



## Supplementary Material

10.1302/2046-3758.122.BJR-2022-0116.R1

**Supplementary Material 1.** Search strategy summary, search terms used, and detailed search results.

Databases searched and date ranges detailed	
Database	Date range after addition of date filters (dd/mm/yyyy)
<b>Primary searches</b>	
Ovid. <b>Medline</b> (Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) 1946 to the 20 <sup>th</sup> of July 2017	01/01/2009 – 20/04/2017
Ovid. <b>Embase</b> 1974 to the 20 <sup>th</sup> of April 2017	01/01/2009 – 20/04/2017
Ovid. <b>PsychINFO</b> 1806 to the 21 <sup>st</sup> of April 2017	01/01/2009 – 21/04/2017
Cumulative Index to Nursing and Allied Health Literature ( <b>CINAHL</b> ) Database. EBSCO 1937 to the 21 <sup>st</sup> of April 2017	01/01/2009 – 21.04.2017
Cochrane <b>CENTRAL</b> 1996 to the 11 <sup>th</sup> of May 2017	01/01/2009 – 12/05/2017
Search updates	
<b>Embase</b> 1974 to present, <b>Medline</b> (Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) 1946 to the 12 <sup>th</sup> of July 2019	01/01/2017 – 12/07/2019
<b>Search strategy summary and terms used.</b>	
	<b>Search type</b>

1	Open Fracture search component. Combined with Boolean terms: <b>'OR'</b>	
	Fractures, Open/	MeSH
	((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	Title and abstract search
2	Anatomical area search component. Combined with Boolean terms: <b>'OR'</b>	
	exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/ or Leg Bones/ or exp Foot Bones/ or exp Toes/ or Leg/	MeSH
	"lower extremit*".ti,ab or "lower limb*".ti,ab. or (leg or legs).ti,ab. or (foot or feet).ti,ab. or thigh*.ti,ab. or ankle*.ti,ab. or (hip or hips).ti,ab. or knee*.ti,ab. or femur*.ti,ab. or tibia*.ti,ab. or patella*.ti,ab. or talus*.ti,ab. or fibula*.ti,ab. or calcaneus*.ti,ab. or navicular*.ti,ab. or cuneiform*.ti,ab. or cuboid*.ti,ab. or metatarsal*.ti,ab. or phalan*.ti,ab. or (toe or toes).ti,ab. or pilon*.ti,ab.	Title and abstract search
3	1 <b>'AND'</b> 2	
MeSH - Medical Subject Heading (MeSH) exp – exploded MeSH heading * – Truncation/wildcard symbol ti – Title search (search for key word in article titles) ab – Abstract search (search for keyword in article abstracts) adj3 – Proximity search term (two words next to each other, in any order, up to 2 words in between)		

### Primary searches

Medline (Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) 1946 to 20 July 2017

Searches	Results
1 Fractures, Open/	5,041
2 ((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	10,342
3 1 or 2	12,576
4 exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	153,269
5 "lower extremit*".ti,ab.	46,287
6 "lower limb*".ti,ab.	40,713
7 (leg or legs).ti,ab.	99,855
8 (foot or feet).ti,ab.	97,562
9 thigh*.ti,ab.	25,165

10	ankle*.ti,ab.	49,851
11	(hip or hips).ti,ab.	119,217
12	exp Leg Bones/	87,046
13	knee*.ti,ab.	121,914
14	femur*.ti,ab.	45,068
15	tibia*.ti,ab.	73,410
16	patella*.ti,ab.	17,803
17	talus*.ti,ab.	4,094
18	fibula*.ti,ab.	10,540
19	calcaneus*.ti,ab.	4,884
20	navicular*.ti,ab.	2,185
21	cuneiform*.ti,ab.	1,321
22	cuboid*.ti,ab.	4,749
23	metatarsal*.ti,ab.	7,996
24	exp Foot Bones/	16,512
25	phalan*.ti,ab.	9,815
26	Leg/	62,724
27	(toe or toes).ti,ab.	17,450
28	exp Toes/	11,385
29	pilon*.ti,ab.	2,304
30	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 18 or 17 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	671,851
31	3 and 30	<b>57,67</b>

Embase 1974 to 20 April 2017

**Searches**

**Results**

1	exp open fracture/	5,640
2	*open fracture/	2,603
3	((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	11,677
4	1 or 3	13,474
5	exp lower limb/	352,703

6	*lower limb/	843
7	exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	357,372
8	exp leg/	295,179
9	exp foot/	56,040
10	exp knee/	91,003
11	exp hip/	73,237
12	exp femur/	87,374
13	exp tibia/	43,709
14	exp fibula/	8,840
15	exp ankle/	40,546
16	exp talus/	5,334
17	exp calcaneus/	8,506
18	exp navicular bone/	156
19	exp cuneiform bone/	71
20	exp cuboid bone/	46
21	exp metatarsal bone/	6,527
22	exp toe phalanx/	264
23	exp foot bone/	20,513
24	exp toe/	14,142
25	"lower extremit*" .ti,ab.	59,556
26	"lower limb*" .ti,ab.	56,681
27	(leg or legs).ti,ab.	127,677
28	(foot or feet).ti,ab.	123,942
29	exp thigh/	22,631
30	thigh* .ti,ab.	33,234
31	ankle* .ti,ab.	64,262
32	(hip or hips).ti,ab.	151,631
33	knee* .ti,ab.	151,705
34	femur* .ti,ab.	56,709
35	tibia* .ti,ab.	88,356
36	patella* .ti,ab.	20,358

37	exp patella/	10,542
38	talus*.ti,ab.	4,676
39	fibula*.ti,ab.	12,385
40	calcaneus*.ti,ab.	5,616
41	navicular*.ti,ab.	2,451
42	cuneiform*.ti,ab.	1,452
43	cuboid*.ti,ab.	5,378
44	metatarsal*.ti,ab.	9,363
45	phalan*.ti,ab.	11,785
46	(toe or toes).ti,ab.	22,731
47	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46	822,119
48	4 and 47	<b>6,123</b>

PsychINFO 1806 to 21 April 2017

<b>Searches</b>	<b>Results</b>
1 ((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	180
2 open fracture*.ti,ab.	4
3 1 or 2	180
4 "lower extremit*".ti,ab.	1,788
5 "lower limb*".ti,ab.	2,401
6 (leg or legs).ti,ab.	9,136
7 (foot or feet).ti,ab.	9,141
8 thigh*.ti,ab.	794
9 ankle*.ti,ab.	2,117
10 (hip or hips).ti,ab.	5,023
11 knee*.ti,ab.	3,769
12 femur*.ti,ab.	325
13 tibia*.ti,ab.	1,703
14 patella*.ti,ab.	237
15 talus*.ti,ab.	11

16	fibula*.ti,ab.	84
17	calcaneus*.ti,ab.	35
18	navicular*.ti,ab.	8
19	cuneiform*.ti,ab.	107
20	cuboid*.ti,ab.	26
21	metatarsal*.ti,ab.	46
22	phalan*.ti,ab.	215
23	(toe or toes).ti,ab.	1,226
24	exp thigh/	44
25	exp foot/	1,456
26	exp knee/	954
27	exp ankle/	412
28	exp toe/	641
29	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	32,034
30	3 and 29	<b>19</b>

Cumulative Index to Nursing and Allied Health Literature (CINAHL) Database.  
EBSCO 1937 to 21 April 2017

	<b>Searches</b>	<b>Results</b>
S1	(MM "Fractures, Open")	
S2	TI open fracture*	507
S3	TI compound fracture*	26
S4	AB open fracture*	954
S5	AB compound fracture*	40
S6	S1 OR S2 OR S3 OR S4 OR S5	1,399
S7	(MH "Lower Extremity+")	
S8	TI lower limb	
S9	AB lower limb	
S10	TI lower extremity	
S11	AB lower extremity	
S12	(MH "Hip")	
S13	TI hip	

S14 AB hip  
S15 (MM "Fractures, Open")  
S16 TI open fracture\*  
S17 TI compound fracture\*  
S18 AB open fracture\*  
S19 AB compound fracture\*  
S20 S15 OR S16 OR S17 OR S18 OR S19  
S21 (MH "Lower Extremity+")  
S22 TI lower limb  
S23 AB lower limb  
S24 TI lower extremity  
S25 AB lower extremity  
S26 (MH "Hip")  
S27 TI hip  
S28 AB hip  
S29 (MH "Femur+")  
S30 TI femur  
S31 AB femur  
S32 (MH "Knee")  
S33 TI knee  
S34 AB knee  
S35 (MH "Patella")  
S36 TI patella  
S37 AB patella  
S38 "tibial plateau"  
S39 TI tibial plateau  
S40 AB tibial plateau  
S41 (MH "Tibia")  
S42 TI tibia  
S43 AB tibia  
S44 (MH "Fibula")  
S45 TI fibula

S46	AB fibula	
S47	(MH "Ankle")	
S48	TI ankle	
S49	AB ankle	
S50	(MH "Talus")	
S51	TI talus	
S52	AB talus	
S53	(MH "Calcaneus")	
S54	TI calcaneus	
S55	AB calcaneus	
S56	(MH "Tarsal Bones") OR "navicular"	
S57	TI navicular	
S58	AB navicular	
S59	"cuboid"	
S60	TI cuboid	
S61	AB cuboid	
S62	"cuneiform"	
S63	TI cuneiform	
S64	AB cuneiform	
S65	(MH "Metatarsal Bones")	
S66	TI metatarsal	
S67	AB metatarsal	1,534
S68	"phalanx"	
S69	TI phalanx	
S70	AB phalanx	
S71	(MH "Foot") OR (MH "Foot Bones")	
S72	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71	130,012
S73	S6 AND S72	1,399



Cochrane CENTRAL 1996 to 11 May 2017

<b>Searches</b>	<b>Results</b>
#1 open fracture*:ti,ab,kw (Word variations have been searched)	1,485
#2 MeSH descriptor: [Fractures, Open] explode all trees	101
#3 #1 or #2	1,485
#4 lower limb:ti,ab,kw (Word variations have been searched)	6,146
#6 MeSH descriptor: [Thigh] explode all trees	413
#7 MeSH descriptor: [Hip] explode all trees	369
#8 MeSH descriptor: [Femur] explode all trees	1,170
#9 MeSH descriptor: [Knee] explode all trees	690
#10 MeSH descriptor: [Tibia] explode all trees	512
#11 MeSH descriptor: [Leg] explode all trees	2,865
#12 MeSH descriptor: [Ankle] explode all trees	443
#13 MeSH descriptor: [Foot] explode all trees	1,450
#14 MeSH descriptor: [Leg Bones] explode all trees	1,845
#15 MeSH descriptor: [Foot Bones] explode all trees	266
#16 hip:ti,ab,kw (Word variations have been searched)	13,792
#17 femur:ti,ab,kw (Word variations have been searched)	3,889
#18 knee:ti,ab,kw (Word variations have been searched)	16,216
#19 fibula:ti,ab,kw (Word variations have been searched)	185
#20 MeSH descriptor: [Fibula] explode all trees	72
#21 MeSH descriptor: [Patella] explode all trees	296
#22 patella:ti,ab,kw (Word variations have been searched)	742
#23 tibia:ti,ab,kw (Word variations have been searched)	1,503
#24 ankle:ti,ab,kw (Word variations have been searched)	5,560
#25 MeSH descriptor: [Foot Bones] explode all trees	266
#26 "talus":ti,ab,kw (Word variations have been searched)	73
#27 MeSH descriptor: [Talus] explode all trees	33
#28 MeSH descriptor: [Calcaneus] explode all trees	150
#29 Calcaneus:ti,ab,kw (Word variations have been searched)	309
#30 navicular:ti,ab,kw (Word variations have been searched)	36

#31	cuboid:ti,ab,kw (Word variations have been searched)	10
#32	cuneiform:ti,ab,kw (Word variations have been searched)	8
#33	MeSH descriptor: [Metatarsal Bones] explode all trees	62
#34	metatarsal:ti,ab,kw (Word variations have been searched)	260
#35	MeSH descriptor: [Tarsal Bones] explode all trees	196
#36	phalan*:ti,ab,kw (Word variations have been searched)	174
#37	toe or toes:ti,ab,kw (Word variations have been searched)	813
#38	#4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37	<b>42,552</b>

### Search update

Medline (Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) 1946 to 12 July 2019

Searches	Results
1 Fractures, Open/	8,995
2 ((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	24,342
3 1 or 2	27,936
4 exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	524,638
6 "lower limb*".ti,ab.	113,075
7 (leg or legs).ti,ab.	253,197
8 (foot or feet).ti,ab.	247,500
9 thigh*.ti,ab.	66,484
10 ankle*.ti,ab.	130,736
11 (hip or hips).ti,ab.	307,815
12 exp Leg Bones/	192,500
13 knee*.ti,ab.	316,636
14 femur*.ti,ab.	113,307
15 tibia*.ti,ab.	181,369
16 patella*.ti,ab.	42,426
17 talus*.ti,ab.	9,619
18 fibula*.ti,ab.	25,838

19	calcaneus*.ti,ab.	11,324
20	navicular*.ti,ab.	4,897
21	cuneiform*.ti,ab.	2,977
22	cuboid*.ti,ab.	11,131
23	metatarsal*.ti,ab.	18,957
24	exp Foot Bones/	36,140
25	phalan*.ti,ab.	23,221
26	Leg/	133,989
27	(toe or toes).ti,ab.	44,724
28	exp Toes/	25,104
29	pilon*.ti,ab.	5,338
30	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 18 or 17 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	169,6412
31	3 and 30	<b>13,022</b>

Embase 1974 to the 12 July 2019

	<b>Searches</b>	<b>Results</b>
1	Fractures, Open/	8,995
2	((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	24,342
3	1 or 2	27,936
4	exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	524,638
6	"lower limb*".ti,ab.	113,075
7	(leg or legs).ti,ab.	253,197
8	(foot or feet).ti,ab.	247,500
9	thigh*.ti,ab.	66,484
10	ankle*.ti,ab.	130,736
11	(hip or hips).ti,ab.	307,815
12	exp Leg Bones/	192,500
13	knee*.ti,ab.	316,636
14	femur*.ti,ab.	113,307
15	tibia*.ti,ab.	181,369
16	patella*.ti,ab.	42,426

17	talus*.ti,ab.	9,619
18	fibula*.ti,ab.	25,838
19	calcaneus*.ti,ab.	11,324
20	navicular*.ti,ab.	4,897
21	cuneiform*.ti,ab.	2,977
22	cuboid*.ti,ab.	11,131
23	metatarsal*.ti,ab.	18,957
24	exp Foot Bones/	36,140
25	phalan*.ti,ab.	23,221
26	Leg/	133,989
27	(toe or toes).ti,ab.	44,724
28	exp Toes/	25,104
29	pilon*.ti,ab.	5,338
30	4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 18 or 17 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	1,696,412
31	3 and 30	13,022
32	limit 31 to last 2 years	<b>1,701</b>

**Supplementary Material 2.** List of verbatim outcomes, and frequency of reporting. Grouped by standardized outcome headings, outcome domains, and core areas using the Core Outcomes in Effectiveness Trials Initiative (COMET) Taxonomy of Outcomes.

