versus staged (delayed) closure
HAASBEEK1995[143]	No comparison between immediate (early) versus staged (delayed) closure
HAMMER1992[145]	No comparison between immediate (early) versus staged (delayed) closure
HARLEY2002[147]	Inadequate adjustment for confounders
HARRIS2006[149]	No comparison between immediate (early) versus staged (delayed) closure
HARVEY2002[150]	No comparison between immediate (early) versus staged (delayed) closure
HARWOOD2006[151]	No comparison between immediate (early) versus staged (delayed) closure
HAS1995[152]	No comparison between immediate (early) versus staged (delayed) closure
HEE2001[155]	No comparison between immediate (early) versus staged (delayed) closure
HEIER2003[156]	No comparison between immediate (early) versus staged (delayed) closure
HELLAND1996[158]	No comparison between immediate (early) versus staged (delayed) closure
HENLEY1998[160]	No comparison between immediate (early) versus staged (delayed) closure
HERNIGOU2013[161]	No comparison between immediate (early) versus staged (delayed)

Reference	Reason for exclusion
	closure
HOFFMANN2013[167]	No comparison between immediate (early) versus staged (delayed) closure
HOHMANN2007[168]	Incorrect comparison
HONG1998[171]	No comparison between immediate (early) versus staged (delayed) closure
HOU2011[176]	Inadequate adjustment for confounders
HULL2008[181]	Not a systematic review
HULSKER2011[183]	Incorrect study design included
HUTCHINSON2012[184]	No comparison between immediate (early) versus staged (delayed) closure
HUTSON2010[185]	No comparison between immediate (early) versus staged (delayed) closure
JONES2003[195]	No comparison between immediate (early) versus staged (delayed) closure
JOSHI2006[196]	No comparison between immediate (early) versus staged (delayed) closure
KAI1998[198]	No comparison between immediate (early) versus staged (delayed) closure
KAKAR2007[200]	No comparison between immediate (early) versus staged (delayed) closure
KAMATH2012[202]	Inadequate adjustment for confounders
KEELING2008[209]	No comparison between immediate (early) versus staged (delayed) closure
KESEMENLI2004[212]	No comparison between immediate (early) versus staged (delayed) closure
KIM2012[216]	Outcomes of the protocol not reported
KINZEL2006[218]	Does not meet our protocol
KREDER1995[222]	Outcomes of the protocol not reported
KULSHRESTHA2008[224]	No comparison between immediate (early) versus staged (delayed) closure
LAUGHLIN1993[230]	No comparison between immediate (early) versus staged (delayed) closure
LENARZ2010[232]	No comparison between immediate (early) versus staged (delayed) closure
LEONG1988[233]	Inadequate adjustment for confounders
LERNER2006	No comparison between immediate (early) versus staged (delayed) closure
LOWENBERG1996[239]	No comparison between immediate (early) versus staged (delayed) closure
MACK2013[243]	No comparison between immediate (early) versus staged (delayed) closure
METSEMAKERS2015[268]	Did not cover the review question
MIN2011[269]	Inadequate adjustment for confounders
MODA1994[272]	No comparison between immediate (early) versus staged (delayed) closure
NAIQUE2006[282]	Inadequate adjustment for confounders

Reference	Reason for exclusion
PAPAKOSTIDIS2011[307]	No comparison between immediate (early) versus staged (delayed) closure
PARK2007[308]	No comparison between immediate (early) versus staged (delayed) closure
PARRETT2006[309]	No comparison between immediate (early) versus staged (delayed) closure
POLLAK2000[319]	Intervention does not meet the protocol
POLLAK2010[320]	Outcomes did not meet the protocol
Radoicic 2014[329]	Comparison covered by an RCT. Cohorts with severe contamination were also used in that comparison to allow for fact that the RCT did not include high contamination (Grade III), but Radoicic2014 only involved open fractures with Grade I and II contamination, so was not included.
RAJASEKARAN2009[330]	No comparison between immediate (early) versus staged (delayed) closure
RAO2010[331]	No comparison between immediate (early) versus staged (delayed) closure
RINKER2005[343]	Population does not match the protocol (includes patients who do not have open fractures)
RINKER2008[342]	Inadequate adjustment for confounders
ROMMENS1986[348]	No comparison between immediate (early) versus staged (delayed) closure
RUSSELL1990[355]	No comparison between immediate (early) versus staged (delayed) closure
SHEPHERD1998[366]	Inadequate adjustment for confounders
STALEKAR2003[378]	Inadequate adjustment for confounders
STANNARD2010[379]	Not a systematic review
STEIERT2009[381]	Inadequate adjustment for confounders
SWANSON1991[386]	Inadequate adjustment for confounders
THO1994[391]	No outcomes for comparison between immediate (early) versus staged (delayed) closure
TORCHIA1996[395]	Inadequate adjustment for confounders
TOWNLEY2010[397]	No comparison between immediate (early) versus staged (delayed) closure
WEBB2007[415]	MVA variables unclear
WIDENFALK1979[418]	No comparison between immediate (early) versus staged (delayed) closure
WOOD2012[422]	SR does not match our protocol.
YAREMCHUK1987	No comparison between immediate (early) versus staged (delayed) closure
YOKOYAMA1995[428]	Inadequate controlling for confounders
YOKOYAMA2006A[429]	Inadequate controlling for confounders
YUSOF2013[432]	No comparison between immediate (early) versus staged (delayed) closure
ZATTI2000[434]	No comparison between immediate (early) versus staged (delayed) closure
ZIRAN2004[438]	No comparison between immediate (early) versus staged (delayed)

Reference	Reason for exclusion
	closure

J.1.8 Cover

Table 8: Studies excluded from the clinical review

Reference	Reason for exclusion
ALLISON2011[11]	No comparison between immediate (early) versus staged (delayed) closure
BALDWIN2009[26]	No comparison between immediate (early) versus staged (delayed) closure
BARTLETT1997[34]	No comparison between immediate (early) versus staged (delayed) closure
BERRY2004[41]	No comparison between immediate (early) versus staged (delayed) closure
BHANDARI2001[43]	No comparison between immediate (early) versus staged (delayed) closure
BLICK1989[48]	No comparison between immediate (early) versus staged (delayed) closure
BREUGEM2006[53]	SR does not meet our inclusion criteria
BUCKLEY1996[55]	Inadequate adjustment for confounders
BURGESS1987[57]	No comparison between immediate (early) versus staged (delayed) closure
BYRD1981[58]	No comparison between immediate (early) versus staged (delayed) closure
BYRD1985[59]	Inadequate adjustment for confounders
CAUDLE1987	Inadequate adjustment for confounders
CIERNY1983[67]	Inadequate adjustment for confounders
COX1970[74]	No comparison between immediate (early) versus staged (delayed) closure
CULLEN1996[78]	No comparison between immediate (early) versus staged (delayed) closure
DAVISSEARS2012[83]	No comparison between immediate (early) versus staged (delayed) closure
DELONG1999[89]	Inadequate adjustment for confounders
DONG2011[93]	No comparison between immediate (early) versus staged (delayed) closure
EDWARDS1983[101]	Not a systematic review
EDWARDS1988[102]	No comparison between immediate (early) versus staged (delayed) closure
ERDMANN1997[108]	No comparison between immediate (early) versus staged (delayed) closure
FERRERA1999[113]	No comparison between immediate (early) versus staged (delayed) closure
FISCHER1991[114]	No comparison between immediate (early) versus staged (delayed) closure
FRANCEL1992[121]	Inadequate adjustment for confounders
GLASS2009A[124]	No comparison between immediate (early) versus staged (delayed) closure

Reference	Reason for exclusion
GODINA1986[126]	Inadequate adjustment for confounders
GOPAL2000[129]	Inadequate adjustment for confounders
GOUGOULIAS2009A[130]	No comparison between immediate (early) versus staged (delayed) closure
GREENBAUM2001[133]	No comparison between immediate (early) versus staged (delayed) closure
GRIMARD1996[135]	Inadequate adjustment for confounders
GUSTILO1976[141]	No comparison between immediate (early) versus staged (delayed) closure
HAASBEEK1995[143]	No comparison between immediate (early) versus staged (delayed) closure
HAMMER1992[145]	No comparison between immediate (early) versus staged (delayed) closure
HARLEY2002[147]	Inadequate adjustment for confounders
HARRIS2006[149]	No comparison between immediate (early) versus staged (delayed) closure
HARVEY2002[150]	No comparison between immediate (early) versus staged (delayed) closure
HARWOOD2006[151]	No comparison between immediate (early) versus staged (delayed) closure
HAS1995[152]	No comparison between immediate (early) versus staged (delayed) closure
HEE2001[155]	No comparison between immediate (early) versus staged (delayed) closure
HEIER2003[156]	No comparison between immediate (early) versus staged (delayed) closure
HELLAND1996[158]	No comparison between immediate (early) versus staged (delayed) closure
HENLEY1998[160]	No comparison between immediate (early) versus staged (delayed) closure
HERNIGOU2013[161]	No comparison between immediate (early) versus staged (delayed) closure
HOFFMANN2013[167]	No comparison between immediate (early) versus staged (delayed) closure
HONG1998[171]	No comparison between immediate (early) versus staged (delayed) closure
HOU2011[176]	Inadequate adjustment for confounders
HULL2008[181]	Not a systematic review
HULSKER2011[183]	Incorrect study design included
HUTCHINSON2012[184]	No comparison between immediate (early) versus staged (delayed) closure
HUTSON2010[185]	No comparison between immediate (early) versus staged (delayed) closure
JONES2003[195]	No comparison between immediate (early) versus staged (delayed) closure
JOSHI2006[196]	No comparison between immediate (early) versus staged (delayed) closure
KAI1998[198]	No comparison between immediate (early) versus staged (delayed)

Reference	Reason for exclusion
	closure
KAKAR2007[200]	No comparison between immediate (early) versus staged (delayed) closure
KAMATH2012[202]	Inadequate adjustment for confounders
KEELING2008[209]	No comparison between immediate (early) versus staged (delayed) closure
KESEMENLI2004[212]	No comparison between immediate (early) versus staged (delayed) closure
KIM2012[216]	Outcomes of the protocol not reported
KINZEL2006[218]	Does not meet our protocol
KREDER1995[222]	Outcomes of the protocol not reported
KULSHRESTHA2008[224]	No comparison between immediate (early) versus staged (delayed) closure
LAUGHLIN1993[230]	No comparison between immediate (early) versus staged (delayed) closure
LENARZ2010[232]	No comparison between immediate (early) versus staged (delayed) closure
LEONG1988[233]	Inadequate adjustment for confounders
LERNER2006	No comparison between immediate (early) versus staged (delayed) closure
LOWENBERG1996[239]	No comparison between immediate (early) versus staged (delayed) closure
MACK2013[243]	No comparison between immediate (early) versus staged (delayed) closure
MIN2011[269]	Inadequate adjustment for confounders
MODA1994[272]	No comparison between immediate (early) versus staged (delayed) closure
NAIQUE2006[282]	Inadequate adjustment for confounders
PAPAKOSTIDIS2011[307]	No comparison between immediate (early) versus staged (delayed) closure
PARK2007[308]	No comparison between immediate (early) versus staged (delayed) closure
PARRETT2006[309]	No comparison between immediate (early) versus staged (delayed) closure
POLLAK2000[319]	Intervention does not meet the protocol
RAJASEKARAN2009[330]	No comparison between immediate (early) versus staged (delayed) closure
RAO2010[331]	No comparison between immediate (early) versus staged (delayed) closure
RINKER2005[343]	Population does not match the protocol (includes patients who do not have open fractures)
RINKER2008[342]	Inadequate adjustment for confounders
ROMMENS1986[348]	No comparison between immediate (early) versus staged (delayed) closure
RUSSELL1990[355]	No comparison between immediate (early) versus staged (delayed) closure
SHEPHERD1998[366]	Inadequate adjustment for confounders
STANNARD2010[379]	Not a systematic review