		Core Area							
		Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
Death	Survival (1)	Survival	21	1	20	8	Death	2	
			Early mortality	1					
			Late mortality	1					
			Mortality	11					
			Mortality rate	2					
			Risk of one-year mortality	1					
			Standard mortality ratios	1					
			Survival	2					
Physiological or clinical	Blood and lymphatic	Venous	10	0	10	8	Deep vein thrombosis	3	
			DVT	1					
			Embolism	1					
			PE	1					
			Presence of arterial thrombosis	1					
			Pulmonary embolism	1					
			Rate of DVT	1					
			Venous thromboembolism	1					
	General outcomes	Systemic sepsis or	3	0	3	2	Bacteraemia	2	
			The risk for sepsis	1					
	Musculoskeletal and connective tissue outcomes (15)	Adverse events of orthopaedic	5	2	3	5	A major complication	1	
			Achilles tendon contracture	1					
			Adverse events	1					
			Bleeding haematoma	1					
			Orthopaedic complications	1					
Musculoskeletal and	Complications and	71	1	70	35	Chronic bone complications	1		
		Complication	3						
		Complication rate	3						
		Complication rates	3						
		Complication subtype (i.e., cardiac, respiratory, gastrointestinal, urinary, haemorrhage, and infection)	1						
		Complications	29						
		Complications and re-operation	1						

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Complications from external fixator application	1
							Complications-including infection, nonunion, and any cases that progressed to amputation.	1
							Early post-operative complications	1
							Early postoperative complications	1
							Incidence of complication	1
							Major and minor complications	1
							Major complication	1
							Major complications	1
							Minor complications	2
							Occurrence of any complication	1
							Other complications	1
							Other postoperative complications	1
							Overall complication rate	1
							Operatively treated complications related to the study injury	1
							Perioperative complications	2
							Pin site hypergranulation	1
							Post operative wound complications	1
							Postoperative complication	1
							Postoperative complications	4
							Potential complications	1
							Rate of complications	1
							Secondary fracture	1
							Suture failure	1
							Total complications	1
							Wound complications	1
	Hardware or implant	12	0	12	8		Fixation failure	1
							Hardware failure	4
							Hardware failure rate	1
							Implant failure requiring reoperation	1
							Implant failure	1
							Implant breakage/loosening	1
							Implant failure	2
							Metal failure	1
	Pin site	3	1	2	2		Pin loosening	2
							Pin site loosening	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
	Time in	3	0	3	3		External fixator time	1
							Mean duration of fixator application	1
							Time of frame wearing	1
	Amputation	77	8	69	23		Amputation or salvage	1
							Amputation	49
							Amputation or salvage	1
							Amputation rate	5
							Below knee amputation	1
							Below-knee amputation	1
							Consideration of lower leg amputation	1
							Delayed secondary amputation	1
							Early amputation	1
							Early amputation or salvage	1
							Knee range of motion	1
							Limb salvage	1
							Need for amputation	1
							Primary amputation	1
							Progression to amputation	1
							Rate of amputation	1
							Rate of limb salvage	1
							Rate of primary amputation	1
							Rate of secondary amputation	2
							Secondary amputation rates	1
							Secondary amputation	3
							Secondary amputation rate	1
	Bone	2	0	2	2		Bone results	1
							Limb shortening	1
	Bone union or healing	265	15	250	76		Aseptic nonunion	1
							Average time to bone union	1
							Bone consolidation	1
							Bone healing	7
							Bone healing index days/cm	1
							Bone healing status	1
							Bone healing time	4
							Bone hypertrophy	1
							Bone union	79



Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Bone union rates	2
							Bony union and malunion	1
							Bony complications	1
							Bony union	5
							Clinical bone union	1
							Clinical healing	1
							Clinical union	2
							Complete fracture healing	1
							Consolidation of fracture	1
							Days to radiological consolidation	1
							Defective healing	1
							Delayed union	15
							Early bone complications	1
							Early union rate	1
							Fracture healing duration	1
							Fracture consolidation	1
							Fracture healing	13
							Fracture healing problems	1
							Fracture healing rate	1
							Fracture healing time	3
							Fracture union	10
							Fracture union (clinical)	1
							Fracture union (radiological)	1
							Healing	2
							Healing after primary procedure	1
							Healing assessment	1
							Healing index	1
							Healing time	3
							Healing time for bone	1
							Heterotopic ossification	1
							Heterotrophic ossification	1
							Mean fracture healing time	1
							Mean time to healing	1
							Mean time to union	1
							Non union	1
							Presence of union	1
							Presence of union at 6 and 12 months	1
							Primary union rate	1
							Presence of callus	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Radiographic healing	1
							Radiographic fracture union	1
							Radiographic union	4
							Radiological bone union	2
							Radiological outcome	1
							Radiological union	2
							Rate of bone union	1
							Rate of delayed union	1
							Rate/time to union	1
							Requirement for secondary bone grafting	1
							Time taken to radiological union	1
							Time to bone union	15
							Time to bony union	3
							Time to clinical union	1
							Time to complete bone union	1
							Time to fracture union	2
							Time to osseous union	1
							Time to radiographic fracture healing	1
							Time to radiographic fracture union	1
							Time to radiographic union	3
							Time to radiological fracture healing	1
							Time to union	22
							Timing of union and callus formation	1
							To union	1
							Union	10
							Union of fracture	1
							Union rate	3
							Union rates	1
	Malunion or alignment		77	0	77	47	Ability to maintain alignment	1
							Alignment	7
							Anatomical reduction of the calcaneus	1
							Angular deformity	1
							Angular deformity >10 degrees	1
							Angular deformity of fracture	1
							Angular malalignment	1
							Angulation of fixation	1
							Angulation deformity	1
							Angulation of fracture	1
							Anterior distal tibial angle	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Articular reduction at the ankle	1
							Axial alignment	1
							Axial deformity on radiographic assessment	1
							Axis	1
							Bone alignment	1
							Bone malalignment	1
							Bony union and malunion	1
							Deformity	1
							Deformity at the docking site	1
							Final Alignment of the Fracture	1
							Fracture alignment	1
							Fracture union quality	1
							Hind foot angle	1
							Limb alignment	1
							Lower limb axis alignment	1
							Mal-union	1
							Malalignment	1
							Malalignment (or malunion)	1
							Malrotation	1
							Malunion or malalignment	1
							Malunion rate	1
							Malunion	24
							Medial proximal tibial angle	1
							Post operative femoral axis	1
							Posterior proximal tibial angle	1
							Presence of bone defect	1
							Problems with union	1
							Quality of fracture reduction	1
							Quality of reduction	1
							Radiographic examination for degenerative joint changes or malignment	1
							Rate of mal-union	1
							Rate of malrotation	1
							Rate of malunion	1
							Reduction radiographically	1
							Rotational deformity	2
	Non-	53	2	51	9		Delayed or nonunion	1
							Fracture non-union	1
							Non-union and delayed union rate	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Non-union rate	1
							Nonunion/non-union	42
							Nonunion rates	2
							Nonunions	1
							Rate of non-union	1
							Rate on non-union	1
	Osteonecrosis	5	1	4	5		Avascular necrosis	1
							Necrosis of tibial segment	1
							Osteonecrosis	1
							Posttraumatic osteonecrosis	1
							Radiographic osteoarthritis	1
	Pseudoarthrosis	2	0	2	2		Pseudoarthrosis	1
							Rate of Atrophic pseudoarthrosis	1
	Compartment	17	0	17	6		Compartment syndrome rate	1
							Compartment syndrome	11
							Fasciotomy	1
							Fasciotomy rate	1
							Post-operative compartment syndrome	1
							Rate of compartment syndrome	2
	Infection	157	27	130	29		Acute infection	1
							Bone union	1
							Deep infection	1
							Development of infection	1
							Increased infection rate	1
							Infection	105
							Infection in the wound of an open fracture, either deep or superficial	1
							Infection rate	6

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Infection rates	6
							Infection reported at any follow-up visit	1
							Infections	4
							Infectious complication	1
							Infectious complications	1
							Infective complications	1
							Infective symptoms	1
							Non-operatively managed infections	1
							Number of infections	1
							Overall infection rate	1
							Post-operative infection	3
							Postoperative infection	1
							Presence of infection	1
							Presence of Infection/Non-union/Mal-union	1
							Rate of infection	7
							Recurrent infection	1
							Response to infection	1
							Sepsis	1
							SSI	1
							Surgical site infection	4
							Wound infection	1
	Deep infection	88	14	74	17		Deep incisional infection	1
							Deep infection	60
							Deep infection rate	4
							Deep infection with 90 days	1
							Deep infection within one year of initial injury	1
							Deep infections	1
							Deep infective complications	1
							Deep soft tissue infection	2
							Deep surgical site infection	3
							Deep tissue infection	1
							Deep wound infection	4
							Deep wound infection rates	1
							Infection	2
							Infection deep	1
							Organ or space infection	1
							Postoperative deep infection	1
							Presence of deep infection	3

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
	Flap	2	0	2	2		Flap infection	1
							Flap infections	1
	Osteomyelitis	48	6	42	9		Chronic osteomyelitis	2
							Deep infection or osteomyelitis	1
							Infection at fracture site	1
							Infection of fracture site	1
							Osteomyelitis	39
							Osteomyelitis rate	1
							Presence of osteomyelitis	1
							Rate of chronic infection leading to osteomyelitis	1
							Recurrence of Osteomyelitis	1
	Pin site infection	30	2	28	10		Needle tract infection	1
							Pin site infection	10
							Pin site infections	1
							Pin track infection	2
							Pin track infections	1
							Pin tract infection	11
							Pin-site infection	1
							Pin-tract infection	1
							Pintract infection	1
							Presence of pin tract infection	1
	Septic	5	4	1	5		Implant sepsis	1
							Knee sepsis	1
							Occurrence of ipsilateral knee sepsis	1
							Septic joint	1
							Superficial infection	1
	Superficial or wound infection	41	1	40	13		Infection superficial	1
							Local wound infection	1
							Percentage of wound infection	1
							Postoperative superficial infection	1
							Soft tissue infection	2
							Superficial incisional infection	1
							Superficial infection	20
							Superficial infections	2
							Superficial wound infection	1
							Surface infection	1
							Wound infection	8

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Wound infection rate	1
							Wound infection rates	1
	Laboratory	4	0	4	4		Histological analysis of muscle tissue	1
							IL-6 level	1
							Infection cultures	1
							Positive CRP level	1
	Leg length or leg shortening	25	0	25	13		Bone shortening	2
							Leg length	1
							Leg length discrepancy	6
							Leg length ratio	1
							Leg length shortening	3
							Limb length discrepancy	1
							Limb length shortening	1
							Limb shortening	2
							Limb-length discrepancy	1
							Mean lengthening distance	1
							Rate of shortening	2
							Shortening	3
							Shortening deformity	1
	Microbiology cultures	17	1	16	15		Bacteria isolated	1
							Bacterial culture	1
							Causative organisms of infection	1
							Clostridium difficile infection	1
							Culture result	1
							Drug resistant microbiology	1
							Infectious pathogen causing infection and antibiotic resistance	1
							Microbiological profile of deep infection	1
							Microbiology cultures	1
							Pathogen cultured	1
							Positive culture	1
							Specific pathogen on culture	1
							Time taken to negative culture	1
							Wound culture	3
							Wound culture results	1
	Woun	13	1	12	5		Positive wound culture	1
							Wound culture	9
							Wound culture result	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Wound cultures	1
							Wound cultures from infected cases	1
	Numbness	3	0	3	2		Neurovascular disturbance	1
							Presence of trophic change	2
	sensory or motor impairment	17	1	16	12		Donor site power	1
						Foot strength	1	
						Muscle wasting	1	
						Muscle weakness,	1	
						Peripheral nerve deficit	1	
						Persistent foot drop	1	
						Rate of residual neurological deficit	1	
						Sensation	5	
						Sensory recovery	2	
						Severity of injury	1	
						Strength of affected extremity	1	
						Touch sensation	1	
	Osteoarthritis	4	0	4	3		Ankle osteoarthritis	2
						Traumatic osteoarthritis	1	
						Traumatic arthritis incidence	1	
	Pain or discomfort	48	1	47	24		Ache	1
						Ankle pain	1	
						Anterior knee pain	1	
						Calf discomfort	1	
						Hardware pain	1	
						Knee pain	1	
						Mechanical pain	1	
						Midfoot pain	1	
						Neuropathic pain	1	
						Pain	24	
						Pain and discomfort	1	
						Pain during walking	1	
	Pain free	1						
	Pain on walking	2						



Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Pain or joint stiffness	1
							Pain or pain interference	1
							Painful hardware	1
							Persistent post-surgical pain and functional outcomes	1
							Postoperative pain rate	1
							Postoperative pain	1
							Rate of Anterior knee pain	1
							Stump pain	1
							Tenderness	1
							Visual pain scores	1
	Medication	1	0	1	1	1	Pain medication use	1
	Plastics	2	0	2	2	2	Donor-site morbidity	1
							Need for skin graft or flap coverage	1
	Adverse event or complication of graft or flap	18	1	17	17	17	Donor site complications	1
							Donor site problems	1
							Flap complication	1
							Flap complications	1
							Flap donor site problems	1
							Flap oedema	1
							Flap reconstruction	1
							Flap take backs	1
							Flap thrombosis	1
							Flap venous congestion	2
							Flap-related complications	1
							Partial flap failure	1
							Partial flap loss	1
							Postoperative circulatory disturbances of flap	1
							Postoperative venous stasis in flap	1
							Skin invagination at the docking site	1
							Venous congestion	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
	Flap failure or survival	51	4	47	17	Complete flap loss	1	
						Flap failure	12	
						Flap failures	2	
						Flap healing	2	
						Flap loss	4	
						Flap necrosis	1	
						Flap outcome	1	
						Flap salvage	1	
						Flap success	1	
						Flap survival	13	
						Free flap survival	3	
						Need for second stage procedure of partial or complete flap failure	1	
						Partial flap loss	2	
						Time to flap healing	1	
						Total and partial flap failure	1	
	Total flap failure	1						
	Total flap loss	4						
	Graft or	10	0	10	4	Flap necrosis	6	
						Graft necrosis	1	
						Marginal necrosis	1	
						Partial necrosis	2	
	Reoperations	21	5	16	16	Characteristics of external fixator revisions	1	
						Conversion to IM nailing	1	
						Need for additional operations	1	
						Need for re-exploration with reason	1	
						Need for reoperation	1	
						Need for unplanned reoperation	1	
						Number of flap take backs (taking back to theatre for revision)	1	
						Number of soft tissue coverage procedures	1	
						Reoperation	4	
						Reoperation due to loss of reduction or non-union	1	
						Reoperations	2	
Revision surgery						2		
Secondary interventions						1		
Total number of debridements until wound closure	1							
Unplanned surgeries	1							

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Unplanned, clinically important reoperations	1
	Number of	7	0	7	7		Frequency of debridement	1
							Need for debridement	1
							Number of debridements and irrigation procedures	1
							Number of debridements before discharge	1
							Number of debridements	1
							Number of serial debridements	1
							The number of debridements	1
	Number of operations	62	1	61	40		Additional procedures	2
							All-cause reoperation	1
							Average number of revision surgeries	1
							Complications leading to reoperation	1
							Further theatre visits for infection during the index admission	1
							Incidence of reoperation	1
							Incidence of revision surgery	1
							Mean number of operations	1
							Need for additional procedures	1
							Need for further surgery	1
							Need for secondary procedure	1
							Number of external fixator construct revisions	1
							Number of further procedures	1
							Number of operations	8
							Number of Operative Procedures after index admission	1
							Number of orthopaedic operations	1
							Number of procedures	4
							Number of reinterventions on the bone	1
							Number of reoperations	1
							Number of revisions	2
							Number of secondary procedures performed	1
							Number of surgical interventions	1
							Number of surgical procedures	3
						Number or reoperations	1	
						Rate of secondary surgeries	1	
						Re-operation rates	3	
						Reoperation	2	

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Repeat surgery	1
							Requirement of secondary procedures for delayed flap healing	1
							Revision surgery	2
							Secondary procedures	1
							Secondary intervention rate	2
							Secondary operation rates	1
							Secondary outcomes included number of venous anastomoses, rates of venous anastomotic revision, and operative take backs, as well as rates of arterial and venous compromise necessitating return to the operating room	1
							Secondary procedures	2
							Secondary surgical procedures	1
							Total number of operations	3
							Total number of surgical procedures	1
							Total operations per patient	1
							Unplanned surgical procedures	1
	Swelling	2	0	2	2		Limb oedema	1
							Peripheral oedema	1
	Wound	3	0	3	3		Wound complications	1
							Wound haematoma	1
							Wound problems	1
	Wound closure	7	1	6	3		Successful closure of the soft tissue defect was our primary outcome measure.	1
							Time to wound closure	1
							Wound dehiscence	5
	Wound healing	43	2	41	22		Delayed healing	1
							Delayed healing of the stump	1
							Healing assessment	1
							Healing time	2
							Healing time for soft tissue	1
							Incidence of acute fracture wound complications	1
							Primary wound healing	1

Core Area		Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported	
Life impact	Physical functioning		Wound necrosis	14	1	13	9	Rates of wound healing complications	1	
								Skin maceration	1	
								Soft tissue healing	1	
								Tie for soft tissue healing	1	
								Time taken for wound to heal	2	
								Time to complete granulation tissue coverage	1	
								Time to skin healing	1	
								Time to wound healing	1	
								Type of healing	1	
								Ulcer development	1	
								Wound healing	17	
								Wound healing problem	1	
								Wound healing problems	4	
								Wound healing time	1	
					Wound infection	1				
		Renal and urinary	Acute	Wound necrosis	14	1	13	9	Partial necrosis	1
								Postoperative wound necrosis	1	
								Rate of tissue necrosis	1	
								Rate of wound necrosis	1	
								Skin necrosis	6	
								Soft tissue necrosis	1	
								Tissue breakdown	1	
								Tissue necrosis	1	
		Renal and urinary	Acute	Wound necrosis	14	1	13	9	Wound necrosis	1
								Acute kidney injury	1	
								Aki	1	
								AKI rate	1	
	Renal and urinary	Renal	Wound necrosis	14	1	13	9	Improvement in renal function	1	
							Renal failure	1		
	Physical functioning	Ability to	Wound necrosis	2	0	2	2	Ability to climb stairs	1	
							Climbing stairs	1		
	Physical functioning	Abi	Wound necrosis	4	0	4	4	Ability to resume activities of daily living	1	
							Activities of daily living	1		

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Regain of walking and activities of daily living	1
							Status of activities of daily living	1
	Disability	3	1	2	3		Average overall disability rating	1
							Disability	1
							Overall disability rating	1
	Function - lower limb functional and general physical function	88	8	80	30		Bony and functional assessment	1
							Clinical and functional outcomes	1
							Donor site function	1
							Foot functional outcomes	1
							Function	20
							Function evaluation	1
							Functional and bone results	1
							Functional and clinical outcomes	1
							Functional assessment	2
							Functional outcome	18
							Functional outcomes	3
							Functional results	3
							Functionality	1
							Functional outcomes	1
							Limb function	13
							Long term function	1
							Lower extremity function	1
							Lower leg and ankle function	1
							Lower limb function	5
							Measure of function	1
							Objective physical function	1
							Overall function	1
							Patient function	1
							Patient-reported outcome	1
							Patient-reported function	1
							Physical activity	2
							Physical functioning	1
						Return to limb function	1	
						Time to return to full function	1	
						Upper limb donor site assessments	1	
A		16	0	16	7		Ankle and foot function	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Ankle function	8
							Ankle functional outcome	1
							Ankle joint function	1
							Foot and ankle function	3
							Functional outcome	1
							Knee functionality	1
	Foot	7	0	7	4		Ankle and foot function	1
							Foot and ankle function	3
							Foot function	2
							Foot functional outcomes	1
	Knee function	12	0	12	7		Additional functional assessment	1
							Functional outcome	1
							Knee function	5
							Knee functional results	1
							Knee range of movement	2
							Knee Society scoring	1
							Ligament integrity of knees	1
	Shoulder	1	0	1	1		Shoulder function	1
	Gait, walking and mobility	29	3	26	22		Ability to walk	3
							Able to walk without aids	1
							Ambulating without support	1
							Ambulation	1
							Ambulatory status	1
							Gait	2
							Impairment of walking function	1
							Limping	1
							Mobility	5
							Mobility - Objective outcome	1
							Mobility status	1
							Observable limp	1
							Post operative ambulation status	1
							Regain of walking and ADLs	1
							Return to ambulation	1
							Return to ambulation and discharge destination	1
							Time to weight bearing status	1
							Use of a walking aid	1

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Use of crutches	1
							Walking speed	1
							Walking ability	1
							Walking without assistance	1
	Weight	2	0	2	2	2	Ability to fully weight bear pain free	1
							Time to weight bearing	1
	Weight bearing status and time to	14	0	14	10	10	Full weight bearing	2
							Partial or painless weight bearing	1
							Time to full weight bearing	3
							Time to full weight bearing without crutches	1
							Time to full weightbearing ambulation without an aid	1
							Time to weight bear without crutches	1
							Time to weight bearing	2
							Time to weight bear	1
							Weight bearing capacity	1
							Weight bearing status	1
	Movement, range of movement and stiffness	25	0	25	19	19	Active range of motion of the tibiotalar joint	1
							Ankle stiffness	1
							Fixed flexion deformity	1
							Joint mobility	1
							Joint stiffness	3
							Joint stiffness at the ankle and knee	1
							Jumping	1
							Knee stiffness	1
							Mobility	2
							Presence of subtalar arthrosis	1
							Range of motion	4
							Range of motion in nearby joints	1
							Range of motion of joints close to fracture site	1
							Range of movement	1
							Range of movement at the hip	1
							Ranges of movement	1
							Stiffness	1
							The active range of motion of the subtalar joint	1
							Time taken to achieve complete range of movement	1



Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
	Ankle range of movement	22	0	22	14		Ankle arthrosis	1
							Ankle joint stiffness	1
							Ankle range of motion	1
							Ankle range of movement	6
							Ankle rom	1
							Ankle stiffness	1
							Knee joint stiffness	1
							Mange of motion at the ankle	1
							Mobility of the ankle	1
							Range of ankle motion	1
							Range of motion at ankle	2
							Range of motion at the ankle	3
							Range of motion of the ankle	1
							Range of movement of the ankle	1
	Knee range of movement	25	0	25	16		Knee and ankle range of movement	1
							Knee joint stiffness	1
							Knee range of movement	1
							Knee range of motion	2
							Knee range of motion/knee stiffness	1
							Knee range of movement	1
							Knee range of movement	2
							Knee rom	1
							Knee stiffness	4
							Mobility of the knee	1
							Postoperative knee range of motion	1
							Range of knee motion	2
							Range of motion at knee	1
							Range of motion at the knee	3
							Range of motion at the knee	1
							Range of movement at the knee	2
	Sports, exercise	7	0	7	7		Ability to jump	1
							Ability to run	1
							Ability to squat	1
							Return to adapted sports activity	1
							Return to sport	1
							Running	1
							Sporting activity	1

Core Area		Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
Emotional functioning and	Wearing	1	0	1	1	Ability to wear shoes			1
	Social functioning (26)	Participation	3	0	3	3	Ability to resume recreation activities		1
							Patient activity		1
							Recreational activity		1
	Social functioning (26)	Reliance on others	1	0	1	1	Ancillary requirements		1
	Role functioning (27)	Work and	1	0	1	1	Return to work		1
		Return to work or duty	16	2	14	8	Employment status		4
							Employment status before and after injury.		1
							Occupation status		1
							Return to work		4
	Appearance	5	0	5	3	Aesthetic outcome		2	
Cosmetic outcome							1		
Scar quality							2		
Donor site	1	0	1	1	Donor site appearance		1		

Core Area		Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported	
Resource	Economic	Cost	Mood	1	0	1	1	Mood		
			Worry	1	0	1	1	Fear	1	
			Stress	3	1	2	3	Physical and mental stress	1	
									Post-traumatic stress	1
									Stress	1
		Global quality of life	Quality of life	32	0	32	7	General health status	1	
								General Health/quality of life	1	
								Health related quality of life	9	
								Health-related quality of life	3	
								Preference-based health-related quality-of-life outcomes	1	
								Quality of life	7	
								Quality of life and physical function	1	
		Perceived health	Subjective	2	0	2	1	Subjective assessment of success	2	
		Delivery of care (32)	Communication	1	0	1	1	Whether the leaflets were used to improve communication with other healthcare professionals.	1	
			Patient	5	0	5	4	Patient satisfaction	2	
								Patient satisfaction with the treatment result at the time of consultation	1	
								Satisfaction with treatment	1	
						Subjective outcome: satisfaction	1			
		Economic	Cost	24	8	16	12	Cost	10	
								Cost analysis	1	
								Cost saving	2	
						Describe the economic burden on the healthcare system from the perspective of a payer.	1			

Core Area	Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported
							Healthcare costs	1
							Hospital costs	1
							Patient level costing	1
							Projected lifetime disability cost	1
							Resource use	2
							Total healthcare costs	1
							Treatment cost	2
							True remuneration	1
	Hospital (35)	Hospital re-	5	0	5	5	Re-admission rates	1
							Number of secondary surgical admissions	1
							Rates of readmission	1
							Readmissions	1
							Re-hospitalisation rates at 1 year	1
		Length of hospital	52	0	52	22	Average hospital stay	1
							Duration of hospital stay	1
							Duration of hospitalisation	1
							Hospital duration	1
							Hospital length of stay	1
							Hospital LOS	1
							Hospital stay	4
							Hospitalisation period	2
							Inpatient length of stay	2
							Inpatient stay	1
							Length of hospital stay	16
							Length of hospitalisation	3
							Length of in-hospital stay	1
							Length of inpatient stay	1
							Length of stay	9
							Length of stay	1
							Length of stay in hospital	1
							Mean inpatient hospital costs	1
							Mean length of hospital stay	1
							Number and length of hospital stays	1
							Number of in-patient days	1
							Total duration of hospitalisation	1
	Length		6	0	6	5	Intensive care unit length of stay	2
							Intensive care unit length of stay	1
							Intensive treatment unit length of stay	1

Core Area		Outcome domain (domain)	Standardised outcome	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome	Verbatim outcomes	Number of times reported	
Adverse events or	Adverse events	Adverse events	Number of	1	0	1	1	Length of ICU stay	1	
				5	0	5	4	Length of stay in ICU	1	
				1	0	1	1	Number of emergency department attendances	1	
				Number of	5	0	5	4	Number of clinic visits	1
									Outpatient appointments	2
									Outpatient attendances	1
									Total number of outpatient visits	1
				1	0	1	1	Primary care encounters	1	
				Adverse events	5	0	5	1	Adverse events	5

**Supplementary Material 3.** An inventory of outcome measurement instruments for open lower limb fractures.

Name	Description of OMI including definitions	Frequency of reporting
<b>1. Death outcome measurement instruments (OMIs)</b>		
<b>Survival (1)</b>		
<b>Charlson co-morbidity index<sup>1</sup></b>	Physician reported outcome measurement instrument used to predict 10-year survival in patients with multiple co-morbidities <sup>1</sup> .	1
<b>Definitions of mortality</b>	<ol style="list-style-type: none"> <li>1. Early mortality, defined as death within 90 days after injury.</li> <li>2. Defined as death between 90 days and 2 years</li> <li>3. Mortality was defined as overall in-hospital death from any cause.</li> </ol>	3
<b>2. Physiological or clinical outcome measurement instruments</b>		
<b>1. Musculoskeletal and connective tissue outcome measurement instruments (15)</b>		
<b>Bone outcome measurement instruments</b>		
<b>Definitions of bone union</b>	<ol style="list-style-type: none"> <li>1. A fracture was considered healed if, on clinical assessment, there was no fracture site tenderness on manual palpation or no pain at the fracture site with full weight-bearing, radiographic fracture union demonstrated by the presence of bridging callus or the disappearance of the fracture lines on at least one diaphyseal aspect of each orthogonal radiograph, no hardware failure resulting in intra- medullary nail dynamization or dislocation, and no secondary procedure recommended or performed to promote fracture-healing or any other procedure that would interfere with the process of fracture-healing. The reason for the use of two of four cortices to define fracture union was to detect the earliest signs of fracture union and therefore optimize the detection of any acceleration of fracture-healing.</li> <li>2. Bone consolidation was clinically assessed by a non-painful callus palpation and a full weight bearing without any contention system. Radiological bone consolidation was analysed by two incidences on standard radiographs (anteroposterior and lateral). Consolidation was attested when a bone bridge or a fracture disappearance was seen on three out of four cortices. Radiographs were analysed by two different orthopaedic surgeons.</li> </ol>	50

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>3. Union was determined both clinically and radiographically. Clinical union was based on direct documentation by the treating surgeon. Radiographic union was declared when cortical bridging was seen on at least 2 of 4 cortices with a stable implant. Nonunion was declared when documented by the treating physician and scheduled for nonunion surgery, or, when documentation was lacking, by a lack of radiographic union on the most recent available radiographs.</li> <li>4. Malunion was defined as deformity of united bone with angulation &gt; 5 degrees, shortening &gt; 1 cm and distal fragment rotation &gt; 15 degrees.<sup>13</sup> Nonunion was defined when fractures were not developed union up to nine months after applying external fixator judged on clinically and radiologically. Delayed union was defined when fractures were not developed union up to 6 months judged on clinically and radiologically.</li> <li>5. Fractures were considered clinically united when walking without pain was possible. On radiographs, union was defined as callus on two radiographic views with disappearance of the fracture line.</li> <li>6. X-rays showed corticalization with bone thickness equal to that of the bone adjacent to the regenerated bone and/or consolidation of the docking site.</li> <li>7. Early, delayed and late unions were defined when complete bone healing took place within the following time frames, respectively: &lt; 6 months, 6–9 months and &gt; 9 months.</li> <li>8. Union was defined as the time when a bridging callus was identified on the radiographs and the fracture site was painless during weight bearing.</li> <li>9. Time when both clinical (absence of pain or movement with the patient bearing full weight on the limb; the fixator attached but dynamised) and radiological union (presence of bridging callus in two planes) were complete and all types of support or immobilisation was removed.</li> </ol>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>10. Radiological union was defined as the presence of bridging callous in at least three out of the four cortices [18]. Clinical union was defined as a full painless weight bearing with the circular frame having been dynamised. The frame was removed when there was evidence of union across a minimum of three cortices and a painless full weight bearing.</p> <p>11. Fracture union was assumed when bone healing progressed uneventfully.</p> <p>12. Union was determined both clinically and radiographically. Clinical union was defined as pain-free full weight-bearing and radiographic union was defined as bridging callus of at least three of four cortices on final imaging. The computed tomography (CT) scan was obtained in the setting of uncertainty of radiographic union on plain film radiographs.</p> <p>13. Bridging bone on 3 of 4 cortices and resolution of pain in the supracondylar region.</p> <p>14. When callus maturation was closed over 3/4 of the fracture faces, according to the anteroposterior and lateral radiographs, and the fracture site showed movement or tenderness, clinically.</p> <p>15. Bone union was evaluated based on the clinical evaluation of the fracture site, as well as radiologically. The definition of bone union was: (1) no fracture line and a continuous bridge of four cortices on X-rays (A-P and lateral views), (2) no instability at the fracture site, and (3) no pain at the fracture site on full weight bearing.</p> <p>16. We defined fracture union as bridging callus being present on both the anteroposterior and lateral radiographs, the patient being nontender at the fracture site, and the patient being able to bear full weight on the affected extremity</p> <p>17. The progress of bony union was assessed clinically and radiographically at 3-week intervals until union was sound. Radiographic criteria for union were the same for both groups (i.e. good evidence of bridging periosteal and endosteal callus formation as seen by the obliteration of the</p>	