Reference	Reason for exclusion
STEIERT2009[381]	Inadequate adjustment for confounders
SWANSON1991[386]	Inadequate adjustment for confounders
THO1994[391]	No outcomes for comparison between immediate (early) versus staged (delayed) closure
TORCHIA1996[395]	Inadequate adjustment for confounders
TOWNLEY2010[397]	No comparison between immediate (early) versus staged (delayed) closure
WEBB2007[415]	MVA variables unclear
WIDENFALK1979[418]	No comparison between immediate (early) versus staged (delayed) closure
WOOD2012[422]	SR does not match our protocol.
YAREMCHUK1987	No comparison between immediate (early) versus staged (delayed) closure
YOKOYAMA1995[428]	Inadequate controlling for confounders
YOKOYAMA2006A[429]	Inadequate controlling for confounders
YUSOF2013[432]	No comparison between immediate (early) versus staged (delayed) closure
ZATTI2000[434]	No comparison between immediate (early) versus staged (delayed) closure
ZIRAN2004[438]	No comparison between immediate (early) versus staged (delayed) closure
JENKINSON2014 [193]	No timing data
EGOL2005 [103]	Non comparative study
SCHEMITSCH2012 [363]	No timing data
LIU2012[237]	No immediate cover group

J.1.9 Definitive dressings after debridement

Table 9: Studies excluded from the clinical review

Study	Reason for exclusion
Back 2013[23]	Systematic review is not relevant to review question or unclear PICO
Blum 2012[49]	Study design not relevant to review. Cohort study
Calhoun 1993[60]	Not review population. Chronic osteomyelitis
Contractor 2008[71]	Systematic review is not relevant to review question or unclear PICO
Halvorson 2011[144]	Incorrect study design. Non-comparative study
Kazakos 2009[206]	Incorrect interventions. Plasma rich platelet gel
Keating 1996[207]	Incorrect intervention: bead group not given concomitant IV antibiotics
Keen 2012[210]	Incorrect study design
Liu 2012[237]	Study design not relevant to review. Cohort study
Moehring 2000[276]	Incorrect interventions: antibiotic beads not given alongside IV antibiotics
Moues 2004[281]	Not guideline condition
Ogbemudia 2010[297]	Not review population
Rinker 2008[342]	Incorrect study design
Runkel 2011[354]	Systematic review is not relevant to review question or unclear PICO

Study	Reason for exclusion
Stannard 2010[379]	Study design not relevant to review. Review
Tang 2010[389]	Incorrect study design. Case series
Wright 2007[423]	Incorrect study design
Yuenyongviwat 2011[430]	Incorrect interventions. Only standard dressings

J.2 Pelvic fractures

J.2.1 Transfer to MTC

Table 10: Studies excluded from the clinical review

Study	Reason for exclusion
Bouzat 2013[51]	Article in French
Demetriades 2005[90]	Does not compare intervention of interest directly with each other

J.2.2 Decision for pelvic binders

Table 11: Studies excluded from the clinical review

Reference	Reason for exclusion
Baumann 2011[35]	Evaluated eFAST - not a risk tool and eFAST not used pre-hospital
Reynolds 2014A[338]	Abstract only

J.2.3 Timing of log roll

Table 12: Studies excluded from the clinical review

Reference	Reason for exclusion
Block2001	Review

J.2.4 Pelvic imaging

Table 13: Studies excluded from the clinical review

Reference	Reason for exclusion
Dormagen 2010[94]	Inappropriate study design: Diagnosis of arterial injury
Duane 2008[97]	Inappropriate study design: Initial CT as reference standard
Falchi 2004[111]	Systematic review no meta-analysis: Used to source references only
Guillamondegui 2003[138]	Inappropriate study design: Initial CT as reference standard
Harley 1982[148]	Inappropriate study design: Initial CT+X-ray as reference standard
Henes 2012[159]	Inappropriate study population: Low or moderate energy pelvic fractures in elderly population
Holmes 2012[169]	Inappropriate study design: Initial CT as reference standard
Kirby 2010[219]	Inappropriate study design: MRI as reference standard
Obaid 2006[295]	Inappropriate study design: Initial CT as reference standard
O'Shea 2006[292]	Inappropriate study design: Post-operative imaging
O'Toole 2001[294]	Inappropriate study design: Inter-rater reliability of imaging strategies
Magid 1986[247]	Inappropriate study design: Initial CT as reference standard
Nuchtern 2015[289]	Inappropriate study population: Low or moderate energy pelvic fractures

Reference	Reason for exclusion
	in elderly population
Paydar 2013[312]	Case series: No comparative or diagnostic accuracy data
Potter 1994[323]	Inappropriate study design: Surgical findings as reference standard, but evidence of missed fractures with gold standard
Resnik 1992[336]	Inappropriate study design: Initial CT as reference standard
Robertson 1995[345]	Inappropriate study design: Initial CT as reference standard
Their 2005[390]	Inappropriate study design: Initial CT as reference standard
Vo2004[411]	Inappropriate study design: Initial CT as reference standard
Yugueros1995 [431]	Inappropriate study design: No relevant index test

J.2.5 Pelvic cystourethrogram

Table 14: Studies excluded from the clinical review

Reference	Reason for exclusion
Carroll 1983[63]	Incorrect population: all patients had bladder rupture
Deck 2000[86]	CT scanner utilised not MDCT
Deck 2001[87]	CT scanner utilised not MDCT
Haas 1999[142]	CT scanner utilised not MDCT
Horstman 1991[174]	CT scanner utilised not MDCT
Kailidou 2005[199]	No separate data for bladder injury
Kane 1989[203]	CT scanner utilised not MDCT
Luckhoff 2011[240]	Incorrect diagnostic test: urethral injury
Marks 2012[252]	Case report
Mokoena 1995[277]	Prognostic factor study
Morey 2001[278]	Not a diagnostic accuracy or effectiveness study
Morgan 2000[279]	Prognostic factor study
Pao 2000[305]	CT scanner utilised not MDCT
Peng 1999[313]	CT scanner utilised not MDCT
Quagliano 2006[328]	One CT scanner utilised not MDCT
Rehm 1991[335]	No accuracy data presented
Spencer Netto 2008[374]	Incorrect population: all patients had bladder/urethral injuries
Stengel 2012[382]	No separate data for bladder injury
Udekwu 1996[402]	CT scanner utilised not MDCT
Ziran 2005[439]	Not a diagnostic accuracy or effectiveness study

J.2.6 Pelvic haemorrhage control

Table 15: Studies excluded from the clinical review

Study	Reason for exclusion
Abrassart 2013[3]	Groups in the study not adjusted for confounders
Akbar 2012[6]	Internal fixation is not used to treat pelvic haemorrhage
Anandakumar 2013[12]	Compared angiogram (with some that had EA) against no angiogram.
Baylis 2004[36]	No intervention of interest

Study	Reason for exclusion
Beard 1988[37]	No comparison of intervention in the study
Biffl 2001[45]	study does not report outcomes separately for the interventions
Burgess 1990[56]	No comparison of interventions in the study
Clamp 2011[68]	Review
Cook 2002[72]	No direct comparison of interventions in the study
Croce 2007[75]	POD vs. Ex fixation. POD is not an invasive technique
Cullinane 2011[79]	Review
Davis 2008[84]	Review
Ertel 2001[109]	No direct comparison of interventions in the study
Evers 1989[110]	Groups not adjusted for confounders
Flint 1990[115]	No outcomes reported for interventions and groups in the study not adjusted for confounders
Goins 1992[127]	No comparison of interventions in the study
Grubor 2011[137]	Groups were not adjusted for confounders and data was not reported for groups separately
Hu 2013[179]	Review
Keel 2005[208]	review
Lai 2008[226]	case-series with no relevant data
Langford 2013[228]	Review
Lustenberger 2011[241]	looks at intervention pelvic c-clamp followed by pelvic packing
Mauffrey 2014[255]	Review
Mlyncek 2005[271]	Review
O'flanagan 1992[291]	Internal fixation is a technique to stabilise fracture, not control pelvic haemorrhage
Osborn 2009[302]	half of the angiogram group did not undergo embolisation
Pizanis 2013[316]	c-clamp compared against non-invasive techniques in study
Plaisier 2000[317]	No comparison of interventions in the study
Ricci 2014[339]	Review
Richardson 1982[341]	Case-series study
Ruchholtz 2004[353]	Groups in the study not adjusted for confounders
Sadri 2005[356]	Groups not adjusted for confounders
Sriussadaporn 2002[376]	Groups in the study not adjusted for confounders
Uchida 2011[401]	Groups in the study not adjusted for confounders
Van veen 1995[405]	No direct comparisons between interventions in the study
Verbeek 2008[408]	Review
Vigdorchik 2012[410]	Internal fixation device only
Waikakul 1999[412]	external fixation compared with a non-invasive conventional method of treatment
Yang 2008[426]	No direct comparison of interventions in the study
Zhao 2011[437]	Review

J.3 Pilon fractures

J.3.1 Pilon early fixation

Table 16: Studies excluded from the clinical review

Study	Reason for exclusion
Anglen 1999[13]	Incorrect interventions
Bacon 2008[24]	Inappropriate comparison
Bacon 2008[24]	Both groups with same timing
Binda 2011[46]	Abstract
Blauth 2001[47]	No adjustment for open or closed
Calori 2010[61]	Incorrect interventions
Court-brown 1999[73]	Incorrect interventions
Cronier 2012[76]	Non-systematic review
Crutchfield 1995[77]	Incorrect interventions
Gulabi 2012[139]	Incorrect interventions
Horn 2011[173]	Incorrect interventions
Kapukaya 2005[204]	Case series
Katsenis 2009[205]	Incorrect interventions
Ketz 2012[214]	Incorrect interventions
Ketz 2012[213]	Case series
Korkmaz 2013[220]	Incorrect interventions
Li 2012[236]	Incorrect interventions
Mandracchia 1999[250]	Non-systematic review
Marsh 1995[254]	Incorrect interventions
Mauffrey 2011[256]	Non-systematic review
Mcferran 1992[260]	Incorrect interventions
Okcu 2004[299]	Incorrect interventions
Papadokostakis 2008[306]	Systematic review is not relevant to review question or unclear PICO
Pollak 2003[321]	The staging/timing categories in protocol were not evaluated in this cohort study
Pugh 1999[325]	Incorrect interventions
Purghel 2012[327]	Non-systematic review
Richard 2012[340]	Both groups had same category of delay to definitive treatment
Salton 2007[360]	No protocol outcomes
Sirkin 1999[369]	Incorrect interventions
Trumble 1993[400]	Incorrect interventions
Vasiliadis 2009[407]	Not relevant to protocol
Wang 2010[413]	Both groups had same delay to definitive treatment
Watson 2000[414]	Incorrect interventions
Wyrsch 1996[425]	No analysis for staging or timing
Zeng 2011[435]	No outcomes reported for group comparison

J.3.2 Pilon fixation

Table 17: Studies excluded from the clinical review

Reference	Reason for exclusion
Anglen1999[13]	Mixed groups (temporary external fixation)
Babis1997[22]	Inadequate reporting of confounders.
Bacon 2008 [24]	Non-randomised study. Does not report health-related quality of life.
Baloch2009[29]	Cancelled order- descriptive study and was unable to be found
Blauth2001[47]	Inadequate reporting of confounders
Binda2011[46]	Abstract
Calori2010[61]	Includes case series.
Crutchfield1995[77]	Inadequate reporting of confounders
Davidovitch 2011 [82]	Non-randomised study. Does not report health-related quality of life.
Elkhechen2012[104]	Duplication - not ordered
Endres2004[106]	Not in English
Gulabi2012[139]	Inadequate reporting of confounders
Harris2006[149]	Inadequate adjustment of confounders. Unbalanced for age, and grade at baseline.
Helfet1994[157]	Unclear who had initial ext. fixation. Inadequate reporting of confounders.
Joveniaux2010[197]	Not pilon fracture specific
Kendig1997[211]	Not a systematic review
Korkmaz2013[220]	Inadequate reporting of confounders
Koulouvaris2007[221]	Interventions were not those specified in protocol
Marsh1999[253]	Not a systematic review
Ovadia 1986[303]	Comparator was a mixed treatment. No adjustment for key confounders
Pierce1979[314]	All internal fixation
Pollack 2003[321]	Non-randomised study. Does not report health-related quality of life.
Pugh1999[325]	Inadequate reporting of confounders
Puha2014[326]	Doesn't meet protocol comparisons
Ristiniemi2011[344]	Not pilon fracture specific
Salmenkivi1999[359]	Not in English
Watson2000[414]	Inadequate reporting of confounders
Willet2008[419]	Cochrane protocol.
Williams1998[420]	Does not meet protocol comparisons
Williams2004[421]	All patients had external fixation with limited internal fixation.
Wyrsch1996[425]	Not a proper RCT. Inadequate adjustment of confounders at baseline.
Zeng2011[435]	No baseline characteristics (age included)

J.4 Other

J.4.1 Identifying vascular compromise

Table 18: Studies excluded from the clinical review

Reference	Reason for exclusion

Reference	Reason for exclusion
Eastman2006[100]	Not extremity trauma.
Fry1993[122]	No baseline characteristics.
Levy2005[235]	Not a systematic review
Lord1974[238]	Not a systematic review
Maclean1964[245]	Only includes case reports
Pieroni2009[315]	Not a systematic review
Redmond2008[334]	Not a systematic review
Romano2012[347]	Not a systematic review
Rose1987[349]	27% had blunt injury – rest were penetrating. No mention of fractures.
Rose1988[350]	Not a diagnostic paper.