Name	Description of OMI including definitions	Frequency of reporting
	<p>fracture line on two orthogonal views). The clinical assessment of the union was mainly based on complete absence of pain and tenderness at the fracture site.</p> <p>18. Fracture union was defined as bridging callus on 2 of 4 cortices on biplanar radiographs combined with a lack of patient symptoms. Radiographic data were available using the picture archiving and communication system and were re-viewed by 2 trauma fellowship-trained orthopedic attending surgeons. Agreement was obtained by consensus.</p> <p>19. Union was declared when the patient was able to bear weight without pain or walking aid and formation of good callus.</p> <p>20. Union was defined as callus formation involving at least three cortices or fading of fracture lines on each anteroposterior and lateral radiograph, combined with painless full weight bearing on the affected limb.</p> <p>21. According to radiographic (bridging of the fracture by bone, callus or trabeculae) and clinical criteria (absence of pain or tenderness when weight-bearing)</p> <p>22. We considered union to have occurred when radiologically anteroposterior and lateral radiographs showed bridging of at least three of the four bony cortices and clinically patient was able to walk full weight bearing without any pain.</p> <p>23. Early, delayed and late unions were defined when complete bone healing took place within the following time frames, respectively: &lt;6 months, 6–9 months and &gt;9 months.</p> <p>24. Union was determined both clinically and radiographically. Clinical union was defined as pain-free full weight-bearing and radiographic union was defined as bridging callus of at least three of four cortices on final imaging. The computed tomography (CT) scan was obtained in the setting of uncertainty of radiographic union on plain film radiographs.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>25. Fracture healing was defined as: clinically, no pain or tenderness over the fracture zone and radiographically, three solid bridging callus ridges connecting the fracture fragment on both the anteroposterior (AP) and the lateral views. We followed the US Food and Drugs Administration (FDA) guidelines, defining nonunion as a fractured bone that had not completely healed within nine months of injury and that had not shown progression towards healing over the past three consecutive months on serial radiographs</p> <p>26. Fracture union was clinically defined as the ability to walk without aids and no pain or tenderness at the site. Radiographically, fracture union was defined as a solid bridging callus connecting the fracture fragments in both the AP and lateral radiographs</p> <p>27. Bone union was defined as the ability to bear weight without pain with evidence of callus bridging at <math>\geq 3</math> cortices on radiographs.</p> <p>28. Healing is determined by the treating surgeon based on the modified radiographic union scale in tibias (mRUST) and clinical assessments. Due to acknowledged uncertainty of these assessments, surgeons grade the radiographic, clinical, and overall assessment of fracture healing together with their certainty of these assessments.</p> <p>29. As either - non-union - Failure of the fracture to progress towards healing as observed by the treating surgeon and that requires further intervention to promote healing either surgical (i.e. bone graft) or non-surgical (i.e. bone stimulator). - Or Failure of progression of fracture healing for at least 2 or 3 successive months with pain at the fracture site.</p> <p>30. The definition of malunion was documented for each article. The rate of malunion according to the authors' definition was extracted from each article. The non-union rate included those fractures that developed osseous non-union after 1-year follow-up. Delayed unions were not included in the non-union rate if the fractures subsequently healed</p> <p>31. Time to fracture union was based on radiological evidence of calus bridging at least three cortices.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>32. All radiographs were reviewed and healing was defined as follows: bridging callus on at least three cortices as assessed on orthogonal plain radiographs and weight bearing without pain at the fracture site.</p> <p>33. When both clinical (absence of pain) and radiological union (presence of bridging callus in two planes)</p> <p>34. Evidence of callus formation. Localised osteolysis around fracture site if any. Locking bolt loosening/Nail loosening/Bone destruction if any/ Loss of fixation.</p> <p>35. With regard to fracture healing, fractures were classified as union, delayed union or nonunion. Owing to disagreement in the literature regarding the accuracy of radiographs in diagnosing fracture union, 20 we used a combination of clinical and radiological criteria. To be classified as union, fractures had to meet 2 criteria: 1) radiographic evidence of callus cortical bridging and 2) clinical evidence of being able to tolerate functional axial and torsional load at 16 weeks or less postoperatively. Delayed union was defined as fractures that did not meet both of the previously mentioned criteria at 16 weeks post- surgery. Delayed fractures were treated either with a prolonged period of immobilization or with operative debridement and stabilization. Delayed unions that did not meet the criteria for union following treatment were defined as nonunions.</p> <p>36. Union was defined on orthograde plain radiographs at the 6 month-and 12-month mark. For the definition of bony union, the Radiographic Union Score for Tibial fractures was used. This was then correlated with clinical information (tender and painful fracture area).<sup>11–14</sup> The Radiographic Union Score for Tibial fractures score assigns a score based on the healing (callus formation) at each of the four cortices on an anterior-posterior and lateral radio- graph.<sup>15</sup> Patients were categorized into two groups. The first group with a score from 4 to 6 and tenderness or pain in the fracture side was categorized as not united (radiologic and clinical nonunion). The second group was patients with a score of 10 to 12 without pain and tenderness and classified as united (radiologic and clinical union). Patients with a score from 7 to 9 were allocated to 1 of the 2 groups</p>	

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	<p>depending on the clinical finding. Patients with tenderness and pain over the fracture area (clinical nonunion) were considered as not united and included into the first group. Patients without tenderness and pain over the fracture area (clinical union) were categorized as united and included into the second group.</p> <p>37. Diagnosis of nonunion will include a failure of the fracture to progress towards healing as observed by the treating surgeon and that requires further intervention to promote healing either surgical (i.e. bone graft) or non-surgical (i.e. bone stimulator). Final consensus on nonunion will be determined by the Central Adjudication Committee.</p> <p>38. Delayed union is defined as union after 3e6 months of definitive treatment 12 without the need for revision surgery to effect union.</p> <p>39. Non-union was defined as lack of healing within 6 months requiring operative care. Delayed union was defined as lack of any healing on radiographs within 3 months that required further surgical treatment. Mal-union was defined as angular deformity, translation, or rotational alignment that required surgical correction.</p> <p>40. Non-union was defined as lack of healing within 6 months requiring operative care. Delayed union was defined as lack of any healing on radiographs within 3 months that required further surgical treatment. Mal-union was defined as angular deformity, translation, or rotational alignment that required surgical correction.</p> <p>41. We considered union to have occurred when radiologically anteroposterior and lateral radiographs showed bridging of at least three of the four bony cortices and clinically patient was able to walk full weight bearing without any pain.</p> <p>42. Fracture union where no local tenderness or percussion pain, blurred fracture lines or the formation of a continuous callus, and the ability to walk three minutes with- out external fixation. Fracture radiographic union was defined as a bridging callus across three of four cortices on</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>orthogonal radiographs evaluated by a research investigator, as previously described.</p> <p>43. The fracture was considered as united radiologically if three of four cortices showed bridging callus. Implant was removed after achieving union at fracture site.</p> <p>44. Bony union was defined as radiographic union or clinical union (full painless weight bearing) reported by the radiologist or surgeon.</p> <p>45. Defined as lack of bridging callus at 5 months that eventually healed within seven to nine months.</p> <p>46. Union was assess radiographically using Hammer <i>et al.</i> criteria which has 5 grades with grade 1 &amp; 2 regarded as union with “obliterated and barely discernible fracture line” with “union” achieved. The grade 3 has “uncertain” union with “discernible fracture line” and grade 4 &amp; 5 defined as stage of union “not achieve”.</p> <p>47. Defined union as &gt; 50% visible bridging callus across the fracture on the conventional radiographs and no movement or tenderness was present.</p> <p>48. Normal healing was defined as healing within 6 months, and delayed union was regarded as healing after 6 months. A fractured bone that did not completely heal within 9 months of injury, as well as showing inapparent progression towards healing over three consecutive months on serial radiographs was characterized as non-union.</p> <p>49. Fracture union was based on radiological evidence of callus bridging at least three cortices. Assessment of radiographic union was independently performed using two of the authors.</p> <p>50. Union was defined as the presence of 3 cortices in continuity on the anteroposterior (AP) and lateral (L) x-rays and concomitant ability of the patient to fully weight-bear without pain.</p>	
<p><b>Definitions of clinical union</b></p>	<p>1. Clinical union where patients were able to walk without pain.</p>	<p>6</p>

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>2. If the patient could walk on the affected limb without aid or discomfort at the fracture site.</li> <li>3. Clinical union assessed by the absence of movement at fracture site and time to painless weight-bearing.</li> <li>4. Clinical healing was arbitrarily defined as having achieved full weight-bearing and VAS pain score less than 4 while walking. VAS &lt; 4 was selected because it represents mild pain.</li> <li>5. Painless weight bearing and lack of local tenderness over the site on physical examination.</li> <li>6. Clinical union was defined as absence of tenderness at the fracture site.</li> </ol>	
<p><b>Definitions of malunion</b></p>	<ol style="list-style-type: none"> <li>1. Malunions were defined as more than 5° of angular deformity in any plane. Nonunions were defined by lack of bony continuity and/or failure of progression toward healing with the need for an additional unplanned procedure to gain union.</li> <li>2. Malunion is defined as: 1) valgus; 2) varus, both with an angulation of more than 5 degrees in the coronal or sagittal plane; 3) malrotations; and 4) limb length discrepancy, larger than 1.5 centimeters.</li> <li>3. In evaluation of fracture reduction, an angle of less than 5° was considered excellent, an angle of 5–10° fair, and an angle of more than 10° is poor.</li> <li>4. Malunion or malalignment defined as an angular or rotational deformity exceeding 5° or shortening exceeding 15 mm.</li> <li>5. Initial and united anatomic lateral distal femoral angles (81°65°) were evaluated on anteroposterior views. Sagittal plane reductions were evaluated on lateral views. Clinically significant bone loss was defined as the radiographic presence of antibiotic beads within a cavitary metaphyseal defect. All patients had a minimum 3-month follow-up.</li> </ol>	20

Name	Description of OMI including definitions	Frequency of reporting
	<p>6. Malalignment (or malunion) was defined as angulation or rotational deformity of 5 or more, compared to the uninjured leg.</p> <p>7. As more than 5 degrees of varus/valgus, more than 10 degrees of anterior/posterior angulation, more than 15 degrees of rotation or shortening of more than 1 cm.</p> <p>8. Lower limb axis alignment in both the frontal and the sagittal planes. Mechanical axis deviation (MAD) was measured on the anteroposterior view standing radiograph; MAD was assessed as normal within the range of 6 mm lateral to 17 mm medial from the center of the knee.</p> <p>9. &gt; 5deg angulation.</p> <p>10. Rotational alignment was checked by looking at the foot progression angle to see any excessive in toeing or out toeing as compared to the opposite foot.</p> <p>11. Malalignment was evaluated as varus/valgus angulation greater than 7 degrees on radiographs.</p> <p>12. Deformity was defined as angulation, when there was &gt; 5° angulation.</p> <p>13. Angular malalignment (.5 degrees of sagittal or coronal angulation referenced in contralateral leg radiographs, if non-injured).</p> <p>14. Shortening was defined as &gt; 10 mm shortening compared to the unaffected side.</p> <p>15. Bony complications were defined as mal-union, non-union, delayed union or a failure of the implant.</p> <p>16. Limb alignment was determined by angulation, shortening, and rotation. Angulation was measured in the coronal or sagittal plane. Shortening was determined by clinical comparison with the contralateral leg. Rotational malalignment was measured in both lower extremities clinically</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>as the thigh-foot angle (TFA) and when suspicions remained, a determination was made by CT. Unsatisfactory alignment was defined when one of the following criteria was met: [1] shortening of 1 cm or more; [2] varus or valgus angulation of 5 degrees or more; [3] anterior or posterior angulation of 10 degrees or more; or [4] rotational malalignment of 10 degrees or more compared with the contralateral leg.</p> <p>17. Malrotation (.10 degrees, determined by the foot-thigh angle).</p> <p>18. Defined as a varus or valgus angulation of more than 5 degrees, anterior or posterior angulation of more than 10 degrees, shortening of more than 1.5 cm or more than a 0.5 cm gap at the fracture site.</p> <p>19. Malunion was defined as more than 5 of angular or rotational malposition or of more than 1 centimeter of shortening.</p> <p>20. Malunion defined as leg length discrepancy (.1 cm shortening)</p>	
<p><b>Definitions of non-union</b></p>	<ol style="list-style-type: none"> <li>1. Nonunion, was defined as lack of union requiring unplanned surgical intervention after definitive wound closure or incomplete radiographic healing at 1 year.</li> <li>2. Nonunion was indicated by recommendation of bone-grafting or other surgical intervention for nonunion.</li> <li>3. Nonunion was defined as lack of radiological union 12 months post injury, as evidenced by bridging callus across three of four cortices, in two views on plain radiographs. Fractures requiring secondary procedures to promote union, excluding simple dynamization, or if diagnosed as such by an attending surgeon, were also classified as a nonunion.</li> <li>4. Nonunion was described when either there was no progression of healing for continuous 3 months with the sclerosis of fracture ends or there was gap between fracture ends. Union was</li> </ol>	<p>16</p>



Name	Description of OMI including definitions	Frequency of reporting
	<p>considered to be delayed whenever the progression of bridging callus is slow as evident from the serial radiographs usually diagnosed early at 24–28 weeks.</p> <ol style="list-style-type: none"> <li>5. Non-union was described when either there was no progression of healing for continuous 3 months with sclerosis of fracture ends or there was gap between fracture ends.</li> <li>6. Nonunions were defined by lack of bony continuity and/or failure of progression toward healing with the need for an additional unplanned procedure to gain union.</li> <li>7. Failure of the fracture to progress toward healing, as observed by the treating surgeon, and required further surgical (i.e., bone graft) or nonsurgical (i.e., bone stimulator) intervention to promote healing</li> <li>8. Final outcome was assessed in terms of presence or absence of non-union at 16 weeks on AP and lateral X-rays of the tibia and Fibula.</li> <li>9. Nonunion was described when either there was no progression of healing for continuous 3 months with the sclerosis of fracture ends or there was gap between fracture ends.</li> <li>10. Nonunion was described when either there was no progression of healing for continuous 3 months with the sclerosis of fracture ends or there was gap between fracture ends.</li> <li>11. Diagnosis of nonunion was based on clinical and radiological findings over a minimum follow-up period of &gt;1.2 years. A fracture was not considered to be a nonunion until 12 months after the injury, to account for potential cases of delayed union. The clinical criteria used to define nonunion included the presence of pain and/or motion in response to physiological strain of the affected limb (e.g., the inability to fully weight bear without pain). The radiographic confirmation of union relied on the presence of bridging callus in at least 3 of 4 cortices assessed on anteroposterior and lateral radiographs.</li> </ol>	

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>12. Non-union was defined as failure of union of two or more cortices on biplanar radiographs at six months or no radiological progress in union for the preceding three months in the presence of bone defect involving two or more cortices</li> <li>13. Time to union was defined by the radiographic union score in the tibia (RUST) score at 6 months.</li> <li>14. Defined as absence of a bridging callus across a fracture site after the expected time interval for that injury (usually 10 months)</li> <li>15. Diagnosis of nonunion was based on clinical and radiological findings over a minimum clinic follow-up period of &gt;1.2 years, according to the principle outlined by Frölke et al 2007,<sup>2</sup> which reaffirms the contribution of the Weber and Cech model of nonunion, specifying that in long bones, a minimum of 6 months should pass before nonunion is considered.</li> <li>16. Nonunion was defined as painful fracture with inadequate healing of the fracture 6 months after injury and requiring revision surgery to achieve union.</li> </ol>	
<p><b>Definitions of radiographic bone union</b></p>	<ol style="list-style-type: none"> <li>1. X-rays were rechecked regularly to examine the status of fracture healing, and we used the Lane-Sandhu score (Table II) to evaluate the callus formation rate and visible level of fracture line at the same time points as above.</li> <li>2. The main outcome measure was fracture healing (i.e. adequate callus formation) on X-ray at twenty four weeks.</li> <li>3. Radiographic union if callus on two radiographs with absence of the fracture line.</li> <li>4. Union and consolidation were defined as the union of three of four cortices on antero-posterior and lateral radiographs.</li> <li>5. Radiological union was defined as bridging callus formation and absence of a fracture line at the site of three out of four cortices. Time to heal was defined as the time of radiologic union allowing</li> </ol>	33