J.4.2 Detecting compartment syndrome

Table 19: Studies excluded from the clinical review

Reference	Reason for exclusion
BROOKER1979[54]	Mixed population (extremity wounds)
HANSEN2013[146]	Not RCT/diagnostic accuracy study
KALYANI2011[201]	Systematic review (irrelevant inclusion criteria)
MCQUEEN1996B[263]	Not RCT/No sensitivity or specificity data
MITTLMEIER1991[270]	Not RCT/No sensitivity or specificity data
OGUNLUSI2005A[298]	Not RCT/No sensitivity or specificity data
OVRE1998[304]	Not RCT/No sensitivity or specificity data
ROYLE1992[352]	Not RCT/diagnostic accuracy study
SAIKIA2008[358]	Not RCT/No sensitivity or specificity data
TRIFFITT1992[398]	Not RCT/No sensitivity or specificity data
UPPAL1992[404]	Not RCT/No sensitivity or specificity data
WHITNEY2014[417]	Not RCT/No sensitivity or specificity data

J.4.3 Splinting of lower limb long bone fractures

Table 20: Studies excluded from the clinical review

Reference	Reason for exclusion
CHU2003[66]	Incorrect interventions: not box splint
IRAJPOUR2012[189]	Incorrect interventions: not box splint
LEMBO1975[231]	Study not in English
PODESZWA2004[318]	Incorrect interventions: not box splint
SHORT1984[367]	Incorrect interventions: not box splint
THOMAS1981[393]	Incorrect interventions: not box splint

J.4.4 Hip reduction

Table 21: Studies excluded from the clinical review

Reference	Reason for exclusion
Ashley, 1972 [19]	Review; references screened

Reference	Reason for exclusion
Barquet, 1982 [31]	Inadequate adjustments for key confounders
Barquet, 1982 [32]	Only some with open reduction and analysis not sub-grouped for these.
Bergman, 1994 [40]	Unrelated to review question
Bhandari, 2006 [44]	Dislocation reduction was closed; only fracture repair was open
de Palma, 2014 [85]	No analysis of timing
Dwyer, 2006 [99]	Inadequate adjustments for key confounders
Epstein, 1974 [107]	Inadequate adjustments for key confounders
Fordyce, 1971 [118]	Case report
Herwig-Kempers, 1993 [162]	Unrelated to review question
Hillyard, 2003 [165]	Unclear if reductions were open
Hougaard, 1986 [177]	Only some with open reduction and analysis not sub-grouped for these.
Jacob, 1987 [191]	Only some with open reduction and analysis not sub-grouped for these.
Marchetti, 1996 [251]	Timing was <24 hours versus >24 hours
McKee, 1998 [261]	Inadequate adjustments for key confounders
Mehlman, 2000 [265]	Only some with open reduction and analysis not sub-grouped for these.
Mehta, 2008 [266]	Inadequate adjustments for key confounders
Moed, 2000 [274]	Dislocation reduction was closed; only fracture repair was open
Moed, 2002 [275]	Dislocation reduction was closed; only fracture repair was open
Morsy Drch, 2001 [280]	Dislocation reduction was closed; only fracture repair was open
Rosenthal, 1979 [351]	Only some with open reduction and analysis not sub-grouped for these.
Sahin, 2003 [357]	Only some with open reduction and analysis not sub-grouped for these.
Sanders, 2010 [362]	Review; references screened
Sturrock, 1899 [383]	Unrelated to review question; archaic
Toni, 1985 [394]	Inadequate adjustments for key confounders
Upadhyay, 1981 [403]	Timing not considered
Vialle, 2005 [409]	Only some with open reduction and analysis not sub-grouped for these.
Yang, 1991 [427]	Only some with open reduction and analysis not sub-grouped for these.
Zha, 2013 [436]	Dislocation reduction was closed; only fracture repair was open

J.4.5 Full-body CT

Table 22: Studies excluded from the clinical review

Reason for exclusion	Reason for exclusion
Beck 2012[38]	Review article but no RCT's included
Caputo 2014[62]	Review article but no RCT's included
Ptak 2001[324]	Retrospective study and does not include outcomes of interest
Saltzherr 2009[361]	Correspondence article
Van vugt 2012[406]	All studies included in the review were not RCT's

J.4.6 Documentation of open fracture wound photographs

Table 23: Studies excluded from the clinical review

Reference	Reason for exclusion
Solan MC, Calder JDF, Gibbons CER, Ricketts DM. [373] Photographic wound documentation after open fracture. Injury, Int J care Injured 2001; 32: 33-35	Not relevant to review question

J.4.7 Documentation of neurovascular compromise

Table 24: Studies excluded from the clinical review

Study	Reason for exclusion
Johnston-walker 2011[194]	Not primary research
Mayne 2013[258]	No clinical outcomes linked to completeness of neurovascular documentation
Wright 2007[424]	No clinical outcomes linked to completeness of documentation recording neurovascular compromise

J.4.8 Information and support

Table 25: Studies excluded from the clinical review

Reference	Reason for exclusion
Aravind 2010[14]	No information themes
Archibald 2003[15]	No information themes
Atchison 2005[20]	Not about patients' thoughts and feelings about information desired. This paper concerned whether patients recalled being given specific information
Azam 2011[21]	Non qualitative
Bagely 2011[25]	Non qualitative
Congdon 1994[70]	Hip fracture
Elliot 2014[105]	Hip fracture
Glenny 2013[125]	Hip fracture
Hommel 2012[170]	Hip fracture
Hossieny 2012[175]	Non qualitative
Jariwala 2004[192]	Did not reveal participants' feelings about information desired.
Lam 2011[227]	Non qualitative
Macleod 2005[246]	Hip fracture
Malin Malmgren 2014[249]	Hip fracture
Mayich 2013[257]	Non qualitative
Meadows 2005[264]	Non-trauma population – fragility fractures
Meredith 1993[267]	Non qualitative
Modin 2009[273]	No information themes
Nielsen 2013[287]	Non-trauma population – fragility fractures
Olson 1990[301]	Spinal fractures

Reference	Reason for exclusion
O'Toole 2001[294]	Non qualitative
Shyu 2010[368]	Non qualitative
Toscan 2012[396]	Hip fracture

Appendix K: Excluded economic studies

K.1 Pelvic fractures

K.1.1 Pelvic imaging

Table 26: Excluded studies

Reference	Reason for exclusion
Feeney 2011[112]	This study was assessed as partially applicable with very serious limitations. It is a retrospective cost comparison looking at the savings involved if patients who are haemodynamically unstable and already having a CT are withheld a pelvic X-ray. The study is from a US perspective which is not particularly applicable to the UK setting. It does not include any health effects or downstream costs/consequences and is thus of limited usefulness.
Barleben 2011[30]	This study was assessed as partially applicable with very serious limitations. It is a prospective cost comparison looking at the savings involved if an algorithm is used which outlines that patients who are undergoing a CT should only receive a pelvic X-ray if they fulfil certain haemodynamic/physiologic criteria. The study is from a US perspective which is not particularly applicable to the UK setting. It does not include quality of life and is thus of limited usefulness.

Appendix L: Cost analysis for open fractures

L.1 Introduction

L.1.1 Background

A fracture that breaks through the skin is called an open fracture. There are different grades of open fracture defined by the Gustilo-Anderson fracture classification system, each of which depends on the level of tissue damage and whether there is a vascular injury that requires repair. Those with vascular compromise require emergency treatment to re-vascularise the limb and so are not relevant to the analysis for the timing of debridement. For those who do not have vascular compromise, the main concern is that the wound can become infected. If this infection is only superficial then it can be treated easily with a course of antibiotics. However, if this infection becomes deep then the treatment may require a series of additional procedures which can greatly increase costs. There is also a risk that the limb would require amputation, which would have a further cost and quality of life impact. In some cases deep infection could even result in death.

Treatment for open fractures has three main stages: debridement, fixation and soft tissue cover. Debridement, which is performed by an orthopaedic surgeon, involves cleaning the wound and removing any contaminated, unsalvageable or dead tissue. The timing of debridement is known to affect the risk of infection, and a clinical review (see chapter 6.7 of the complex fractures full guideline) was undertaken to identify to what extent early debridement can improve outcomes. In some hospitals across the UK, debridement is performed with the support of a plastic surgeon. The presence of a plastic surgeon in theatre allows the orthopaedic surgeon to utilise the expert knowledge of the plastic surgeon regarding the quantity of soft tissue that can be removed while still allowing for a successful cover procedure to be performed once fixation is complete. The rationale for this is that without this expert input, the orthopaedic surgeon may be too cautious and try to preserve as much tissue as possible in order to aid the later cover procedure. However, this can lead to a higher risk of infection as some contaminated tissue may still remain. The presence of a plastic surgeon can therefore help to reduce this risk but comes with the additional staffing cost for the duration of the procedure.

Fixation can involve one definitive procedure or it can be staged with an initial temporary fixator followed by later definitive fixation. These fixation procedures are performed by an orthopaedic surgeon and some form of fixation will occur immediately following debridement, whether it is definitive or temporary. Definitive fixation will only be delayed if a temporary fixator is applied immediately after debridement.

After debridement and definitive fixation have been completed, the open wound needs to be closed and covered by the surrounding soft tissue. This cover procedure is performed by a plastic surgeon and can be done immediately after definitive fixation or it can be delayed. Depending on the extent of the tissue damage, either a local flap procedure or a longer free flap procedure maybe required; the need for which can only be determined following the initial debridement. Until soft tissue cover has been successfully achieved, there is a risk of acquiring infection. Therefore the timing of the intervention is important in order to reduce this risk and the risk of other adverse events that require costly treatment and can have long term quality of life implications. The optimal timing of soft tissue cover may require a service delivery change by increasing the number of surgery lists, that is, the number of theatre days dedicated to orthoplastic procedures each week.

L.1.1.1 Exploration of TARN

Initially, a discrete event simulation model was planned, using the TARN database as a source of data to estimate the treatment effect of the interventions outlined above (see more detail on this in Appendix O:).The TARN database was explored primarily to find the effect of the timing of debridement, with and without the presence of a plastic surgeon, on the risk of deep infection and subsequent amputation as key outcomes. The analysis would also incorporate the number of theatre sessions the operations may take place in. In other words, this was attempting to inform the cost effectiveness of questions 1, 2 and 4 above. A brief overview of this model is provided below.

The population will include adults and children with open fractures. The strategies included in the model can be seen in Table 27.

Table 27: Proposed model strategies

Procedure combination	Theatre session 1	Theatre session 2	Theatre session 3
Option 1	A. Debridement B. Definitive fixation C. Definitive soft tissue cover	NA	NA
Option 2	A. Debridement B. Definitive fixation	C. Definitive cover	NA
Option 3	A. Debridement B. Temporary fixation	C. Definitive fixation D. Definitive soft tissue cover	NA
Option 4	A. Debridement B. Temporary fixation	C. Definitive fixation	D. Definitive soft tissue cover

Other components of the strategies include:

- The time of the initial debridement (<6 hours, 6-12 hours, 12-24 hours, >24 hours.)
- The presence of a plastic surgeon at the initial debridement

Outcomes included are:

- Time to death
- Time to deep infection
- Flap failure
- Amputation
- Length of hospital stay
- Number of unplanned operations (between debridement and cover)
- Time to soft tissue cover

Confounders that it felt should be adjusted for include:

- Age
- Grade of fracture (Gustilo Anderson)
- Upper/lower limb
- ISS
- The type and timing of prophylactic antibiotics that are given.
- Type of dressings used pre-debridement and post debridement.
- Type of definitive fixation (Temporary fixation should always be external).
- Method of soft tissue cover used (local flap or free flap).
- Polytrauma

- Major Trauma Centre or Trauma Unit

This model approach however was not developed further, after initial exploration of TARN for other guidelines on the trauma suite revealed that TARN data had limitations that deemed it not appropriate to use for our research purposes. For further detail on these limitations please see Major trauma economic model in appendix M of the major trauma guideline.

In addition to these limitations, for the complex fracture guideline, TARN was not felt to be appropriate because of difficulties in analysing certain codes in the database. A key limitation of the TARN database is that there is no direct link between each specific injury code and the related procedure code. This makes it difficult to identify the time of debridement for a specific open fracture in a patient with polytrauma. Although a clinician may be able to identify the sequence of procedures when looking at the data for each individual, it is not feasible to do this for 25,000 records and the computational coding cannot be adjusted to identify this accurately.

Another key limitation is that some of the procedure codes are not specific enough. This makes it difficult to identify the indication for an amputation for instance. We were interested in amputations resulting from deep infection as an outcome of debridement, however, patients who had an amputation due to an unsalvageable limb, compartment syndrome or a vascular injury would also have the same amputation code. This means that the analysis cannot accurately assess the effect on the risk of amputation that the timing of debridement has. Furthermore, the severity of the infection is not clearly defined, as it is not specified whether the infection is deep or superficial. This also makes it difficult to accurately assess our important outcomes.

The GDG thought a costing analysis would be helpful and alongside the limited clinical evidence identified would help them make a recommendation. The model was therefore downgraded to a costing analysis but was extended to look at the cost implications of the timing of definitive soft tissue cover also. The remainder of this appendix discusses the costing analyses that were undertaken.

L.1.2 Overview of analyses

The aim of this analysis is to inform the GDG of the cost implications for the open fracture questions that relate to the timing of the initial debridement, the provision of plastic surgery services for the initial debridement and the increase in the number of surgery lists made available for definitive soft tissue cover. Three separate analyses are presented in section L.2 to L.4 to help answer the questions outlined in section L.1.3 below.

This analysis was intended to focus on issues of additional plastic surgery services and therefore will not specifically look at the costs of fixation. However, a costing comparing different numbers of theatre sessions is included in section L.4 to demonstrate the cost of performing procedures in either one or more stages. This captures the staff cost implications when fixation and/or soft tissue cover is staged, but the cost of metal implants and fixation devices is not included in this analysis.

L.1.3 Questions and comparators relating to each analysis

The first analysis in section L.2 will address the two questions below:

1. What is the optimal timing of the initial debridement of open fractures?

    1. <6 hours
    2. 6 – 12 hours
    3. 12 – 24 hours

4. >24 hours

2. Is the presence of an orthopaedic surgeon and plastic surgeon at the initial surgical excision and stabilisation of an open fracture clinically and cost effective?

    1. Orthopaedic and plastic surgeon present in theatre
    2. Only orthopaedic surgeon present in theatre

The second analysis in section L.3 will address the question below:

3. What is the most clinically and cost effective time to achieve definitive soft tissue cover in open fractures?

    1. Immediate
    2. 1 day
    3. 3 days
    4. 7 days
    5. >7 days

The third analysis in section L.4 will address the trade-offs in staff time when fixation and/or cover is staged. This will help to inform the impact on cost for the question below and how that is affected by the presence of a plastic surgeon at debridement.

4. Is the use of initial definitive fixation and cover more clinically and cost effective in the management of open fractures compared to with staged fixation and cover?

L.1.4 Population

The population assessed are patients presenting with an open fracture that requires plastic surgery to cover the open wound after initial procedures have been performed.

L.2 Debridement cost analysis

L.2.1 Methods

The key cost impact for earlier debridement is that there will be an increased need for surgery during premium time, when theatre staff receive a higher rate of pay. For consultants, this is defined as 7pm until 7am on weekdays and all day on weekends and public holidays. Nurses and radiographers have different hours for premium time which are defined as 8pm until 6am on weekdays and all day Saturday. On Sundays and public holidays, a higher premium rate is paid for these staff. Registrars have a different arrangement as well and their premium time hours are from 7pm to 8am on weekdays and all day on weekends and public holidays. The salary enhancement for work performed in premium time will increase the cost of treatment for a proportion of patients when the time to debridement falls within this period. According to the clinical review, the outcomes of deep infection and amputation are reduced when debridement is performed earlier and so costs saved here could outweigh the cost of the increased salary for premium time work. Further detail on the times of premium time and the enhancement rates can be seen in Table 28 below. As the premium time bounds are slightly different for different staff, it was assumed for simplicity that no procedures would be performed during the hours where there is discrepancy between the premium and non-premium times.

Having a plastic surgeon at debridement adds another consultant and registrar salary to the theatre staffing with the out of hours enhancements as discussed above. The evidence suggests that there is a reduction in the number of people acquiring a deep infection and subsequent amputation, so this costing will assess the net cost or cost saving when having a plastic surgeon present for debridement at each particular delay to debridement as outlined above.

This costing will include the costs of the core theatre staff with the addition of the relevant surgeons where appropriate for the intervention. Enhancements to salaries will be added for a proportion of patients who would be expected to have debridement out of hours. For the analyses including the presence of a plastic surgeon, additional time will be added for the plastic surgeon to travel in for a call out when procedures are performed in premium time. Only the salary of the plastic surgeon is included in this extra hour for travel. No travel expenses have been calculated.

The costs of the adverse events, based on the risks identified from the clinical review, will also be calculated and combined with the staffing costs to give an overall cost for each strategy.

L.2.2 Inputs

L.2.2.1 Resource use and unit costs of interventions

The costs incurred by the core non-surgical staff required to be available in theatre are presented in Table 29 below. These have been calculated from data published in PSSRU 2014.[80] The costs below include oncosts; qualifications; staff and non-staff overheads; and capital overheads. Oncosts were calculated using the HMRC national insurance rates for 2014-2015[166] and a superannuation rate provided by PSSRU[80]. The total hourly cost of staff presented in PSSRU 2014[80] did not match the sum of the individual components presented and so we have used our own calculations in this analysis. However, the values we calculated were very similar to those presented in the publication.

The third and fourth columns of Table 29 show the hourly costs during premium time. As there is a further enhanced rate is paid to nurses on Sundays and public holidays and so this is separated into another column.

Table 28: Enhancement multiplier for premium time pay

Staff role	Premium time excluding Sundays and public holidays	Sundays and public holidays	Source	Comments
Consultant	1.33	1.33	Consultant contract.[284]	
Registrar	1.50	1.50	Banding of junior doctors.[283]	Assumed to be band 1A to account for the additional cost of unsocial hours.
Nurse and allied professionals (Agenda for Change bands 4-9)	1.30	1.60	Agenda for Change service handbook.[285]	Applies to all core theatre staff outlined in Table 29 below.

Table 29: Core theatre staff costs

Staff role	Cost per hour (normal hours)	Cost per hour (premium time excluding Sundays and public holidays)	Cost per hour (Sundays and public holidays)	SourceError! Reference ource not found.

Staff role	Cost per hour (normal hours)	Cost per hour (premium time excluding Sundays and public holidays)	Cost per hour (Sundays and public holidays)	**Source**Error! Reference ource not found.
Consultant anaesthetist	£139	£159	£159	Consultant medical, calculated using PSSRU 2014 data
Operating department practitioner	£49	£57	£65	Senior staff nurse, calculated using PSSRU 2014 data
Scrub nurse	£49	£57	£65	Senior staff nurse, calculated using PSSRU 2014 data
Running nurse	£41	£47	£54	Staff nurse, calculated using PSSRU 2014 data
Radiographer	£38	£44	£50	Hospital radiograph, calculated using PSSRU 2014 data
Recovery nurse	£41	£47	£54	Staff nurse, calculated using PSSRU 2014 data
TOTAL	£358	£412	£446	

The hourly cost of consultant surgeons during different hours is shown in Table 30 below. This cost applies to both orthopaedic and plastic surgeons and includes oncosts, qualifications and overheads.

Table 30: Surgeon staff costs

Cost per hour	Normal hours	Premium time including Sundays and public holidays
Consultant orthopaedic or plastic surgeon	£140	£161
Orthopaedic and plastic registrars	£58	£72

Source: PSSRU 2014
Costs Include oncosts, qualifications and overheads

The hourly cost of theatre staffing is shown in Table 31 below. This table shows the total cost for the core staff alone as well as with orthopaedic surgeons and with both orthopaedic surgeons and plastic surgeons (it was GDG opinion that there would be a consultant and registrar of each specialty), based on the costs reported in the two tables above. These are also shown for premium rate times as well as non-premium rate times.

Table 31: Theatre costs per hour

Input	Normal hours	Premium time excluding Sundays and public holidays	Sundays and public holidays
Core theatre staff	£358	£412	£446
Core staff plus orthopaedics[a]	£556	£644	£678
Core staff plus orthopaedics and plastics[(a)]	£754	£877	£911

Costs Include oncosts, qualifications and overheads
(a) Orthopaedics and plastics includes one consultant and one registrar for each specialty.

The duration of debridement (including call out time) and the proportion of people who are expected to be debrided during premium time are shown in Table 32 below. These values were estimated by the GDG. A sensitivity analysis will assess how robust the overall costs are to changes in these values.

Table 32: Duration of debridement and proportion requiring out of hours

	Timing of debridement from injury			
	6 hours	12 hours	24 hours	>24 hours
Duration of debridement (hours)[(a)]	3			
Additional hours for call out	1			
Proportion of injuries debrided in premium time (exc. Sunday)	0.2	0.1	0	0
Proportion of injuries debrided on a Sunday	0.1	0.05	0	0

(a) Includes an hour to perform debridement and two hours of theatre preparation and cleaning time

L.2.2.2 Resource use and unit costs of complications

Unit costs for the treatment for deep infection and amputation are shown in Table 33 below.

Table 33: Complications treatment costs

Outcome	Value	Source
Treatment of deep infection	£20,000	GDG assumption
Amputation procedure	£8,589	NHS Reference Costs 2013-2014 (HRG code = YQ22B)

The ranges for the cost of two common types of prosthesis are shown in Table 34 below. To estimate the expected cost of prosthesis, the midpoints for each range were calculated and the midpoint of the two midpoints was used as the base case value. Only leg prostheses were used due to an expected higher demand for leg prostheses and the importance of providing prostheses for ambulatory support.

Table 34: Prosthesis costs

Outcome	Mean Value	Source
Transtibial prosthesis	£2,350	GDG member contact – based on the midpoint between the lower and upper range limits (£700 and £4,000)
Transfemoral prosthesis	£4,750	GDG member contact – based on the midpoint between the lower and upper range limits (£1,500 and £8,000)
Total average	**£3,550**	

The number of prosthetics required, the lifetime of each prosthetic limb and the expected life years remaining for the patient is shown in Table 35 below. These values were used to calculate the expected number of prosthetic limbs required over a lifetime and the overall lifetime cost of these. These values are also presented in Table 35.

Table 35: Prosthetics resource use and lifetime cost

Outcome	Value	Source
Number of different prosthetics required at any time	2	GDG member contact
Life of prosthetics (years)	3	GDG member contact
Mean age at injury	45	GDG assumption
Mean age of death	83	Office for National Statistics[296]
Life years remaining for patient	38	Calculated from above
Expected number of prosthetics over a lifetime	25	Calculated from above
Lifetime prosthetics cost	£92,300	Calculated from above
Discounted lifetime prosthetics cost[(a)]	£53,479	Calculated from above

(a) Discounted at an annual rate of 3.5%

L.2.2.3 Clinical effectiveness data

Table 36: Baseline data and odds ratios for deep infection

Inputs from clinical review	Data	Source
Baseline risk of deep infection (< 6 hours)	5.56%	Noumi 2005[288]
Odds ratio for deep infection per hour of delay	1.033	Hull 2014[182]

The baseline risk of deep infection from Noumi et al.[288] was converted into a baseline odds value (see section L.2.3 for more detail on computations). The odds ratio from Hull et al.[182] (cross ref to review) was then applied to calculate the odds of infection for each debridement time. These odds values were then converted back into risks for each time point. These are shown in Table 37 below.

Table 37: Risks for deep infection

Duration of delay to debridement	Risk of deep infection
6 hours	5.56%
12 hours	6.75%
24 hours	9.97%
48 hours	21.7%

Risks were converted from odds calculated using the odds ratio from Hull 2014 and the baseline risk from Noumi 2005 in the table above.

The risk of amputation following deep infection is shown in Table 38 below. This value is multiplied by the risk of deep infection at the relevant time point to calculate the risk of amputation for the open fracture population.

Table 38: Risks for amputation

Input	Risk of deep infection	Source

Input	Risk of deep infection	Source
Risk of amputation given deep infection has occurred	10%	GDG assumption

With the presence of a plastic surgeon, the risk of deep infection at each time points is reduced by 62%. (see Table 39). There is no difference in the risk of amputation if a plastic surgeon is present because this is only dependent on the risk of deep infection.