Name	Description of OMI including definitions	Frequency of reporting
	<p>removal of external fixation [26]. Callus volume was evaluated by CT scan at 12 months, and compared to the pre-grafting CT scan.</p> <ol style="list-style-type: none"> <li>6. Routine follow-up radiographs were obtained every 4 weeks until solid continuous callus formation was observed; callus formation on 3/4 of the cortices and radiographic evidence of fracture line fading were considered signs of fracture union.</li> <li>7. Bridging callus on anteroposterior and lateral radiographs as well as the absence of pain on palpation and weight bearing</li> <li>8. Delayed healing was defined as at least 2 consecutive postoperative visits with lack of radiographic progression or incomplete radiographic healing with ongoing clinical symptoms between 6 months and up to 1 year after fracture.</li> <li>9. Presence of at least three corticals in anterolateral and lateral x-ray.</li> <li>10. Radiographic union presence of a mature bridging callus in at least three of the four cortices in antero-posterior and lateral radiographs. Clinical union was defined as complete when the patient was able to bear full weight on the operated leg without pain or support.</li> <li>11. Presence of bridging calluses on 2+ cortices.</li> <li>12. Presence of callus.</li> <li>13. Defined as complete union of the cortexes with sufficient callus support and continuity of the medullary canal on both anteroposterior and lateral radiographs.</li> <li>14. Three or more of four cortices had bridging callus in anteroposterior and lateral views.</li> </ol>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>15. Union was considered to have occurred when anteroposterior and lateral radiographs showed bridging of three of the four cortices.</p> <p>16. We defined union as more than 50% visible bridging callus across the fracture on conventional radiographs.</p> <p>17. Callus formation on 3/4 cortices and radiographic evidence of fracture line fading were considered signs of fracture union.</p> <p>18. Bridging callus across three of four cortices on orthogonal radiographs evaluated by one investigator at each site.</p> <p>19. Fracture union was assessed on the basis of clinical and radiographic criteria: 1) bridging cortical bone on at least three cortices; 2) incorporation of the grafted fibula into the tibia; 3) no motion at the fracture site; and 4) painless ambulation.</p> <p>20. Bone union is defined as the return of bone anatomic continuity at the fracture site (radiological union).</p> <p>21. Within an average of 6 months (range 5–9 months), all patients had radiographic evidence of bony union (100 %) with a bridging callus and blunting of the fibula at both the proximal and the distal graft–host bone junction.</p> <p>22. Fracture radiographic union was defined as a bridging callus across 3 of 4 cortices on orthogonal radiographs evaluated by a research investigator, as previously described.</p> <p>23. Bridging callus across three of four cortices on orthogonal radiographs evaluated by one investigator at each site.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>24. Bridging callus across three of four cortices on orthogonal radiographs evaluated by an MD research investigator.</p> <p>25. The presence of external callus bridging the fracture site or absence of fracture lines was regarded as radiological union.</p> <p>26. A radiographic union score for tibia (RUST) fractures.</p> <p>27. The last available radiographs (anteroposterior and lateral) closest to the 52-week visit were independently adjudicated by 3 orthopaedic trauma surgeons blinded to treatment assignment using Radiographic Union Score for Tibial fractures criteria.</p> <p>28. Healing was defined radiologically by the presence of a bridging callus.</p> <p>29. We defined an uncomplicated fracture union as a patient who went on to fracture union without any additional surgeries.</p> <p>30. Radiographic union as measured by the modified Radiographic Union scale in Tibia score. Whelan DB, Bhandari M, Stephen D, et al. Development of the radio- graphic union score for tibial fractures for the assessment of tibial fracture healing after intramedullary fixation. J Trauma. 2010;68:629–632.</p> <p>31. Radiological union: Bridging of the bone on a minimum of three cortices on conventional antero-posterior and lateral radiographs.</p> <p>32. Radiographic union was achieved according to union score described by Hammer et al Hammer RR, Hammerby S, Lindholm B. Accuracy of radiologic assessment of tibial shaft fracture union in humans. Clin Orthop Relat Res 1985;199:233–8.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	33. Time to radiological fracture healing was measured. According to Angelini et al radiographic union was defined as bridging bone on a minimum of 3 cortices in antero-posterior and lateral radiographic views.	
<b>Definitions of amputation</b>	<ol style="list-style-type: none"> <li>1. amputation occurring at or below the knee and up to the ankle.</li> <li>2. Any amputation occurring within the first 3 months of the initial injury.</li> <li>3. Surgical removal of limb or part thereof.</li> <li>4. A late or delayed amputation was defined as one performed more than three months after the injury, an early amputation was performed between twenty-four hours and three months after the injury, and an immediate amputation was defined as one performed less than twenty-four hours after the injury.</li> <li>5. The amputation was defined as “early” if performed within 3 months of the trauma and “delayed” if performed thereafter.</li> </ol>	5
<b>Definitions of pin site loosening</b>	<ol style="list-style-type: none"> <li>1. A pin was considered loose if the pin site demonstrated erythema, pain, or discharge and the concordant radiographs showed at least 1 mm of radiolucency on both sides of the proximal cortex around the pin.</li> </ol>	1
<b>Definitions of range of movement</b>	<ol style="list-style-type: none"> <li>1. Range of movement at knee and ankle.</li> <li>2. Defined as 70° loss of knee flexion or 15° loss of knee extension, 50° loss of ankle motion, all as compared with the normal contralateral side.</li> <li>3. Reported in degrees of motion.</li> <li>4. Reported in degrees of motion.</li> </ol>	5

Name	Description of OMI including definitions	Frequency of reporting
	5. Clinical examination, knee and ankle range of movement were examined by an independent examiner in comparison to the contralateral healthy side using a goniometer.	
<b>External fixation index (EFI)<sup>3</sup></b>	Physician reported outcome measurement instrument. The EFI was calculated by dividing the time (days) in the external fixator by the lengthening achieved (centimeters).	1
<b>Infection outcome measurement instruments</b>		
<b>Definitions of deep infection</b>	<ol style="list-style-type: none"> <li>1. Clear counts of some bacterial organisms from bone or tissue below the muscular fascia.</li> <li>2. Infection of the bone and deep tissue necessitating unplanned operative irrigation and debridement. Planned repeat debridements and superficial infections, which did not need further surgery, were not considered to be deep infections.</li> <li>3. The diagnosis of ‘deep Infection’ was based on the criteria described by the Centers for Disease Control and Prevention (CDC) for ‘deep incisional surgical site infection’ as per Fig. 1. In particular, the definition was not reliant on positive deep cultures and assumed that any intervention, revision or antibiotic use was indicative of infection in this cohort.</li> <li>4. Deep infections were defined as culture positive and requiring surgical debridement.</li> <li>5. Defined as infection of the injured bone and deep tissue necessitating an unplanned operative irrigation and debridement at more than two weeks after the injury. We chose a two-week cutoff in order to address the concern of whether an early debridement was planned or unplanned. Planned repeat debridements and superficial infections not requiring surgery were not considered to be deep infections.</li> <li>6. Deep infection was defined as infection requiring unplanned surgical debridement and/or sustained antibiotic therapy after definitive wound closure. Cellulitis and pin tract infections alone were not considered indicative of deep wound infection, but these were treated with the appropriate antibiotics at the surgeons’ discretion and outcomes recorded. Nonunions were defined as unplanned surgical intervention after definitive wound closure or incomplete radiographic healing 1-year post fracture.</li> </ol>	31

Name	Description of OMI including definitions	Frequency of reporting
	<p>7. Centers for Disease Control criteria for deep surgical site infection. Gopal S, Majumder S, Batchelor AG, et al. Fix and flap: the radical orthopaedic and plastic treatment of severe open fractures of the tibia. J Bone Joint Surg Br. 2000;82:959–966.</p> <p>8. The presence of a deep surgical site infection (SSI) was determined using the criteria of the Centers for Disease Control.<sup>19</sup> Deep SSI is defined as occurring within 30 days after the operation, if no implant is left in place, or within 1 year, if implant is in place and the infection appears to be related to the operation. In addition, the infection must involve deep soft tissues (eg, fascial and muscle layers) of the incision and at least one of the following: (1) purulent drainage from the deep incision; (2) a deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (38.8C), localized pain, or tenderness; (3) an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination; or (4) diagnosis of a deep SSI by a surgeon or attending physician.</p> <p>9. Deep wound infections required surgical debridement for a purulent wound or osteomyelitis and were treated with intravenous antibiotics for at least several weeks.</p> <p>10. wound infections that required an unplanned return to the operating room for irrigation and debridement after wound closure or application of a negative pressure dressing.</p> <p>11. Centers for Disease Control and Prevention definition of a ‘deep surgical site infection’: that is, a wound infection involving the tissues deep to the skin that occurs in the first year following the injury.<sup>14</sup> Any infection that requires continuing medical intervention or has already led to amputation at or after the routine 6-week outpatient appointment will be considered a deep infection.</p> <p>12. Deep infection was defined as present only if the infection required surgical debridement and long-term IV antibiotics based on infectious disease service consultation.</p>	



Name	Description of OMI including definitions	Frequency of reporting
	<p>13. Any infection that warranted operative debridement was considered a deep infection.</p> <p>14. The diagnosis of postoperative wound infection was confirmed using clinical signs and symptoms (erythema, swelling, warmth, constitutional symptoms), documented presence of a draining sinus and elevated serum markers (C-reactive protein, erythrocyte sedimentation rate). Deep infections were those extending to the fracture site, causing abscess formation and/or osteomyelitis.</p> <p>15. Required IV antibiotics and operative intervention including soft tissue or bone debridement, secondary wound closure or soft tissue transfer and possible hardware removal.</p> <p>16. Deep-site infection” was defined as an infection existing in a body part deeper than the skin/adipose tissue, including that leading to abscess formation or osteomyelitis.</p> <p>17. Deep infection involving bone was diagnosed if there was a purulent discharge requiring further bony debridement.</p> <p>18. Apart from explicitly documented, a deep infection was also considered to occur when terms such as fistula, deep abscess, sequestration and infected non-union were used in the manuscripts.</p> <p>19. Infection within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection seems to be related to the operation and infection involves deep soft tissue (e.g., fascia, muscle) of the incision.</p> <p>20. A wound or deep infection is defined as an invasion of the joint or the soft tissues around the joint by pathogenic microorganisms.</p> <p>21. Deep infection was defined as infection requiring surgical debridement with positive deep tissue or bone cultures.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>22. Infection occurred at any point in the study period and appeared to be related to the initial injury, or operation. The diagnosis of deep infection was not reliant on positive deep cultures and assumed that any surgical intervention, revision, or antibiotic use was indicative of infection. And infection involved the deep soft tissues (e.g. fascial and muscle layers) of incision. And at least one of the following: 1. purulent drainage from deep incision. 2. the deep incision spontaneously dehisced, or was deliberately opened by a surgeon when the patient had at least one of the following signs or symptoms: fever (&gt;38 degrees C), localized pain, or tenderness. 3. An abscess or other evidence of infection involving the deep incision was found on clinical examination, during reoperation, or by histopathological/radiological examination.</p> <p>23. Deep incision surgical site infection', as outlined by the Centers for Disease Control and Prevention (CDC).</p> <p>24. Infection requiring surgical debridement and irrigation after operative treatment of an open fracture or the development of an infected nonunion requiring treatment (positive intraoperative cultures), within one year after fracture treatment.</p> <p>25. Deep infection was defined as infection deep to fascia requiring surgical debridement.</p> <p>26. Defined by the surveillance definitions of Center of Disease Control and Prevention.</p> <p>27. Major deep infection' was defined as patients requiring removal or exchange of metalwork for infection, delayed flap failure (partial or complete) due to infection, or deep infected collection requiring surgical drainage. Clinically diagnosed superficial infections that resolved with the administration of antibiotics (e.g., cellulitis) were not included.</p> <p>28. Centers for Disease Control (CDC) definition.<sup>12</sup> This definition covers infection occurring within 30 days of surgery, unless an implant is in place, in which case this period is extended to 12 months. Deep SSI presenting within 12 months of injury and any wound infection requiring continuing</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>medical or surgical intervention after 30 days, including those leading to amputation, were also recorded as a deep SSI.</p> <p>29. Surgical site infection (SSI) at 30 days as per the Centers for Disease Control and Prevention definition.</p> <p>30. Deep surgical site infection (SSI) at 30 days as per the Centers for Disease Control and Prevention definition.</p> <p>31. Defined as purulent drainage or osteomyelitis presenting after definitive wound healing and diagnosed based on clinical suspicion and subsequent culturing, which required prolonged antibiotics or surgical debridement.</p>	
<p><b>Definitions of deep Wound Infection</b></p>	<ol style="list-style-type: none"> <li>1. Deep wound infections included in this study are defined using the criteria set out in the Centers for Disease Control and Prevention document 'Definition of Healthcare- Associated Infection and Criteria for Specific Types of Infections in the Acute Care Setting' [11]. Where studies did not describe infection according to these criteria, judgements on inclusion were taken. CDC. CDC/NHSC Surveillance definition of healthcare-associated infection and criteria for specific types of infections in the acute care setting. 2013 . Available from: <a href="http://www.cdc.gov/nhsn/pdfs/pscmanual/17pscnosindef_current.pdf">http://www.cdc.gov/nhsn/pdfs/pscmanual/17pscnosindef_current.pdf</a>. Cited 8 July 2013</li> <li>2. The diagnosis of postoperative wound infection was confirmed using clinical signs and symptoms (erythema, swelling, warmth, constitutional symptoms), documented presence of a draining sinus and elevated serum markers (C-reactive protein, erythrocyte sedimentation rate). Superficial infections were those limited to the skin and subcutaneous tissues.</li> <li>3. A deep soft tissue infection was defined as any soft tissue infection that was not successfully treated by antibiotics alone and required operative intervention.</li> <li>4. Deep soft tissue infection was defined as any soft tissue infection characterized by redness, warmth, swelling, or purulence that required operative intervention.</li> </ol>	<p>5</p>

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>5. Any soft tissue infection greater than 2 weeks after the coverage procedure that was not successfully treated by antibiotics and required a return to the operating room</li> </ol>	
<b>Definitions of infected implant</b>	<ol style="list-style-type: none"> <li>1. Any chronic wound in the vicinity of the implant, including intermittently draining sinuses.</li> </ol>	1
<b>Definitions of Infection</b>	<ol style="list-style-type: none"> <li>1. Laboratory culture results and presence of clinical infection.</li> <li>2. CRP and/or white cell count was elevated in combination with pus, discharge or wound breakdown, provided it was related to the initial lesion, including the flap.</li> <li>3. Centers for Disease Control criteria. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR; Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol. 1999 Apr;20(4):250-78; quiz 279-80.</li> <li>4. Wound infection or osteomyelitis treated within the first three months after the injury.</li> <li>5. The infection (outcome variable) was identified based on clinical and laboratory findings, according to the criteria of early infection within a two-week interval proposed by Willenegger and Roth 1986.<sup>4</sup> This means that the lesion was considered to be infected if the wound had any aspect of superficial or deep infection with or without fever, leukocytosis and elevated erythrocyte sedimentation rate (ESR).</li> <li>6. The primary outcome variables collected were the presence of infection, type of infection, and the microbiological details of the infections identified. The definition of infection was adapted from the Centre for Disease Control definitions of nosocomial surgical site infections and definitions of infection proposed by Dellinger. Superficial infection was defined as redness and/or discharge from a wound which was treated with antibiotics. Operative debridement may have been performed, but there was no evidence documented of infection below the deep fascia. To be classed as a superficial infection, it must have been managed entirely without exposure of the</li> </ol>	45

Name	Description of OMI including definitions	Frequency of reporting
	<p>underlying bone and/or implants. If symptoms of a superficial infection commenced more than 30 days after injury, it was not included, as this deemed unlikely to be a complication of the initial treatment of the open fracture wound. Deep infection was defined as redness and/or discharge from the wound with documented evidence of infection below the level of the deep fascia. If exposure of the underlying bone or implants occurred, either by wound breakdown or by operative debridement, then the infection was classified as deep. Deep infection was excluded if symptoms commenced more than a year after the injury date, as suggested by the Centre for Disease Control definitions by Horan et al.</p> <p>7. Assessment of wound healing and infective complications were made using a modified version of the ASEPSIS wound scoring system as recommended by the surgical infection study group. The maximum score is 65. According to study by Ashby et al. a score of more than 20 is suggestive of infection. It is objective and repeatable with high sensitivity. For the purpose of this study, a score of 0–20 was taken as normal wound healing and a score of more than 20 as wound infection. The score was recorded at day 2, day 5 and day 14 following debridement. The highest score for each patient was adopted as determined at days 2, 5 and 14. Peel AL, Taylor EW. Proposed definitions for the audit of postoperative infection: a discussion paper. Surgical Infection Study Group. Ann R Coll Surg Eng 1991;73:385–8.</p> <p>8. The definition of infection required the presence of pus and surgical treatment, along with the prescription of antibiotics, targeting the infection. Infections occurring after two months of the first surgical treatment or during a subsequent hospitalisation were considered to be hospital-acquired and excluded, as were patients with infections caused by methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) or methicillin-resistant coagulase-negative staphylococci.</p> <p>9. Infection was defined as chart documentation of either a superficial or deep regardless of culture positivity. Superficial infections involved a documented SSI not affecting bone that required treatment with systemic antibiotics or local debridement. Deep infections involved a documented SSI with bone involvement as well as the need for surgical debridement.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>10. Requiring unplanned surgical debridement and/or sustained antibiotic therapy.</p> <p>11. The determination as to whether a patient incurred an infection varied from institution to institution. Factors that were used as determinants of infection included identification through patient records, the presence of deep wound cultures obtained at surgery, the administration of oral and/or parenteral antibiotics, or consultation with infectious disease physicians. The incidence of infection was then compared between seasons within a given region, and then between institutions for each season.</p> <p>12. Classified by use of a modified CDC criteria: Superficial incisional surgical site infection (SSI) is defined as an infection that involves only the skin or subcutaneous tissue and at least one of the following: <ul style="list-style-type: none"> <li>o Purulent drainage, with or without laboratory confirmation, from the superficial incision. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.</li> <li>o At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by the surgeon, unless incision is culture-negative.</li> </ul>           Deep incisional SSI is an infection that involves deep soft tissues (e.g., fascial and muscle layers) and at least one of the following: <ul style="list-style-type: none"> <li>o Purulent drainage from the deep incision but not from the organ/space component of the surgical site.</li> <li>o A deep incision spontaneously dehisces or is deliberately opened by the surgeon when the patient has at least one of the following signs or symptoms: fever (&gt;38C), localized pain, or tenderness, unless the site culture is negative.</li> <li>o An abscess or other evidence of infection involving the deep incision found on direct examination, during re-operation, or by histopathologic or radiologic examination.</li> </ul>           Organ/space SSI is an infection that involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following: <ul style="list-style-type: none"> <li>o Purulent drainage from a drain that is placed through a stab wound into the organ/space.</li> <li>o Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.</li> <li>o An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.</li> </ul>           When interpreting these criteria, any infections that are superficial to the fascia were considered "Superficial Incisional SSI" and any infections that were deep to the fascia were considered "Deep         </p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>Incisional SSI" (including infections of bone (osteomyelitis)). Organ/Space SSI referred to any infections that affect an organ other than bone.</p> <p>13. Infection was defined when pus was present also when surgical and antibiotic care was considered necessary for the treatment of the infection.</p> <p>14. ASEPSIS19 (Additional treatment, presence of Serous discharge, Erythema, Purulent exudate, Separation of deep tis- sues, Isolation of bacteria, and duration of inpatient Stay) wound score. Wilson AP, Treasure T, Sturridge MF, Grüneberg RN. A scoring method (ASEPSIS) for postoperative wound infections for use in clinical trials of antibiotic prophylaxis. Lancet 1986;1:311–313.</p> <p>15. Pyrexia, raised total leucocyte count and local signs like pus discharge from the wound with erythema of skin edges within 1 week of primary debridement.</p> <p>16. Centers for Disease Control diagnostic criteria for infection were used</p> <p>17. Infection was classified into two groups, namely, superficial or deep (implant-related) infections, which were defined according to Dellinger et al. and CDC-guidelines. A superficial wound infection was one located above the fascia, with erythema and tenderness. A deep implant-related infection was defined as an infection involving deeper tissues as muscular fascia and bone, which could necessitate removal of the osteosynthetic material.</p> <p>18. Superficial infection was defined as cellulitis or presence of serous discharge from the wound or pin tracks that resolved with oral antibiotic therapy and dressings. Deep infection was defined as soft-tissue or bone infection requiring surgical debridement, intravenous antibiotics, and/or removal of implants.</p> <p>19. The diagnosis of infection was based on the presence of discharge, fever, local induration, gaping of the wound, and culture of wound swabs.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>20. Outcome measures included presence of infection requiring rehospitalization and need for soft tissue coverage or limb amputation within 3 months of the initial injury. Infection was determined by positive growth from intraoperative cultures or documentation of the presence of infection by the treating surgeon (to allow inclusion of culture negative infections). Need for soft tissue coverage included local flap or free flap procedures. Limb amputation was subclassified into 2 categories: acute amputation (#1 week from injury) and delayed amputation (1 week–3 months from injury).</p> <p>21. Infections are categorized according to standard Centers for Disease Control and Prevention definitions of surgical site infection. Deep infections are defined as those that require operative treatment; superficial infections are those treated only with antibiotics and wound care, and no operative treatment for the infection. All cases of infection collect the same information recorded on the METRC infection case report form (CRF) to help adjudication of this outcome.</p> <p>22. Deep infection was defined as positive deep wound cultures without positive bone cultures.</p> <p>23. Based on hematological, microbiological, clinical, and, where performed, nuclear medicine investigations - but not clearly defined.</p> <p>24. Deep infection was considered to occur when terms such as fistula, deep abscess, sequestration, osteitis and infected non-union were used in the manuscripts.</p> <p>25. Occurrence of a fistula, an abscess, need for antibiotics or follow-up surgery related to infection was considered as a recurrence of the original infection. Normal kinetics for CRP were defined as an increase after surgery until a peak value was reached, followed by a decrease. Peak value was defined as the earliest value obtained after surgery which was preceded and followed by measurements with lower values. Normalization of CRP was evaluated during follow up.</p> <p>26. Infections will be classified according to the Center for Disease Control (CDC) Criteria. We will define infection in patients as a constellation of clinical symptoms and laboratory examinations.</p>	



Name	Description of OMI including definitions	Frequency of reporting
	<p>These will include (but are not limited to) fever, erythema/cellulitis, positive tissue cultures, and frank purulent drainage.</p> <p>27. Centers for Disease Control and Prevention criteria.</p> <p>28. ASEPSIS19 (Additional treatment, presence of Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria, and duration of inpatient Stay) wound score. Wilson AP, Treasure T, Sturridge MF, Grüneberg RN. A scoring method (ASEPSIS) for postoperative wound infections for use in clinical trials of antibiotic prophylaxis. Lancet 1986;1:311–313.</p> <p>29. Soft tissue and deep metal infection were defined by the presence of clinical signs of infection (increasing erythema and/or suppurative discharge from the wound as assessed by a PRSU surgeon, orthopaedic surgeon or infectious diseases physician) with positive cultures from soft tissues and fixation hardware, respectively.</p> <p>30. Although the definition of wound infection following operative treatment of fractures has considerable variation, we utilized the following Centers for Disease Control and Prevention (CDC) criteria for surgical site infection as applied to orthopaedic wounds. A superficial wound infection was one that was located entirely above the fascia and did not require exposure of the bone or hardware. In those cases in which the fascia was absent secondary to the initial injury or subsequent debridements prior to definitive fracture fixation, the wound infection was considered superficial if there was no exposed bone or hardware and the infection did not track down to these structures. A deep wound infection was one that tracked down to the level of the bone and/or implants. In this study, all deep infections, in addition to meeting the CDC criteria, were required to have positive deep-tissue cultures and/or were treated with six weeks of parenteral antibiotic treatment in addition to irrigation and debridement of the wound.</p> <p>31. Infection was diagnosed when there was purulent discharge with positive bacteriological culture.</p> <p>32. Infection was diagnosed when there was purulent discharge with positive bacteriological culture.</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>33. Infection within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection seems to be related to the operation and infection involves any part of the anatomy (e.g., organs and spaces) other than the incision.</p> <p>34. Presence of culture-positive osteomyelitis, infected nonunion, cellulitis, or abscess requiring treatment.</p> <p>35. The development of infection was identified based on the surgeon's or infectious disease physician's documentation in the chart.</p> <p>36. Clinical criteria for diagnosis of infection included: new pain/tenderness at the level of the fracture, nail insertion site, or locking screws; episodes of fever/chills; night sweats; tachycardia; localized swelling; erythema; or drainage. In addition, radiographs were reviewed for signs of infection: lucency around the nail or locking screws, loss of cortical density around the fracture site, or periosteal reaction around the intra-medullary nail.</p> <p>37. Infection was diagnosed according to the criteria of Willenegger and Roth.<sup>4</sup> The diagnosis was made based on the presence of signs and symptoms of infection such as pain out of the area of injury, swelling, redness, purulent drainage, and high fever with a body temperature &gt;38.5°C, along with laboratory test results such as an increased white cell count, continuously or increasingly raised erythrocyte sedimentation rate and C-reactive protein, as well as positive fluid culture results.</p> <p>38. We considered any infection reported at follow-up to be clinically significant and therefore did not differentiate between deep and superficial infections.</p> <p>39. Infection was assessed using South-Hampton criteria</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>40. Infection included all of bone and joint infection, which required a surgical debridement and shaving procedure associated to an antibiotic delivery</p> <p>41. Infections were defined using standard Centers for Disease Control and Prevention criteria. Deep infections were defined as those requiring operative treatment; superficial infections were treated with antibiotics and wound care.</p> <p>42. Infection was defined using the Horan criteria and definition for surgical site infections.</p> <p>43. Infective complications were defined as osteomyelitis, implant infection or soft tissue infection.</p> <p>44. Infection was diagnosed when there was purulent discharge with positive bacteriological culture.</p> <p>45. Infection was subdivided into pin-track infection, superficial wound infection, and deep tissue infection. A pin-track infection was inflammation around the pin-track. A superficial wound infection was one located in the initial or operative wound that was above the fascia, with erythema and tenderness. A deep infection was defined as infection involving deeper tissues, such as muscular fascia and bone.</p>	
<b>Definitions of joint sepsis</b>	<ol style="list-style-type: none"> <li>1. Knee with infection that required reoperation with arthrotomy or arthroscopy.</li> <li>2. We defined knee sepsis as clinical signs and symptoms of infection leading to reoperation with an arthrotomy or arthroscopy within 1 month.</li> <li>3. Defined as presence of a positive culture from knee aspiration or arthrotomy. Deep infection requiring operative debridement, superficial infection requiring antibiotic therapy alone.</li> </ol>	3
<b>Definitions of osteomyelitis</b>	<ol style="list-style-type: none"> <li>1. Osteomyelitis was identified by a positive bone culture obtained in the operating room that required antibiotic treatment, as documented in the health systems network medical records.</li> <li>2. Deep osteomyelitis is defined as the inflammation of bone, bone marrow, and surrounding soft tissues, characterized by ongoing pain, secretion, or swelling accompanied by a significant</li> </ol>	11

Name	Description of OMI including definitions	Frequency of reporting
	<p>increase in inflammatory markers [increased body temperature &gt; 38°C and white blood count (WBC) &gt; 12,000], with or without radiological evidence.</p> <ol style="list-style-type: none"> <li>3. Discharging sinus, fixed puckered overlying soft tissue and radiological changes consistent with chronic osteomyelitis</li> <li>4. Osteomyelitis was defined as a deep infection with positive intraoperative bone cultures.</li> <li>5. Osteomyelitis was defined as deep infection with positive bone cultures.</li> <li>6. Including the first day surgery, debridements, vacuum dressing placements, fasciotomy closures and all procedures performed later.</li> <li>7. Positive bone and indium or magnetic resonance imaging scan results, or positive bone cultures testing results.</li> <li>8. Osteomyelitis was identified acutely by clinical evidence with positive cultures from bone, and chronically by X-rays, MRI or CT imaging.</li> <li>9. Positive bone culture and those treated for presumptive osteomyelitis with 6 weeks of intravenous antibiotics.</li> <li>10. Deep infection with positive intraoperative bone cultures during the return to the operating room.</li> <li>11. Osteomyelitis diagnostic criteria were classified as definite/probable (positive bone culture, direct evidence of infection, or symptoms with culture and/or radiographic evidence) and 105 were classified as possible (bone contamination, organism growth in deep wound tissue, and evidence of local/systemic inflammation). Osteomyelitis recurrence was defined as a subsequent osteomyelitis diagnosis at the original site ≥ 30 days after completion of initial treatment</li> </ol>	
<p><b>Definitions of pin site infection</b></p>	<ol style="list-style-type: none"> <li>1. Pin site infection was defined using Checkett score. Checketts RG, Otterburn M, MacEachern G. Pin track infection: definition, incidence and prevention. Int J Orthop Trauma 1993;3(Suppl)16–18.</li> </ol>	<p>4</p>

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>2. Pin site infections were classified into 6 grades, from grade 0 to grade V (grade 0, normal; grade I, inflamed; grade II, serous discharge; grade III, purulent discharge; grade IV, osteolysis; and grade V, ring sequestrum).</li> <li>3. Pin site infections were graded according to Paley [14] as follows: grade I (soft-tissue inflammation), grade II (soft-tissue infection), or grade III (bone infection).</li> <li>4. Pin tract infection was classified and treated according to the Checketts-Otterburn classification system.</li> </ol>	
<b>Definitions of recurrent infection</b>	<ol style="list-style-type: none"> <li>1. Recurrent infection was defined as the presence of two of the following signs: • local inflammation with or without pus; 2 • C-reactive protein <math>\geq 10</math> mg/L; 3. • presence of bone sequestrum on radiographs</li> </ol>	1
<b>Definitions of wound infection</b>	<ol style="list-style-type: none"> <li>1. The Cutting and Harding criteria were used to define the presence of infection clinically. These criteria included abscess, cellulitis, wound discharge, discolouration, delayed healing, friable granulation tissue, unexpected pain and tenderness, pocketing at the base of the wound, epithelial bridging, abnormal smell and wound breakdown. Fernandez R (2008) Review: infection rates do not differ for wounds cleansed with saline or water. Evidence-based Medicine 13, 179.</li> <li>2. ASEPSIS scoring system. Wilson AP, Treasure T, Sturridge MF, Grüneberg RN. A scoring method (ASEPSIS) for postoperative wound infections for use in clinical trials of antibiotic prophylaxis. Lancet 1986;1:311-13.</li> <li>3. Which consisted of wounds with skin edge necrosis and prolonged serous drainage</li> <li>4. A diagnosis of superficial soft-tissue infection was made if there were clinical signs of infection with positive bacteriological cultures.</li> <li>5. The presence of cellulitis or pus involving the soft tissues at the traumatic wound in the absence of clinical or radiological features of osteomyelitis (requiring antibiotic treatment or surgical intervention).</li> </ol>	11