Table 39: Relative risks with a plastic surgeon present

Outcome	Data	Source
Deep infection	0.38	Naique 2006[282]
Amputation	N/A	GDG assumption

L.2.3 Computations

1. The total costs for each debridement strategy were calculated as illustrated by the equation below:

$$\boldsymbol{T_{i,j} = \left(CORE_N r_{i,N} + CORE_P r_{i,P} + CORE_S r_{i,S} + ORTH_N r_{i,N} + ORTH_P r_{i,P} + ORTH_S r_{i,S}\right).t_{deb} + j.\left(PLAST_N r_{i,N} + PLAST_P r_{i,P} + PLAST_S r_{i,S}\right).\left(t_{deb} + t_{call}\right)}$$

Where $\boldsymbol{i}$ represents the time of debridement strategy and $\boldsymbol{j}$ represents the plastic surgeon strategy ($\boldsymbol{j} \in \{\mathbf{0} = \textbf{not present}, \mathbf{1} = \textbf{present}\}$)

$\boldsymbol{CORE}$, $\boldsymbol{ORTH}$ and $\boldsymbol{PLAST}$ denote the cost per hour of the core staff, orthopaedics and plastics respectively. The subscripts $\boldsymbol{N}$, $\boldsymbol{P}$ and $\boldsymbol{S}$ specify whether these costs are in normal hours, premium time (excluding Sundays and public holidays) or Sundays and public holidays respectively.

The factors $\boldsymbol{r_{i,N}}$, $\boldsymbol{r_{i,P}}$ and $\boldsymbol{r_{i,S}}$ represent the probabilities that debridement is performed in normal hours, premium time (excluding Sundays and public holidays), and Sundays (and public holidays) respectively.

The factors $\boldsymbol{t_{deb}}$ and $\boldsymbol{t_{call}}$ represent the duration that the costs are applied to i.e. the duration of debridement and the duration of additional travel time given for a plastic surgeon call out respectively.

2. Odds were converted into risks using the equation in the example below:

$$a = number\ of\ patients\ with\ event$$

$$b = number\ of\ patients\ without\ event$$

$$ODDS = \frac{a}{b}, \qquad RISK = \frac{a}{a+b}$$

$$RISK = \frac{ODDS}{1 + ODDS}$$

L.2.4 Sensitivity analyses

A number of sensitivity analyses were undertaken to test the robustness of the results.

SA1: Relative risk of deep infection for the presence of a plastic surgeon threshold analysis

This analysis is a threshold analysis, meaning a value is altered until a certain condition is met. In this case, the relative risk of deep infection with a plastic surgeon present is altered until the total costs of the less than 6 hour debridement strategy, with and without a plastic surgeon present, are equal.

This was only calculated for debridement at less than 6 hours. The threshold value will increase for the later strategies due to the increasing risk of deep infection and reduced out of hours costs i.e. a smaller proportion of the larger number of infections is required to be reduced to cover the additional staffing cost of the plastic surgeons.

SA2: Probabilistic analysis of the relative risk of deep infection for the presence of a plastic surgeon

This analysis further assesses the uncertainty in the relative risk of deep infection when the plastic surgeon is present in the early debridement strategy. It does this by sampling from a distribution of each of the risk of deep infection with and without a plastic and taking the ratio of these two sampled values. This is then used as the input for this parameter in the analysis. This sampling is repeated 10,000 times and the results are summarised. The parameterisation of the distributions is done using data from the study. This is illustrated in Table 40 below.

Table 40: Parameterisation of risks for deep infection

Parameter	Point estimate	Probability distribution	Distribution parameters
Risk of deep infection without plastic surgeon present.	0.04	Beta	α = 1, β = 24
Risk of deep infection with plastic surgeon present.	0.11	Beta	α = 5, β = 42

SA3: Increasing the proportion of patients whose debridement is performed in premium time by 50%

This analysis multiplies the proportion of patients expected to be debrided out of hours by 1.5 and assesses the effect on the overall costs.

SA4: Baseline risk of deep infection threshold analysis

This analysis is similar to SA1 but the value that is varied to find the threshold is the risk of deep infection. This threshold has only been calculated for the point where debridement at less than 6 hours becomes equally costly whether plastics are present or not. This risk will change the risks for each time of debridement when the odds ratio is applied.

SA5: Reducing the odds ratio of deep infection per hour of delay to debridement to 1.01

This analysis reduces the odds ratio of delay to debridement to 1.01, from the base case analysis value of 1.033, and assesses the effect of the overall costs.

SA6: Increasing prosthetic cost to £6,000

This analysis increases the cost of a single prosthesis from £3,550 to £6,000 and assesses the effect on the overall costs.

SA7: Cost of deep infection threshold analysis

This analysis is similar to SA1 but the value that is varied to find the threshold is the cost of deep infection. This threshold has only been calculated for the point where debridement at less than 6 hours becomes equally costly whether plastics are present or not.

L.2.5 Results

L.2.5.1 Base case analysis

The results of the cost analysis are reported in Table 41 for the analysis without the plastic surgeon at debridement and Table 42 including plastics at debridement.

Table 41: Cost of debridement without plastic surgeon present

	Timing of debridement			
	<6 hours	6 to 12 hours	12 to 24 hours	>24 hours
Theatre staff cost	£1,758	£1,713	£1,668	£1,668
Complications cost	£1,379	£1,657	£2,375	£4,677
TOTAL	£3,137	£3,370	£4,043	£6,345

Table 42: Cost of debridement with plastic surgeon present

	Timing of debridement			
	<6 hours	6 to 12 hours	12 to 24 hours	>24 hours
Theatre staff cost	£2,453	£2,358	£2,263	£2,263
Complications cost	£524	£630	£903	£1,777
TOTAL	£2,978	£2,988	£3,166	£4,041

As can be seen from above, the results show that at each time point, it is cheaper to have a plastic surgeon present at each time point because the increase in the plastic surgeon cost is more than covered by the savings from the reduced adverse events. However, both with and without a plastic surgeon, as the time to debridement increases, there is an increasing cost due to the increasing risks of adverse events.

L.2.5.2 Sensitivity analyses

SA1: Relative risk of deep infection for the presence of a plastic surgeon threshold analysis

The threshold for the relative risk of deep infection for the presence of a plastic surgeon at which the two strategies become cost neutral for early debridement (< 6 hours) is 0.50 compared to the base case value of 0.38 as shown in Table 39 above.

SA2: Probabilistic analysis of the relative risk of deep infection for the presence of a plastic surgeon

The total cost for the strategy with a plastic surgeon present increased slightly to £3,077 in the probabilistic analysis compared to £2,978 in the deterministic analysis. This shows that it is fairly robust to the uncertainty in this parameter and importantly remained below the cost of the strategy without plastic surgeons present.

The probability of the cost being less than the cost of the strategy without plastic surgery (£3,137) was approximately 69% based on 10,000 probabilistic samples.

SA3: Increasing the proportion of patients whose debridement is performed in premium time by 50%

Table 43: Results of SA2

Overall cost	<6 hours	6 to 12 hours	12 to 24 hours	>24 hours
Without plastics	£3,182	£3,393	£4,043	£6,345
With plastics	£3,073	£3,036	£3,166	£4,041

When a plastic surgeon is present, the cheapest strategy has now become 6 to 12 hours delay to debridement. However, the difference between this strategy and debridement within 6 hours is very small.

SA4: Baseline risk of deep infection threshold analysis

The presence of a plastic surgeon becomes cost neutral for early debridement (<6 hours) when the baseline risk of deep infection is decreased to 4.28% compared to the base case value of 5.56% as shown in Table 37 above. The resulting risks for the othertimes of debridement are shown in Table 44 below. These are based on the new baseline risk and the original relative risk for each hour of delay to debridement.

Table 44: Updated risks for deep infection

Duration of delay to debridement	Risk of deep infection
6 hours	4.28%
12 hours	5.15%
24 hours	7.43%
48 hours	14.88%

Risks were converted from odds calculated using the odds ratio from Hull 2014 and the baseline risk from Noumi 2005 in the table above.

SA5: Reducing the odds ratio of deep infection per hour of delay to debridement to 1.01

Table 45: Results of SA4

Overall cost	<6 hours	6 to 12 hours	12 to 24 hours	>24 hours
Without plastics	£3,137	£3,173	£3,301	£3,708
With plastics	£2,978	£2,913	£2,884	£3,038

This has substantially reduced the costs of later debridement (>24 hours) without a plastic surgeon because the risks of deep infection were particularly high for this group. Overall for debridement later than 6 hours, the costs have decreased due to a lower risk of infection and therefore amputation. The costs without the presence of a plastic surgeon are now not as high compared to a plastic surgeon being present.

SA6: Increasing prosthetic cost to £6,000

Table 46: Results of SA5

Overall cost	<6 hours	6 to 12 hours	12 to 24 hours	>24 hours
Without plastics	£3,331	£3,604	£4,378	£7,004
With plastics	£3,051	£3,077	£3,293	£4,291

As the lifetime costs of prosthetics is a particularly costly downstream resource, an increase in the costs of this will have an impact on the results because it increases the adverse event costs. However, the savings from reducing the adverse events still outweigh the staff costs from having a plastic surgeon present.

SA7: Threshold analysis for the cost of deep infection treatment

The threshold for the cost of deep infection treatment, at which the presence of a plastic surgeon becomes equally costly as without, for debridement at less than 6 hours, is £15,107 compared to the base case value of £20,000. Therefore, even if the base case estimate of £20,000 is an overestimate, the presence of a plastic surgeon at early debridement is still likely to be cheaper than without a plastic surgeon.

L.2.6 Discussion

L.2.6.1 Summary of results

The results of this cost analysis show that the costs of earlier debridement due to increased out of hours surgery are small in comparison to the costs saved from the complications avoided. This is also the case with the presence of a plastic surgeon. The additional cost of adding a plastic surgeon along with an additional registrar is far outweighed by the costs saved from complications avoided by having the expertise of the plastic surgeon available in theatre.

SA1 shows that the relative risk of deep infection would have to go up by 0.12 for the presence of a plastic surgeon to have an equal cost to early debridement without plastics. This is a fairly large increase from 0.38, however, 0.5 is still within the lower end of the confidence interval around this parameter, please see section L.2.6.2 for further discussion on this.

SA2 shows that the results of the analysis are robust to the uncertainty in the relative risk of deep infection. The mean cost of the 10,000 sampled results remained below the cost of the strategy without the presence of a plastic surgeon. The proportion of samples that were below this cost was high at 69% showing that it is very likely to be cost saving.

SA3 shows that increasing the proportion of patients who will have debridement performed out of hours by 50% makes the 6 to 12 hour strategy slightly cheaper than debridement at less than 6 hours, when a plastic surgeon is present. This minimal difference is likely to be outweighed by the health related quality of life benefits from reducing deep infections and amputations and so debridement in less than 6 hours with a plastic surgeon present is still likely to remain cost effective.

SA4 shows that the risk of deep infection for debridement in less than 6 hours has to reduce from 5.56% to 4.28% to make the presence of a plastic surgeon equally costly to without plastics for debridement at that time. This is only a small change in absolute risk but the base case value is fairly small to begin with and so proportionately it is larger than it may appear.

SA5 shows a similar result to SA2 with debridement at 6 to 12 hours becoming slightly cheaper than less than 6 hours when the plastic surgeon is present. Again, this difference in cost is not large and so taking health related quality of life into account is likely to still favour debridement at less than 6 hours with a plastic surgeon present.

SA6 showed that the overall results were robust to increasing the cost of a prosthetic, as debridement in less than 6 hours with a plastic surgeon present remained the cheapest option.

SA7 showed than the cost of deep infection would have to reduce by almost £5,000 for the presence of a plastic surgeon to be cost neutral for debridement at less than 6 hours. This shows the overall costs are fairly robust to this variable and that the overall conclusions remain.

L.2.6.2 Limitations and interpretation

This analysis only considers the key cost impacts for the debridement of open fractures. It does not explicitly evaluate the health related quality of life implications relating to deep infection and amputationand no mortality has been assumed post injury.

Although the key costs have been included, there are some costs that were difficult to accurately evaluate such as the ongoing cost of rehabilitation including physiotherapy and the support required for patients to become accustomed with a prosthetic limb. Also, further downstream resource use such as potential re-operations for amputees has not been included. However, had these costs been included, they are likely to favour the presence of a plastic surgeon where the risks of adverse events are reduced, and also favour earlier debridement where these risks are smaller.

The data included for the relative risk of deep infection when the plastic surgeon is present is from a very low quality study[282]. This was a key parameter in the analysis; however it was subject to a threshold analysis to find the value at which the strategy becomes cost neutral. It is important to note that this parameter had a large confidence interval (0.047 – 3.037) and therefore the RR used in the analysis and in turn the impact on results is uncertain. However, it was felt by the clinical experts that there are costs and benefits that have not been taken account of in this analysis such as; the resource use associated with infection, and the detriment to quality of life. Therefore, this relative risk could increase further, resulting in a more costly approach if the plastic surgeon is present, yet still remain a *cost effective* strategy.

No probabilistic analysis has been undertaken as this is a simple cost analysis with a small number of parameters. However, a range of deterministic sensitivity analyses have been performed to assess any uncertainty in the inputs.

No data was found for length of hospital stay and so has not been included in the analysis. However, this is thought to increase for those with deep infection and so is likely to favour earlier debridement with a plastic surgeon present.

L.3 Soft tissue cover cost analysis

L.3.1 Methods

To provide definitive soft tissue cover within a specified time requires the availability of a plastic surgeon within the specified time. Soft tissue cover procedures are lengthy and so it is not appropriate for them to be performed by an on-call surgeon. Therefore the cost implications will be assessed by evaluating the cost of additional trauma surgery lists each week to allow for the surgery within a specific timeframe. It is assumed in this analysis that the surgery lists are only used for patients with open fractures who require plastic surgery. There may, of course, be other patients who can benefit from these additional resources and so the results presented are likely to overestimate the cost per patient and underestimate the overall clinical benefits. This is considered further in the discussion of the results and the conclusion.

The costing analysis for this question will include the core theatre staff, an orthopaedic surgeon and a plastic surgeon. Deep infection, amputation (including prosthetics) and length of hospital stay will also be calculated based on the risks from the clinical review, and these will be combined with the staff costs to give an overall cost for each intervention.

The average cost per patient will be presented assuming that all patients who require plastic surgery for definitive soft tissue cover will be transported to the nearest Major Trauma Centre where these skills are available.

L.3.2 Epidemiology

Table 47: Open fractures requiring plastic surgery

	Data	Source
Annual incidence (per 100,000 population)	5.16	BOA/BAPS report[98]
Population of England (millions)	53.0	2011 Census, Office for National Statistics[1]
Expected number in England per year	2,779	Calculated from above
Number of MTCs in England	26	NHS Major Trauma Centres Map[2]
Expected number of fractures per MTC per year	105	Calculated from above

L.3.3 Inputs

L.3.3.1 Resource use and unit costs

The same resource use and unit costs presented in sections L.2.2.1 and (a) were used for this analysis. These values were used to calculate the cost of a theatre list as described in Table 48. The number of lists required each week to meet the each timing of cover strategy are given in Table 49 below shows the number of surgery lists required each week to facilitate soft tissue cover within a certain number of days as per the interventions listed in our review questions.

Table 49 below.

Table 48: Theatre list costs

Input	Data
Cost of theatre staff per hour[(a)]	£754
Number of hours per theatre list	8
Cost per theatre list	£6,035
Annual cost (for each theatre list per week)	£313,841

(a) *Calculated in the debridement analysis in Table 31.*

Table 49 below shows the number of surgery lists required each week to facilitate soft tissue cover within a certain number of days as per the interventions listed in our review questions.

Table 49: Number of lists required

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1

L.3.3.2 Clinical effectiveness data

Clinical data on risk of deep infection associated with the delay to soft tissue cover procedure were obtained from the systematic review conducted for this guideline (Section 6.9 in the full guideline). The main data used for this analysis are reported in the Table below.

Table 50: Risks of deep infection by delay to cover

Delay	Risk	Source
≤ 3 days	4.17%	Liu 2012[237]
4 to 7 days	7.69%	Liu 2012[237]
>7 days	21.4%	Liu 2012[237]

Based on the data reported in Liu 2012, to estimate the risk of deep infection per day, a line of best fit was fitted using the midpoints of the ranges used in the study (more detail on this can be found in section L.3.4). The obtained risk estimates are reported in the table below.

Table 51: Risks of deep infection by delay to cover (estimated from line of best fit)

Delay to cover	Risk	Source
1 day	3.33%	Estimate based on Liu 2012[237] data
2 days	4.39%	Estimate based on Liu 2012[237] data
3 days	5.45%	Estimate based on Liu 2012[237] data
4 days	6.51%	Estimate based on Liu 2012[237] data
7 days	9.68%	Estimate based on Liu 2012[237] data

Similarly to the previous analysis, a proportion of patients experiencing deep infection would also have amputation. The same data used in the previous analysis was applied.

From the systematic review conducted for this guideline, we also obtained data on the length of stay associated with the delay to the soft tissue cover procedure (please see section 6.9 of the Complex fractures full guideline). The main data used for this analysis are reported in the tables below.

Table 52: Length of stay by delay to cover

Delay	Data	Source
≤ 3 days	20.0 days	Liu 2012[237]
4 to 7 days	24.8 days	Liu 2012[237]
>7 days	36.2 days	Liu 2012[237]

Based on the data reported in Liu 2012, to estimate the average length of stay per day of delay, a line of best fit was fitted using the midpoints of the ranges used in the study (more detail on this can be found in section L.3.4). The obtained length of stay estimates are reported in the table below.

Table 53: Length of stay by delay to cover (estimated from line of best fit)

Delay	Data	Source
1 day	19.9 days	Estimate based on Liu 2012[237] data
2 days	20.9 days	Estimate based on Liu 2012[237] data
3 days	21.9 days	Estimate based on Liu 2012[237] data

Delay	Data	Source
4 days	22.8 days	Estimate based on Liu 2012[237] data
7 days	25.7 days	Estimate based on Liu 2012[237] data

L.3.4 Computations

The risk of complications and length of hospital stay for each day of delay was estimated by fitting a line of best fit through the midpoints of the ranges given in the studies. The best fit was achieved by using the Solver package in Microsoft Excel to minimise the square of the errors between the midpoints and the line while varying the gradient and constant term of the line.

The total cost per patient for each strategy was calculated as:

Cost per patient strategy **x =** $\mathbf{N_{list\ x} * Cost_{(7days)} + CostComplications * P\ Complication_x + CostLoS * LoS_x}$

Where:

$\mathbf{N_{list\ x}}$ is the number of lists required for strategy x

$\mathbf{Cost_{(7days)}}$ is the cost of lists per patient for the strategy '7 days'

CostComplications is the cost of complications

$\mathbf{P\ Complication_x}$ is the probability of complications for strategy x

CostLoS is the cost per day of hospital stay

and $\mathbf{LoS_x}$ is the LoS for strategy x.

L.3.5 Sensitivity analyses

A number of sensitivity analyses were undertaken to test the robustness of the results.

SA1: Risk of amputation for those with deep infection increased to 50%

This analysis increases the risk of amputation to 50% of those who have deep infection and assess the effect on the overall results.

SA2: Increasing cost of prosthetics to £6,000

This analysis increases the cost of prosthetics to £6,000 and assesses the effect on the overall results.

SA3: Reducing the cost of deep infection to £15,000

This analysis reduces the cost of deep infection to £15,000 and assesses the effect on the overall results.

L.3.6 Results

L.3.6.1 Base case analysis

Table 54: Theatre list costs on a population level

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per year	£2,196,889	£1,255,365	£941,524	£627,682	£313,841
Cost of outcomes per year	£663,471	£720,332	£777,194	£834,056	£1,004,642
Total cost	£2,860,359	£1,975,697	£1,718,718	£1,461,739	£1,318,483

Table 55: Theatre list costs per patient

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per person	£20,900	£11,943	£8,957	£5,971	£2,986
Cost of outcomes per person	£6,312	£6,853	£7,394	£7,935	£9,558
Total cost	£27,212	£18,796	£16,351	£13,906	£12,543

The results above show that the more theatre lists that are provided, the more this will cost overall. Although this also reduces the cost of adverse events by providing cover quicker, the increased cost of additional lists is higher than the cost savings from reduced adverse events.

L.3.6.2 Sensitivity analyses

SA1: Risk of amputation for those with deep infection increased to 50%

Table 56: Results of SA1 on a population level

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per year	£2,196,889	£1,255,365	£941,524	£627,682	£313,841
Cost of outcomes per year	£750,412	£834,904	£919,397	£1,003,889	£1,257,367
Total cost	£2,947,300	£2,090,269	£1,860,921	£1,631,572	£1,571,208

Table 57: Results of SA1 per patient

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per	£20,900	£11,943	£8,957	£5,971	£2,986

Time to cover (days)	1	2	3	4	7
person					
Cost of outcomes per person	£7,139	£7,943	£8,747	£9,550	£11,962
Total cost	£28,039	£19,886	£17,704	£15,522	£14,948

The cost of outcomes has increased as the number of amputations has increased. The increase is larger for later time points.

SA2: Increasing cost of prosthetics to £6,000

Table 58: Results of SA2 on a population level

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per year	£2,196,889	£1,255,365	£941,524	£627,682	£313,841
Cost of outcomes per year	£676,395	£737,365	£798,334	£859,304	£1,042,212
Total cost	£2,873,284	£1,992,730	£1,739,858	£1,486,986	£1,356,053

Table 59: Results of SA2 per patient

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per person	£20,900	£11,943	£8,957	£5,971	£2,986
Cost of outcomes per person	£6,435	£7,015	£7,595	£8,175	£9,915
Total cost	£27,335	£18,958	£16,552	£14,146	£12,901

SA3: Reducing the cost of deep infection to £15,000

Table 60: Results of SA3 on a population level

Time to cover (days)	1	2	3	4	7
Number of lists needed per week	7	4	3	2	1
Cost of list(s) per year	£2,196,889	£1,255,365	£941,524	£627,682	£313,841
Cost of outcomes per year	£645,961	£697,258	£748,556	£799,853	£953,744
Total cost	£2,842,850	£1,952,623	£1,690,079	£1,427,535	£1,267,586

Table 61: Results of SA3 per patient

Time to cover (days)	1	2	3	4	7
Number of lists	7	4	3	2	1

Time to cover (days)	1	2	3	4	7
needed per week					
Cost of list(s) per person	£20,900	£11,943	£8,957	£5,971	£2,986
Cost of outcomes per person	£6,145	£6,633	£7,121	£7,609	£9,073
Total cost	£27,045	£18,576	£16,078	£13,581	£12,059

L.3.7 Discussion

L.3.7.1 Summary of results

The results showed that the cost of providing an 8 hour orthoplastic theatre list is estimated to be £6,035. The GDG believed that current practice was to have two dedicated theatre lists per week, which would cost an estimated £627,682 per year. This can only guarantee soft tissue cover within four days and the estimated complication cost for this is £834,056 per year. Increasing the number of lists to three per week at an annual cost of £941,524 is estimated to reduce the cost of complications to £777,194. Hence, the overall annual costs for two and three lists per week are £1,461,739 and £1,718,718 respectively. There is, therefore, an increase in costs overall for performing soft tissue cover within 72 hours but this needs to be considered along with the health related quality of life benefits that come with the reduction in complications.

The analysis estimated the mean number of patients who present to a major trauma centre (either directly or indirectly) with an open fracture requiring plastic surgery as 105. On the assumption that these surgery lists will only be used for these patients, the estimated cost per patient for two lists and three lists per week respectively would be £13,906 and £16,351; an increase of £2,445 per patient for the additional list. This would require a mean increase in QALYs per patient of 0.12 in order to be cost effective. Over the estimated life years remaining of 38 years that was used in the model, this equates to a mean increase in utility of 0.003 for the duration of that period. Also taking into account the fact that this is based on assuming that staff are only working when a patient arrives, this is a conservative estimate. In reality, the staff can perform other elective surgical work that can be cancelled at short notice to accommodate any emergency arrivals. Therefore additional lists can be of benefit to other patient groups, which have not been considered here, thus cost effectiveness of additional lists may be underestimated. Increasing the number of lists per week to four would add an additional £2,445 to the overall cost and therefore require an additional 0.12 QALYs in order to be cost effective. Providing a list every day would cost an additional £8,469 per person compared to four lists per week and this would require an additional 0.42 QALYs in order to be cost effective in comparison to four lists a week.

The results remained robust to changes in all sensitivity analyses undertaken and the conclusions did not change.