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>6. Infection within 30 days after the operation and only involves skin and subcutaneous tissue of the incision.</li> <li>7. A superficial infection was defined as local cellulitis with or without serous discharge treated with oral antibiotics.</li> <li>8. The indicators for late deep infection include prolonged courses of antibiotics and/or debridement surgery. For any such outcomes that may be unclear, blinded data and imaging review will be performed by two independent orthopaedic surgeons who will adjudicate the final recorded outcome.</li> <li>9. Defined as clinical findings of superficial and local erythema, swelling, and tenderness of the wound or pin track, which were resolved with the administration of antibiotics</li> <li>10. Superficial infection was defined as infection superficial to fascia, treated with local wound care and/or oral antibiotics.</li> <li>11. As defined by the surveillance definitions of Center of Disease Control and Prevention</li> </ol>	
<b>Pain outcome measurement instruments</b>		
<b>Brief Pain Inventory (BPI)<sup>5</sup></b>	Patient-reported outcome measurement instrument assessing the severity of a patient's pain and the impact of this pain on the patient's daily functioning. The BPI consists of 9 items assessing the following: <ol style="list-style-type: none"> <li>1. pain other than everyday kind of pains</li> <li>2. location of pain (shading diagram)</li> <li>3. worst pain in the last 24-hours</li> <li>4. Pain at its least in the last 24-hours</li> <li>5. Pain on average</li> <li>6. Pain right now</li> <li>7. treatments/medications for pain</li> <li>8. relief of pain from treatment/medication</li> <li>9. pain interference in the last 24 hours (general activity, mood, walking ability, normal work, relations with</li> </ol>	2

Name	Description of OMI including definitions	Frequency of reporting
	other people, sleep, enjoyment of life)	
<b>Visual Analogue Scale (VAS)<sup>6</sup></b>	Patient-reported outcome measurement instrument to assess pain. The VAS is a unidimensional measure of pain intensity. Often assessed on a 0-100mm scale.	6
<b>2. Nervous system outcome measurement instruments (17)</b>		
<b>Oxford MRC score<sup>7</sup></b>	Physician reported OMI to assess muscle strength. Response items: 1. flicker of movement 2. through full range actively with gravity counter balanced 3. through full range actively against gravity 4. through full range actively against some resistance 5. through full range actively against strong resistance	2
<b>3. Renal and urinary outcome measurement instruments (19)</b>		
<b>Acute Kidney Injury outcome measurement instruments</b>		
<b>Definitions of acute kidney injury</b>	<ol style="list-style-type: none"> <li>1. Defined as any increase in the serum creatinine concentration &gt;50% above the patient's admission value.</li> <li>2. Acute kidney injury was defined as a serum creatinine concentration greater than or equal to 1.5 times baseline during hospitalization</li> </ol>	2
<b>RIFLE Criteria<sup>8</sup></b>	Physician reported OMI assessing acute kidney injury Assessment areas: 1. Risk of kidney injury 2. Injury to kidney 3. Failure of kidney 4. Loss of kidney function 5. End-stage kidney disease	1
<b>4. Psychiatric outcome measurement instruments (21)</b>		
<b>Depression outcome measurement instruments</b>		
<b>Patient Health Questionnaire (PHQ-9)<sup>9</sup></b>	Patient-reported outcome measurement instrument measuring depression against 9 domains for depression taken from the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition.	1
<b>Post-traumatic stress disorder outcome measurement instruments</b>		

Name	Description of OMI including definitions	Frequency of reporting
<b>Post-traumatic Stress Disorder (PTSD) Checklist<sup>10</sup></b>	Patient-reported outcome measurement instrument assessing the severity of PTSD symptoms. The checklist has 17 response items based on the Diagnostic and Statistical Manual of Mental Disorders-IV criteria for PTSD.	1
<b>Stress outcome measurement instruments</b>		
<b>Definitions of physical and mental stress</b>	The physical and mental stress of the treatment for the patients and the nearest relative of patients were assessed at the time of frame removal using a custom-made questionnaire on a 10-point rating scale, with 0 indicating no stress and 10 indicating maximum stress.	1
<b>3. Life impact outcome measurement instruments</b>		
<b>1. Physical functioning (25)</b>		
<b>American Orthopedics Foot and Ankle Society (AOFAS) ankle-hindfoot scale<sup>11</sup></b>	Patient and clinical reported outcome measurement instrument. Response domains include: 1. pain 2. functional limitation on recreational and daily activities 3. maximum walking distance in blocks 4. walking ability on different surfaces 5. Gait abnormality 6. Sagittal motion 7. hindfoot motion 8. ankle -hindfoot stability 9. Alignment	23
<b>Association for the Study and Application of the Methods of Ilizarov (ASAMI) criteria<sup>12</sup></b>	Physician reported outcome measurement instrument. The ASAMI criteria assess two domains: 1. bone results (union, infection, deformity, re-fracture and limb length discrepancy) 2. functional results (active walking, limp, stiffness, knee extension, ankle dorsiflexion, reflex sympathetic dystrophy, pain, amputation, employment and return to activities of daily living)	24
<b>Chen grading system<sup>13</sup></b>	Physician reported outcome measurement instrument to grade the functional status of the lower limb. Domains covered include: 1. return to previous work 2. walking with a normal gait 3. range of movement of the knee and ankle 4. sensation 5. trophic ulcers	1



Name	Description of OMI including definitions	Frequency of reporting
<b>Disability Rating Index (DRI)</b> <sup>14,15</sup>	Patient-reported outcome measurement instrument assessing the level of disability. It consists of 3 domains with the following 12 response items: 1. basic activities of daily life: dressing, outdoor walks, climbing stairs and sitting a long time. 2. daily physical activities: standing bent over a sink, carrying a bag, making a bed and running. 3. work-related/more vigorous activities: light work, heavy work, lifting heavy objects and participating in exercise/sports.	3
<b>Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire</b> <sup>16</sup>	Patient-reported outcome measurement instrument specific to the upper-extremity. The DASH is a 30-item symptom scale delivered over 3 domains: 1. degree of difficulty in performing different physical activities because of the arm, shoulder, or hand problem (21 items) 2. the severity of each of the symptoms of pain, activity-related pain, tingling, weakness and stiffness (5 items) 3. the problem's impact on social activities, work, sleep, and self-image (4 items)	3
<b>Enneking score</b> <sup>17</sup>	Physician reported outcome measurement instrument that includes functional assessment measures. It assesses: 1. pain 2. function 3. emotional acceptance 4. supports (walking aids) 5. walking 6. gait	5
<b>Frequency Intensity Time (FIT) index</b> <sup>18</sup>	Patient-reported outcome measurement instrument assessing a person's level of physical activity over 3 domains: 1. frequency of exercise 2. intensity of exercise 3. time spent on workout	1
<b>Functional outcome criteria by Tu et al. 1995</b> <sup>19</sup>	Physician reported outcome measurement instrument assessing functional outcome following open lower limb fractures in the following domains: 1. pain 2. range of motion	1

Name	Description of OMI including definitions	Frequency of reporting
	3. ability to return to normal work	
<b>Hamlyn Mobility Score (HMS)<sup>20</sup></b>	Physical performance and patient-reported outcome measurement instrument to assess the physical performance of patients doing a timed 6-minute walk test, timed up and downstairs test and a timed up and go test. Standard test metrics are recorded, e.g. time and distance with the addition of estimated step variation using a ear-worn accelerometer. The HMS also consists of 4 questions assessing: <ol style="list-style-type: none"> <li>1. use of mobility aids</li> <li>2. participation in work and leisure activities</li> <li>3. satisfaction with walking</li> <li>4. pain</li> </ol>	1
<b>Hospital for Special Surgery (HSS) knee scoring system<sup>21,22</sup></b>	Physician reported outcome measurement instrument to assess outcome after knee replacement surgery. The HSS knee score assesses 7 domains: <ol style="list-style-type: none"> <li>1. pain (rest pain, support required because of pain)</li> <li>2. stability (measured as total varus-valgus arc, extension)</li> <li>3. motion (measured as total passive arc)</li> <li>4. quadriceps strength (measured as a percentage of normal for age and gender)</li> <li>5. subtractions (for extension lag, flexion contracture, fixed varus or valgus deformity)</li> </ol>	1
<b>Iowa ankle-evaluation rating system<sup>23</sup></b>	Physician reported outcome measurement instrument assessing the function of the ankle. Domains assessed include: <ol style="list-style-type: none"> <li>1. function (housework or job, stair climbing, carrying heavy objects, ability to run, participate in athletics or heavy labour, walking independently, able to do garden work, difficulty getting in and out of a car)</li> <li>2. pain</li> <li>3. gait</li> <li>4. range of motion</li> </ol>	5
<b>Johner-Wruhs evaluation<sup>24</sup></b>	Physician reported outcome measurement instrument assessing surgical outcome following a tibial fracture. Domains assessed: <ol style="list-style-type: none"> <li>1. bone union, osteitis or amputation</li> <li>2. neurovascular disturbances</li> <li>3. bone deformity</li> <li>4. range of motion</li> <li>5. pain</li> </ol>	10

Name	Description of OMI including definitions	Frequency of reporting
	6. gait 7. Participation in strenuous activities	
<b>Lower Extremity Functional Scale (LEFS)<sup>25</sup></b>	Patient-reported outcome measurement instrument to assess a broad range of lower-extremity orthopaedic conditions including the hip, knee, leg ankle or foot. The LEFS contains 20-items specifically assessing the International Classification of Functioning, Disability, and Health model (ICF) domains of activity and participation.	3
<b>Lysholm Knee Scale<sup>26</sup></b>	Patient-reported outcome measurement instrument to assess knee function. Is assess 8 domains including: <ol style="list-style-type: none"> <li>1. limp</li> <li>2. walking support</li> <li>3. pain</li> <li>4. instability</li> <li>5. locking</li> <li>6. swelling</li> <li>7. stair-climbing</li> <li>8. squatting</li> </ol>	1
<b>Maryland foot score (MFS)<sup>27</sup></b>	Patient and Physician reported outcome measurement instrument to assess foot injuries. Domains include: <ol style="list-style-type: none"> <li>1. pain</li> <li>2. function (gait, distance walked, stability, support, limp and wearing shoes)</li> </ol>	3
<b>Mazur ankle function evaluation<sup>28</sup></b>	Patient and physician reported outcome measurement instrument to assess ankle function over 12 response items in 2 domains: <ol style="list-style-type: none"> <li>1. pain</li> <li>2. function (limp, walking distance, support, hills up, hills down, stairs up, stairs down, ability to rise on toes, running, range of motion, plantar flexion)</li> </ol>	1
<b>Musculoskeletal Function Assessment (MFA)<sup>29-31</sup></b>	Patient-reported outcome measurement instrument assessing musculoskeletal function consisting of 100 response items over the following domains: <ol style="list-style-type: none"> <li>1. mobility</li> <li>2. hand and fine motor</li> <li>3. housework</li> </ol>	1

Name	Description of OMI including definitions	Frequency of reporting
	4. self-care 5. sleep and rest 6. leisure and recreation 7. family relationships 8. cognition and thinking 9. emotional adjustment and adaptation 10. employment	
<b>Neer knee score</b> <sup>32,33</sup>	Physician reported outcome measurement instrument to assess knee function following a supracondylar fracture. The following domains are assessed: 1. pain 2. function (as before injury, mild restriction, restricted; stairs sideways, cane or severe restriction, crutches or brace) 3. range of motion 4. work 5. gross anatomy 6. roentgenogram	2
<b>Objective physical performance outcome measurement instruments</b>		
<b>6-minute walk test</b> <sup>34</sup>	Objective physical performance measurement instrument used to assess functional exercise capacity. the 6-minute walk test measures the distance an individual is able to walk over a total of 6 minutes on a hard, flat surface.	2
<b>Timed up and downstairs</b> <sup>35,36</sup>	Objective physical performance measurement instrument to assess physical performance by measuring the time taken to ascend and descend a flight of stairs consisting of 14 steps.	1
<b>Timed up and go test</b> <sup>37</sup>	Objective physical performance measurement instrument to determine fall risk and measure the progress of balance, sit to stand and walking. An individual is timed standing up from a chair with an armrest, walking 3m, turning around, walking back and sitting down again.	1
<b>Timed walk test</b> <sup>38</sup>	Objective physical performance measurement instrument to assess mobility by timing a patient to walk 30.5m.	1
<b>Olerud and Molander scoring system</b> <sup>39</sup>	Patient-reported outcome measurement instrument assessing symptoms after ankle fracture in 9 domains: 1. pain	1

Name	Description of OMI including definitions	Frequency of reporting
	2. stiffness 3. swelling 4. stair climbing 5. running 6. jumping 7. squatting 8. supports 9. work and activities of daily living	
<b>Paley Criteria</b> <sup>40-42</sup>	Physician reported outcome measurement instrument assessing bone and functional outcomes of the lower leg. Domains assessed: 1. Bone (consolidation, absence of infection, axial defect, limb-length discrepancy, docking site and osteogenesis zone consolidation solid enough not to require protection, non-union and bone infection) 2. Function (pain free, walking, joint stiffness, talocrural or subtalar motion, use of analgesia, and activities of daily living)	12
<b>Sanders knee score</b> <sup>43,44</sup>	Physician reported outcome measurement instrument assessing knee function following distal femoral fracture assessing the following domains: 1. Range of movement 2. Pain 3. Deformity 4. walking ability (walking and stair climbing) 5. return to work (employment/return to pre-injury functioning)	1
<b>Severn scale scoring system by Puno et al</b> <sup>45</sup>	Physician reported outcome measurement instrument assessing limb salvaged limb function in the following domains: 1. pain 2. activities of daily living 3. range of motion at the ankle and knee 4. residual deformity 5. radiological examination of degenerative joint changes and alignment 6. muscle strength of the foot 7. sensation	7

Name	Description of OMI including definitions	Frequency of reporting
<b>Short Musculoskeletal Function Assessment Questionnaire (SMFA)</b> <sup>46</sup>	Patient-reported outcome measurement instrument assessing musculoskeletal function consisting of 46 items reduced from 101 in the MFA. There are two parts to the SMFA: 1. dysfunction index (34 items assessing patient perceptions of functional performance in 4 categories including daily activities, emotional status, function of the arm and hand and mobility) 2. bother index (12 items assessing broad functional areas including recreation and leisure, sleep and rest, work and family)	3
<b>The knee society clinical rating system</b> <sup>47</sup>	physician and patient-reported outcome measurement instrument assessing: 1. pain (on walking and climbing stairs) 2. range of motion 3. stability (medial/lateral and anterior/posterior) 4. deductions for extension lag, flexion contracture, malalignment and pain at rest	4
<b>Visual Analogue Scale Foot and Ankle (VAS FA)</b> <sup>48,49</sup>	Patient-reported outcome measurement instrument to assess the foot and ankle in the following domains: 1. pain 2. function 3. other complaints	1
<b>2. Emotional functioning and wellbeing (28)</b>		
<b>Appearance outcome measurement instruments</b>		
<b>Cosmetic outcome score by O'Toole et al</b> <sup>50</sup>	Patient-reported outcome measurement instrument to assess satisfaction. The patient's cosmetic outcome score was based on the question, "How satisfied are you with the appearance of your injured leg or artificial leg?" Participants were asked to respond to each question by using a 5-point scale of descriptors that included "not at all satisfied," "slightly satisfied," "moderately satisfied," "very satisfied," and "completely satisfied." This was a novel instrument only cited in this study	1
<b>Vancouver scar scale</b> <sup>51</sup>	Physician reported OMI to assess scar scars and burns. Assessment areas: 1. Vascularity 2. Height/thickness 3. pliability 4. pigmentation	1
<b>3. Global quality of life outcome measurement instruments (30)</b>		