L.3.7.2 Limitations and interpretation

The evidence of risks for timing of cover is based on free flaps for people with Gustilo-Anderson grade 3 fractures and so may overestimate the risks for the whole population.

This analysis assumes that all patients have the delay to cover specified in our review protocol. In reality, some patients will arrive at a time that allows for earlier treatment and so this will overestimate the risks. This applies to all strategies; however there is less variability possible for the earlier strategies i.e. with a list every day the patient can be delayed between 0 and 24 hours depending on their arrival time and for a list every 3 days a patient could be delayed between 0 and 72 hours depending on their arrival time. Assuming that they are delayed for the maximum time may slightly favour the earlier strategy.

L.4 Multiple theatre sessions cost analysis

L.4.1 Methods

The three main types of surgical procedure performed on patients with an open fracture (debridement, fixation and cover) can be performed in one theatre session or across two or three. The first session is always debridement and an initial fixation (temporary or definitive) but a later second session can be used to perform definitive fixation and cover if only temporary fixation was used initially and a third session can be used to perform definitive cover at a later time. The use of multiple theatre sessions increases the time needed for preparation and so increases the costs. However, if the soft tissue cover procedure is performed in the same session following fixation, then there is an inefficient use of the plastic surgeon that is made available for the entire theatre session but is only needed for part of it. This is because the plastic surgeon has to do the final procedure for soft tissue cover as soon as the orthopaedic surgeon has completed the definitive fixation. The plastic surgeon cannot therefore perform any other work in the time before this procedure in case the work takes longer than anticipated.

This cost analysis will evaluate these trade-offs together to assess whether the inefficient use of the plastic surgeons time could actually be cost saving. It is based on the assumed durations of the procedures and preparation of the GDG and uses the staff costs as presented previously. No clinical outcomes are included in this analysis.

L.4.2 Inputs

L.4.2.1 Resource use and unit costs

The same resource use and unit costs presented in section L.2.2.1 were used for this analysis to cost surgery time during normal hours. The duration of each procedure performed for an open fracture is shown in Table 62 below.

Table 62: Duration of procedures

Procedure	Duration (hours)
Debridement	1
Temporary fixation	2
Definitive fixation	3
Local flap	2
Theatre session preparation	2

L.4.3 Results

L.4.3.1 Base case analysis

Table 63: Cost of different pathways with and without plastics present at debridement

Pathway	Cost without plastics present	Cost with plastics present
Strategy 1: Debridement, definitive fixation and definitive cover in one theatre session	£6,035.41	£6,035.41
Strategy 2: Debridement and definitive fixation in one theatre session followed by definitive cover in a later session	£5,561.09	£6,156.04
Strategy 3: Debridement and temporary fixation in one theatre session followed by definitive fixation and definitive cover in a later session.	£7,664.89	£8,259.85
Strategy 4: Debridement and temporary fixation in one theatre session followed by definitive fixation in a later session and definitive cover in a third session.	£7,785.53	£8,380.48

As can be seen from the table above, all strategies are more expensive with a plastic surgeon present except for the first strategy with all procedures in one session, which is equally costly. This is because the plastic surgeon has to be available to perform the soft tissue cover regardless of whether they are present for debridement or not.

Strategy 2 is cheaper if the plastic surgeon is not present at debridement as it removes the plastic surgeon salary cost during debridement and fixation, while adding a smaller cost of the additional preparation time for the second session. When the plastic surgeon is present for debridement strategy 2 is slightly more expensive than 1 as the only difference in cost is from the additional preparation time.

Strategy 3 has a large increase in cost compared to strategy 2 as there is the additional cost of the temporary fixation procedure. The cost of the plastic surgeon for the duration of the definitive fixation procedure still applies.

Strategy 4 has a small increase in cost compared to strategy 3 as there is the additional cost for preparing a third theatre sessions but there is no cost of having the plastic surgeon available during any fixation procedure.

L.4.4 Discussion

L.4.4.1 Summary of results

This cost analysis shows that if a plastic surgeon is not present for debridement then it is cheaper to have definitive cover in a separate session so that the plastic surgeon's time is used more efficiently. If the plastic surgeon is to be present for debridement however, it is then cheaper to have all procedures performed in the same session. This is because the additional preparation time for a second theatre session for definitive cover outweighs the inefficient use of the plastic surgeon while definitive fixation is performed between debridement and definitive cover.

If definitive fixation is delayed to the second session along with definitive cover then the inefficient use of the plastic surgeon still applies as well as the additional preparation time. This is therefore more expensive. Having definitive fixation in a second session and definitive cover in a third is even more expensive due to having another preparation time added for the third theatre session.

L.4.4.2 Limitations and interpretation

This analysis is based on assumptions of the durations of procedures and preparation time provided by the GDG. This analysis does not take into account the different costs of surgical implants required across each strategy.

L.5 Conclusion

From analysis 1: Debridement performed within 6 hours of injury with a plastic surgeon present in theatre is the most likely cost effective strategy and may even be cost saving.

From analysis 2: One theatre list per week is not enough to meet the demand based on the incidence of open fractures and so two lists a week is generally regarded as current practice in the UK. The increase in costs per person for three surgery lists compared to two only requires a small improvement in health related quality of life, which is potential feasible. A further list would add the same overall cost but there may not be as much benefit to be gained and so the cost effectiveness of this is less certain. A list every day would add a much greater cost and so the uncertainty in cost effectiveness of this based on the clinical evidence available is much more uncertain. The incidence of open fractures is low and is an important consideration with regards to the cost effectiveness. However there may be other population that would benefit from additional theatre lists.

From analysis 3: If a plastic surgeon is to be present at debridement as the first analysis suggest is cost saving, performing all procedures in one session can save further costs. However, this may not always be possible due to the restrictions of the conclusions to the other analyses.

The analyses are inter-related as they reflect different parts of the same pathway. It may be possible that a costly change in strategy in one part of the pathway could be offset by savings made via a change in strategy in another part of the pathway. For the overall conclusions of these analyses and the discussion given by the GDG, please see the link to evidence section for treatment of open fractures (please see section 6.9.6 of the Complex fractures full guideline).

Appendix M: Research recommendations

M.1 Cystourethrogram

Research question: How accurate is the first CT scan with contrast (trauma scan) for detecting bladder injuries in people with suspected bladder injuries after a trauma?

Why this is important: Bladder injuries usually occur in people with high-energy pelvic fractures after a traumatic incident. Currently people with suspected bladder injuries have a CT scan with intravenous contrast (a trauma scan) to diagnose non-bladder injuries. People who do not have injuries needing urgent treatment may then either be given another CT scan or a fluoroscopic cystogram to check for bladder injury. People with injuries needing urgent treatment (for example, bleeding or a neurological injury) are taken to the resuscitation room after the initial CT scan (trauma scan). Once the person's condition is stabilised they are taken to either the CT or fluoroscopy suite for a retrograde cystogram to check for bladder injury. The Guideline Committee agreed that these strategies are accurate for the diagnosis of bladder injuries, but felt that there were advantages to a strategy that did not involve a second set of images. The Guideline Comittee was interested in whether the first CT scan with intravenous contrast (trauma scan) could accurately diagnose bladder injuries.

Criteria for selecting high priority research recommendations:

PICO question	Population • People with suspected bladder injury after a traumatic incident. This would include multiply injured patients. Index test • Trauma CT with IV contrast (no additional scanning). The contrast should be administered as early as is safely possible. Reference standards • Later imaging: cystogram (CT / conventional fluoroscopy) • Later clinical and surgical findings Outcomes • Diagnostic accuracy Stratify/subgroup • Pelvic fracture type (or no fracture)
Importance to patients or the population	If the initial trauma CT with contrast is found to have the requisite diagnostic accuracy for diagnosing bladder injuries then it would be a much faster strategy than the two scan approach currently in place. The GDG agreed that earlier definitive diagnosis of bladder injuries would lead to better outcomes for patients. The better outcomes would be realised through faster diagnosis of bladder injury, no dedicated further imaging for bladder injury that could impede or delay treatment of the patient and increase their radiation burden.
Relevance to NICE guidance	It would inform the Complex Fractures guideline question around the most effective method for diagnosis of bladder injuries.
Relevance to the NHS	Accurately identifying the injury using only one scan (the initial trauma CT scan) would mean management decisions would be made faster because the need for additional investigations is negated. This would lead to less downstream resource use in terms of imaging and staff time – which have an opportunity cost, and also potentially improve outcomes because; the injury can be

	diagnosed quicker, and also because in the context of a multiply injured patient – there is less time spent exploring the bladder injury which could be at the detriment of the other injuries the patient has.
National priorities	There are no specific national priorities pertaining to the diagnostic imaging of people with suspected bladder injuries.
Current evidence base	The studies included in the diagnostic accuracy review did not encompass the strategy proposed in this research recommendation. They investigated the accuracy of a dedicated cystogram for diagnosing bladder injuries. In addition they were relatively old studies, published in 2006 or earlier, but using two, four or occasionally 16 slice multi-detector CT machines. Ten years ahead and modern CT scanners can be dual source and reach 128 slices. The possibilities for diagnosis that may not have been considered using the previous generations of scanners may now be a reality.
Equality	This research recommendation would potentially benefit all children, young people and adults who are involved in a traumatic incident and are suspect of bladder injury.
Study design	A diagnostic accuracy study would be the most appropriate form of research methodology for this question.
Feasibility	The research would be very feasible, with low cost and no serious technical issues. It would require very little change in practice as the index test and reference standards are part of current clinical practice.
Other comments	Those interpreting the cystogram (reference standard) should be blinded to the bladder injury results of the trauma CT with IV contrast (index test). The timing of administration of contrast is important because very early administration could allow some of the contrast to reach the bladder, increasing the accuracy of the scan.
Importance	This research recommendation is of high importance: the research is essential to inform future updates of key recommendations in the guideline

M.2 Pilon fractures

Research question: In adults with closed pilon fractures what method of fixation provides the best clinical and cost effective outcomes as assessed by function and incidence of major complications at 2 years? (stratified for timing of definitive surgery early [<36hrs] vs later [>36hrs])

Why this is important: Pilon fractures involve a significant proportion of the weight-bearing surface of the distal tibia. The damaged joint surface is vulnerable to degeneration. Therefore, the injury can lead to long-term disability, most commonly arthritis with pain and stiffness. Surgery can improve outcomes, allowing reduction and fixation of the fracture and early movement of the ankle joint. However, it has a high incidence of serious complications, particularly related to the vulnerability of the soft tissues around the ankle. The potential for life-changing adverse consequences of both the injury and its treatment is known, but the best management strategy to minimise these consequences is unclear.

Criteria for selecting high priority research recommendations:

PICO question	• Population: adults with closed pilon fractures • Intervention: fine wire frame fixation vs. internal fixation with plates and screws vs. spanning external fixation (each augmented by joint reconstruction as required)

	• Comparator: see above • Outcomes: function, health-related quality of life, major complications
Importance to patients or the population	The best management of patients with pilon fractures is unknown. Although relatively rare injuries, pilon fractures are associated with a high rate of early complications and have inevitable long-term effects on patients' function and health-related quality of life. Therefore, research which identifies the optimal management strategy is of vital importance for patients.
Relevance to NICE guidance	Research which identifies the best method and timing of surgical fixation of pilon fractures addresses a key area identified in the scope of the NICE guidelines for complex fractures.
Relevance to the NHS	The identification of the most clinical and cost-effective method of surgical fixation and timing/staging of that fixation, would improve the outcome for patients and reduce the long-term costs associated with ankle arthritis and the need for further surgery.
National priorities	Pilon fractures affect the main weight-bearing portion of the ankle joint leading to early arthritis. Arthritis of the ankle has life-long effects in terms of mobility, pain and the patients' ability to perform their work and recreational activities. Improving the diagnosis and treatment of patients with this injury has been identified as a research priority by the Orthopaedic Trauma Society and Arthritis Research UK.
Current evidence base	Current evidence for the type of fixation is very limited. The two existing RCTs and the single cohort study are all at very high risk of bias. Furthermore, one of the RCTs described a method of fixation which is no longer used in the NHS as it has been associated with a higher incidence of complication such as wound breakdown. In addition, the cohort study did not specify the type of external fixation system used. Evidence for all outcomes included in the review were either imprecise or reported with very low event rates. The GDG felt the quality of the evidence underlined the need for further research in this area. Current evidence concerning the timing of fixation is also very limited and imprecise. The three non-randomised studies included a mixture of closed and open pilon fractures, so the timing of fixation was confounded by the extent of the soft-tissue injury. For the non-randomised study looking at closed fractures alone, there was insufficient statistical power to detect a difference between groups in the key outcome of deep infection. Again, the GDG felt the quality of the evidence underlined the need for further research.
Equality	This research recommendation would potentially benefit all groups of patients.
Study design	A randomised controlled trial with stratification for timing would be the most appropriate form of research methodology for this question.
Feasibility	The research would be feasible. Although this is a relatively rare injury, the current UK model for the management of complex fractures means that pilon fractures are increasingly concentrated in a smaller number of specialist centres where there is expertise in each of the different methods of fixation.
Other comments	Potential funders of this study may include the National Institute for Health Research and Arthritis Research UK.
Importance	This research recommendation is of high importance. Pilon fractures have a high risk of early complications and cause long-term disability. The current evidence base does not allow NICE to make a clear recommendation regarding the most clinically effective and cost effective method of fixation, nor the timing of fixation. The research is essential to inform future updates of key recommendations in the guideline.

Appendix N: 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

Appendix O: Additional cost data

O.1 Assessment of cost effectiveness for diagnostic interventions and prognostic tools

The cost effectiveness of a diagnostic modality stems from how accurately it can identify people with the injury and rule out people without the injury, as well as the true prevalence of the condition within the population being imaged. For the major trauma population, who are subject to polytrauma, systemic injury and fast deterioration, cost effectiveness of a diagnostic intervention is also impacted by the trade-off between time efficiency and accuracy of the intervention, as well as the potential for incidental findings. In the absence of economic evidence for a diagnostic review, the GDG were routinely asked to consider the below when assessing cost effectiveness of a diagnostic modality for a particular indication. The same considerations were applied to prognostic reviews on risk tools. Aspects of note are detailed in the respective Evidence and Link to Recommendation section of each review.

Impact of sensitivity, specificity and prevalence on the cost effectiveness of a diagnostic intervention

A modality or risk tool with a low sensitivity will lead to more false negatives (i.e. people missed or incorrectly predicted to have low risk and therefore do not need onward management). This will impact, resource use as well as health outcomes because these people who have been missed could therefore deteriorate, which in turn leads to longer hospital stay or higher mortality. All else being equal and assuming onward management is cost effective, a diagnostic intervention with a higher sensitivity than alternatives will be cost effective.

A modality or risk tool with a low specificity will lead to more false positives (i.e. people incorrectly labelled as having a condition or at high risk needing onward management). This will impact resource use as this leads to unnecessary treatment (which may carry potential harm). All else being equal and assuming onward management is costly and may carry harm, a diagnostic intervention with a higher specificity than alternatives will be cost effective.

Prevalence is important in the consideration of cost effectiveness. If the traumatic injury or condition being investigated is not common within the population suspected of the injury, prevalence of the injury is low. This indicates that a high proportion of people will be investigated, incurring cost, without any benefit. The lower the prevalence of the condition within the population tested the less cost effective the diagnostic intervention will be, regardless of its accuracy.

Incidental findings and cost effectiveness

When employing a diagnostic modality for a particular population group, there is normally "indirect benefit" afforded to other population groups through incidental findings. The incidental findings are of particular relevance for the trauma population for two reasons. Firstly due to the potential for poly-trauma (i.e. chest trauma and major haemorrhage are not mutually exclusive conditions). Secondly, and importantly, one injury may have systemic symptoms, signs and complications (i.e. blood may collect elsewhere to the injury site). Without consideration of potential for incidental findings, the overall benefit from undertaking the diagnostic intervention and therefore cost effectiveness may be underestimated. The sensitivity of the diagnostic intervention to find ANY injury increases as you increase the number and type of injuries that you are trying to identify with one diagnostic test. Furthermore, predictive power of finding ANY injury increases as the proportion of patients with injury in the pool that you are testing increases. Where appropriate onward management of the type of injury you are assessing is similar, i.e. in systemic injury, cost effectiveness of the diagnostic modality is increased.

On the other hand, if incidental findings are taken into consideration of cost effectiveness, it also needs to be acknowledged that the potential of definitively ruling out ANY injury decreases (that is to say specificity and negative predictive power decreases). If onward management is costly and risky (for example surgery or interventional radiology) then this can decrease the cost effectiveness of the diagnostic intervention.

Radiation risk and cost effectiveness

Please refer to the chapter in Spinal injuries.

A concern raised around imaging is the risk of radiation. This was incorporated in a sensitivity analysis in the Spinal Injuries guideline model. The cost per patient on average is low, and particularly when time preference is taken into account (i.e. discounting of future costs and benefits), the costs and health risks are minimal. None the less, all else being equal, the diagnostic test with least radiation risk will be the most cost effective.

The trade-off between time efficiency and accuracy

Some modalities such as CT may take more time (from time of presentation) to undertake than others, particularly when issues such as scheduling and reporting are taken into account. Clinicians may need time to decide whether they should undertake these modalities only following a primary assessment (whether this is clinical or prior imaging such as x-ray). Thus there is potentially a trade-off between the quicker (and sometimes more readily available modalities) yet less accurate modalities, versus taking a bit more time for a more precise diagnosis. It is assumed that as net benefit increases (due to lack of deterioration), net cost will decrease (i.e. due to reduced length of stay, less complicated and costly treatment).

The service delivery costs of enabling timely diagnostic intervention (such as providing 24/7 CT) were considered outside the remit of this guideline and further considered in Guidance for Trauma Services (CG XXX). Where appropriate this guideline cross references these considerations. The trade-off between time efficiency and accuracy is therefore reflected in determining net clinical benefit, rather than in determination of net cost.

Consideration of overall resource use and costs of a diagnostic strategy

In the absence of economic evidence, the intervention cost of the diagnostic modality, as well the cost associated with each diagnostic outcome (in terms of the indicated onward management), was considered. The total cost of a diagnostic strategy was considered as the sum of the intervention cost and the product of each diagnostic outcome and the respective costs of indicated onward management. Costs of each diagnostic strategy are offset by the net clinical benefit that the strategy brings (i.e. through incidental findings or through time efficient management).

O.1.1 Full body CT

Table 64: Imaging costs [91]

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Notes
X-ray	Direct Access Plain Film (DAPF)	£28	£22	£33	The number of data submissions for this code was 153, with 5,254,817 units of activity (examinations)
CT	Computerised Tomography Scan, one area, no contrast, 19 years and over (RA08A)	£60	£62	£62	The number of data submissions for this code was 4, with 70 units of activity (examinations)
	Computerised Tomography Scan, one area, with post contrast only, 19 years and over (RA09A)	£71	£71	£71	The number of data submissions for this code was 1, with 10 units of activity (examinations)
	Computerised Tomography Scan, one area, pre and post contrast (RA10Z)	£301	£301	£301	The number of data submissions for this code was 1, with 1 unit of activity (examinations)
	Computerised Tomography Scan, two areas without contrast (RA11Z)	£58	£58	£58	The number of data submissions for this code was 1, with 12 units of activity (examinations)
	Computerised Tomography Scan, two areas with contrast (RA12Z)	£76	£72	£72	The number of data submissions for this code was 2, with 22 units of activity (examinations)
	Computerised Tomography Scan, more than three areas (RA14Z)	£146	£102	£190	The number of data submissions for this code was 2, with 2 units of activity (examinations)

(a) For CT, the costs are from the 'trauma and orthopaedics' service description.
(b) Note for CT, there is no category under the trauma and orthopaedics service description for below 19 years of age.
(c) The number of data submissions for the activity level recorded for CT indicate that the unit cost was likely to be reflective of the costs only incurred by a few providers. This may explain why the ultrasound of more than 20 minutes costs less than the ultrasound of less than 20 minutes.
(d) Note that for some of the modalities the lower and upper quartile costs are the same, however it is reported here as it is reported in NHS reference costs 2012-13.
(e) Where the number of submissions and activity levels is low, this may imply that the cost is not likely to be representative of the national average.

O.1.2 Pelvic imaging

Table 65: Imaging costs [91]

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	NOTES
X-ray	Direct Access Plain Film (DAPF)	£28	£22	£33	The number of data submissions for this code was 153, with 5,254,817 units of activity (examinations)
CT	Computerised Tomography Scan, one area, no contrast, 19 years and over (RA08A)	£60	£62	£62	The number of data submissions for this code was 4, with 70 units of activity (examinations)
	Computerised Tomography Scan, one area, with post contrast only, 19 years and over (RA09A)	£71	£71	£71	The number of data submissions for this code was 1, with 10 units of activity (examinations)

(a) For CT, the costs are from the 'trauma and orthopaedics' service description.
(b) Note for CT, there is no category under the trauma and orthopaedics service description for below 19 years of age.
(c) The number of data submissions for the activity level recorded for CT indicate that the unit cost was likely to be reflective of the costs only incurred by a few providers.
(d) Note that for some of the modalities the lower and upper quartile nit costs are the same, however it is reported here as it is reported in NHS reference costs 2012-13.

O.1.3 Cystourethrogram

Table 66: Imaging costs[92]

Resource	Description	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	NOTES
Fluoroscopy	Contrast Fluoroscopy Procedures, less than 20 minutes	£69	£40	£86	The number of data submissions for this code was 119, with 48,617 units of activity (examinations)
CT	Computerised Tomography Scan, one area, no contrast, 19 years and over	£80	£62	£97	The number of data submissions for this code was 124, with 90,108 units of activity (examinations)
	Computerised Tomography Scan, one area, with post contrast only, 19 years and over	£91	£70	£105	The number of data submissions for this code was 116, with 18,505 units of activity (examinations)

(a) The costs here differ from those in the tables above because the costs for this question were gathered when the latest version on NHS reference costs had been published (NHS reference costs 2013/14)

(b) The number of data submissions for the activity level recorded for CT indicate that the unit cost was likely to be reflective of the the national average.

O.2 Limb Salvage

Table 67: Amputation cost[92]

Resource	Description	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Notes
Amputation	Amputation of Single Limb with CC Score 0-9 (HRG: YQ22B)	£8,589	£6,439	£10,358	Data submissions for this code was 112, with 1,378 units of activity

(a) The number of data submissions for the activity level recorded indicate that the unit cost was likely to be reflective of the the national average.

This is the acute care cost associated with an amputation. Further lifetime resource use would include further re-operations and the prodthetics.

O.3 Arterial shunts

See the previous section for amputation costs.

O.4 Pelvic haemorrhage control

Table 68: IInterventional radiology costs[92]

Intervention/ Diagnosis	Reference cost HRG	National average unit cost	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Average cost of excess bed day	Lower Quartile Unit Cost	Upper Quartile Unit Cost	Weighted national average	Weighted average length of stay	NOTES
Percutaneous Transluminal Embolisation of Blood Vessel	Percutaneous Transluminal Embolisation of Blood Vessel with CC Score 3+ (YR21A); as recorded for Non-Elective Inpatients long stay	£5,465	£2,779	£6,958	£259	£203	£284	£5,987	9.92	The number of data submissions for this code was 92, with 492 units of activity.
Percutaneous Transluminal Embolisation of Blood Vessel	Percutaneous Transluminal Embolisation of Blood Vessel with CC Score 0-2 (YR21B); as recorded for Non-Elective Inpatients long stay	£3,691	£2,370	£4,335	£329	£225	£391	£4,232	4.41	The number of data submissions for this code was 57, with 130 units of activity.
Percutaneous Transluminal Embolisation of Blood Vessel	Weighted for complications and co morbidities for HRG codes: YR21A, YR21B and ; as recorded for Non-Elective Inpatients long stay							£5,620	8.77	

(a) The number of data submissions for the activity level recorded indicate that the unit cost was likely to be reflective of the the national average.

O.5 Detecting compartment syndrome

See section O.2 for amputation costs.

Table 69: Fasciotomy costs [92]

Resource	Description	National average unit cost	Lower quartile unit cost	Upper quartile unit cost	Notes
Fasciotomy	Minor Knee Procedures for Trauma, Category 2, without CC (HA25C)	£3,477	£2,333	£4,297	Data submissions for this code was 112, with 265 units of activity

(a) The number of data submissions for the activity level recorded indicate that the unit cost was likely to be reflective of the the national average.

Appendix P: Qualitative study checklist

P.1 Information and support

Table 70: <Insert Table Title here>

Link to GRADE criteria	Question	Forsberg 2014[119]	Sleney 2014[372]	Okonta 2011[300]	O'Brien 2010[290]
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/ Sufficiency of evidence	Are the conclusions adequate?	✓	✓	✓	✓

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