Name	Description of OMI including definitions	Frequency of reporting
<b>EuroQol 5-Dimensions 3-Level (EQ-5D-3L)<sup>52</sup></b>	<p>The EQ-5D-3L descriptive system comprises the following five dimensions:</p> <ol style="list-style-type: none"> <li>1. mobility</li> <li>2. self-care</li> <li>3. usual activities</li> <li>4. pain/discomfort</li> <li>5. anxiety/depression</li> </ol> <p>Each dimension has 3 levels: no problems, some problems, and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions.</p>	2
<b>EuroQol 5-Dimensions 5-Level (EQ-5D-5L)<sup>53</sup></b>	<p>Patient-reported outcome measurement instrument. The descriptive system comprises five dimensions:</p> <ol style="list-style-type: none"> <li>1. mobility</li> <li>2. self-care</li> <li>3. usual activities</li> <li>4. pain/discomfort</li> <li>5. anxiety/depression</li> </ol> <p>Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions.</p>	6
<b>Short Form-12 (SF-12)<sup>54</sup></b>	<p>Patient-reported outcome measurement instrument. Assessing the following domains:</p> <ol style="list-style-type: none"> <li>1. physical functioning</li> <li>2. role-physical</li> <li>3. bodily pain</li> <li>4. general health</li> <li>5. vitality</li> <li>6. social functioning</li> <li>7. role-emotional</li> <li>8. mental Health</li> </ol>	5
<b>Short Form-36 (SF-36)<sup>55</sup></b>	<p>Patient-reported outcome measurement instrument. Assessing the following domains:</p> <ol style="list-style-type: none"> <li>1. physical functioning</li> <li>2. role-physical</li> </ol>	17

Name	Description of OMI including definitions	Frequency of reporting
	3. bodily pain 4. general health 5. vitality 6. social functioning 7. role-emotional 8. mental Health	
<b>Short Form-6 Dimensions (SF-6D)<sup>56</sup></b>	Patient-reported outcome measurement instrument. Assessing the following domains: 1. physical functioning 2. role limitations 3. social functioning 4. pain 5. mental health 6. vitality	1
<b>Sickness Impact Profile (SIP)<sup>57,58</sup></b>	Patient-reported outcome measurement instrument to assess perceived health status. The full-length SIP consists of 136 items within 12 domains: 1. sleep and rest 2. eating 3. work 4. home management 5. recreation and pastimes 6. ambulation 7. mobility 8. body care and movement 9. social interaction 10. alertness behaviour 11. emotional behaviour 12. communication	5
<b>Veterans Affairs System of Rating Disabilities<sup>59</sup></b>	Physician/technician reported outcome measurement instrument used to assess the level of disability for calculation of disability compensation. Each body system is assessed separately for the level of disability, and a combined score is generated.	2



Name	Description of OMI including definitions	Frequency of reporting
<b>Veterans RAND 12 Item Health Survey (VR-12)<sup>18</sup></b>	Patient-reported outcome measurement instrument assesses domains: <ol style="list-style-type: none"> <li>1. general health perceptions</li> <li>2. physical functioning</li> <li>3. role physical</li> <li>4. role emotional</li> <li>5. bodily pain</li> <li>6. vitality/mental health</li> <li>7. social functioning</li> <li>8. change physical</li> <li>9. change emotional</li> </ol>	1
<b>4. Delivery of care outcome measurement instruments (32)</b>		
<b>Satisfaction outcome measurement instruments</b>		
<b>Definitions of satisfaction</b>	<ol style="list-style-type: none"> <li>1. All patients were asked to evaluate their satisfaction with the function of the lower leg, the cosmetic appearance and overall outcome at final follow-up on a 10-point rating scale, with 0 indicating highest satisfaction and 10 indicating maximum dissatisfaction. The patients were additionally asked to rate the function of the affected lower extremity in percent with the contralateral uninjured side serving as a 100 % reference.</li> </ol>	1
<b>The Patient Satisfaction Questionnaire Short Form (PSQ-18)<sup>60</sup></b>	Patient-reported outcome measurement instrument assessing satisfaction in the following domains: <ol style="list-style-type: none"> <li>1. general satisfaction</li> <li>2. technical quality</li> <li>3. interpersonal manner</li> <li>4. communication</li> <li>5. financial aspects</li> <li>6. time spent with doctor</li> <li>7. accessibility and convenience</li> </ol>	1
<b>Visual Analogue Scale for satisfaction<sup>61</sup></b>	Patient-reported outcome measurement instruments assessing satisfaction on a continuous scale (0-100mm). Novel score only used in citing study.	1
<b>4. Resource use outcome measurement instruments</b>		

Name	Description of OMI including definitions	Frequency of reporting
<b>1. Economic outcome measurement instruments (35)</b>		
<b>Definitions of cost</b>	<ol style="list-style-type: none"> <li>1. Cost utility analysis</li> <li>2. Health care system costs (direct health care costs) and costs for productivity losses (indirect health care costs).</li> <li>3. The cost calculations represent a weighted average of actual expenses for similar entities, during a previous period, indexed to current time.</li> <li>4. The analysis of surgical costs was based on operative time (including anaesthetic time), theatre staff present (grade, discipline and number) and consumables (all drugs administered, dressings, sutures, etc.)</li> <li>5. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care (20). Where these are not available, the unit cost will be estimated in consultation with the UHCW finance department. The cost-consequences following discharge, including NHS costs and patients' out-of-pocket expenses, will be recorded via a short questionnaire which will be administered at 3, 6, 9, and 12 months post-surgery. Patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.</li> <li>6. Standard approaches developed for all METRC studies.</li> <li>7. Cost of treating patients based on Patient-Level Information Costing Systems (PLICS) data.</li> <li>8. Unit cost data were obtained from national databases such as the BNF24 and Personal Social Services Research Unit (PSSRU)'s Unit Costs of Health and Social Care 2012.25 When these were not available, the unit cost was estimated in consultation with the University Hospitals Coventry and Warwickshire (UHCW) NHS Trust finance department. The cost-consequences following hospital discharge, including NHS costs and patients' out-of-pocket expenses, were estimated using questions included within a questionnaire sent to participants at 3, 6, 9, and 12 months post</li> </ol>	10

Name	Description of OMI including definitions	Frequency of reporting
	<p>randomisation. Patient self-reported information on service use has previously been shown to be accurate in terms of the intensity of use of different services.</p> <p>9. Hospital facility bills for each patient's graft surgery admission were requested from participating centers. Billed charges were converted to cost through application of Medicare cost-to-charge ratios. Professional fees for the surgeon and anesthesiologist were based on Medicare 2016 national average payment for the associated graft surgery procedures.</p> <p>10. Real income received for service provision as determined per Human Resource Group remuneration.</p>	
<b>2. Need for intervention outcome measurement instruments (36)</b>		
<b>Definitions of reoperation</b>	<ol style="list-style-type: none"> <li>1. All unplanned operations deemed clinically important.</li> <li>2. Composite of all subsequent operative procedures to treat an infection, a wound healing problem, or a nonunion within 1 year of the initial surgical intervention</li> <li>3. Re-operation is defined as a surgery that occurs subsequent to the initial procedure. This composite endpoint of re-operation will include a narrow spectrum of patient-important procedures: irrigation and debridement for infection, revision and closure for wound dehiscence, wound coverage procedures for infected or necrotic wounds, bone grafts or implant exchange procedures for established nonunion in patients with postoperative fracture gaps less than 1 cm, intramedullary nail dynamizations in the operating room, and fasciotomies for compartment syndrome.</li> <li>4. An operation to revise or augment fracture fixation after arriving to a Level V facility.</li> <li>5. The third evaluation factor of the psychosocial evolution of the patients was represented by the number of later readmissions for secondary surgical interventions.</li> <li>6. Reoperation was defined as at least one surgical procedure following the index procedure.</li> </ol>	10

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li>7. Metal work exchange or reinsertion, joint fusion, bone resection and bone grafting) in addition to the routine.</li> <li>8. The secondary surgical procedure rate included any reported secondary surgical procedure related to the ankle fracture. This also included partial and complete hardware removals.</li> <li>9. Composite, all-cause reoperation within 1 year of definitive skeletal stabilization, excluding bedside irrigation and debridement for superficial pin tract infections, or planned ex-fix removal.</li> </ol>	
<b>5. Adverse events outcome measurement instruments</b>		
<b>1. Adverse events or effects (38)</b>		
<b>Definitions of complications</b>	<ol style="list-style-type: none"> <li>1. Orthopedic complications were defined as local cellulitis, wound infections, infections documented by delayed wound culture, osteomyelitis, non-union or malunion, and secondary amputation. Infections of primary amputation sites were included, whereas infections of pin sites remote from the wounds were excluded.</li> <li>2. Early postoperative complications were defined as any 1 or more of the following having occurred within 6 months from surgical reconstruction: hematoma, wound infection, deep venous thrombosis, thromboembolism, partial flap loss, complete flap loss, continued osteomyelitis, and progression to amputation occurring within the first 6 months after the injury.</li> <li>3. This is a composite measure defined as the occurrence within 2 weeks of injury of one or both of significant soft tissue necrosis developing after the initial surgery, or significant wound infection. Significant soft tissue necrosis will be determined based upon the amount of tissue surgically debrided after the initial surgery. Minimal trimming of skin edges removing no more than a few millimeters of tissue to clean the surface of a wound which was not obviously necrotic will be considered normal surgical practice and will not be scored as indicating 'significant necrosis'. ▶ Wound infection occurring during the acute phase will be assessed via review of data based upon those used in the USA Centre for Disease Control guide- lines for assessing surgical wound infections.<sup>43</sup> ▶ The final adjudication on any cases where the presence of infection or necrosis is</li> </ol>	18

Name	Description of OMI including definitions	Frequency of reporting
	<p>equivocal will be determined via review of available clinical data, photos and X-rays by clinical adjudicators not involved in the patient's care and blinded to the identity and location of the patient, and the allocation to HBO or no-HBO group.</p> <ol style="list-style-type: none"> <li>4. Primary study outcome is defined as having a major complication that results in either: (1) operative treatment during the index hospitalization; (2) rehospitalization during the 12 months after injury (involving operative or nonoperative treatment of the complication); or (3) same day surgery during the 12 months after injury. Major limb complications include 7 predefined occurrences: infection, flap failure, amputation, non-union, malunion, loss of reduction, or hardware failure as diagnosed by the treating surgeon.</li> <li>5. Complications were subclassified into problems, obstacles and sequelae [14]. Problems did not require surgical interventions, while obstacles needed surgical revisions to be resolved.</li> <li>6. Postoperative complications were determined by noting any return trips to the operating room. Complications encountered included deep infection, heterotopic ossification/arthro- fibrosis, nonunion, and prominent hardware requiring removal.</li> <li>7. Complications included acute respiratory distress syndrome (ARDS), pneumonia, deep venous thrombosis, deep surgical site infections (DSSIs), myocardial infarction occurring within 30 days of injury, organ/space surgical site infection, superficial surgical site infection, stroke/cerebral vascular accident, cardiac arrest requiring cardiopulmonary resuscitation, wound disruption, sepsis, and overall/any complication.</li> <li>8. We recorded complications requiring reoperation.</li> <li>9. Pseudoarthrosis, chronic osteitis and angular deformities of over 10 degrees</li> <li>10. All complications and surgical interventions related to the open fracture will be recorded.</li> </ol>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>11. Neurovascular injury because of frame application, mechanical frame failure as evident by pin, clamp, or bar breakage, pin tract osteomyelitis, and septic arthritis because of intra-articular pin placement.</p> <p>12. Pins within 1 inch of the fracture site, 17 loss of fracture reduction, 9 deep pin overpenetration ≥26 mm, 18 soft-tissue pin placement (no cortical purchase), and intra-articular pin placement defined as pins within 14 mm of the tibial plateau or 10 mm of the tibial plafond.</p> <p>13. Complication subtypes were coded as established in the Healthcare Cost and Utilization Project Clinical Classification Software manual.</p> <p>14. Assessment of complications like muscle contractures, joint subluxation, axial deviation, neurological or vascular insult, premature consolidation, delayed consolidation, refracture and pin-site infection were done at each follow up visit and were managed accordingly.</p> <p>15. Complications are defined as issues that required further treatment or surgery after frame removal.</p> <p>16. Major complications were defined as any flap loss, return to operating room, amputation, or death.</p> <p>17. Complication subtypes were coded as established in the HCUP CCS manual.</p> <p>18. All complications and further surgical interventions related to the open-fracture wound or treatment of the wound were recorded using multiple approaches. Complications were documented at routine follow-up appointments, were self-reported by patients or were notified as adverse events (AEs) or serious adverse events (SAEs) (see Approval for main trial). All participants were invited for clinical review and a radiograph at 12 months, as per routine practice after this type of injury. If a participant had not returned a 12-month postal questionnaire, this was completed in clinic.</p>	

Name	Description of OMI including definitions	Frequency of reporting
<p><b>Definitions of flap complications</b></p>	<ol style="list-style-type: none"> <li>1. Defined as any flap- related adverse outcome requiring a return to the operating room. This included infection, dehiscence, necrosis, and thrombosis of the flap or its anastomosis, if applicable. Infection was defined as any infection in, adjacent to, or beneath the flap, to include osteomyelitis. Because nonunion of open fractures can be related to many variables that are unrelated to coverage, such as bone loss and soft-tissue stripping, it was not considered a flap-related complication in this study.</li> <li>2. Partial flap loss was considered when debridement occurred for partial flap necrosis.</li> <li>3. Total flaps loss required complete removal of the free-flap.</li> <li>4. partial flap necrosis that required a return to the operating room for debridement but did not require a revision coverage procedure.</li> <li>5. Flap failure was defined as any flap with tissue necrosis secondary to microvascular thrombosis, ischaemia, and/or infection.</li> <li>6. Including: split skin graft, secondary suturing, fasciocutaneous flap to cover necrosed flap.</li> <li>7. Total flap loss, partial flap loss, or return to the operating room in the postoperative period for impending flap failure.</li> <li>8. Deep infection with positive intraoperative bone cultures, radiographic changes consistent with osteomyelitis, or clinical documentation of operative findings consistent with osteomyelitis.</li> <li>9. Flap take-back was defined as any free- flap complication which required the return to theatre during the same inpatient stay.</li> </ol>	<p>15</p>

Name	Description of OMI including definitions	Frequency of reporting
	<p>10. Total flap failure was defined as flap compromise requiring complete debridement during the index hospitalization. Partial flap failure was defined as those requiring additional surgical procedure(s) related to wound breakdown or need for flap debridement during the first 3 months after free flap coverage. Secondary outcomes included operative take- backs and success rates, as well as arterial and venous complications.</p> <p>11. Total flap failure was defined as flap compromise requiring complete debridement during the index hospitalization.</p> <p>12. Flap failure was defined as total or partial necrosis of the transferred tissue. This complication always requires return to theatre for excision of the necrotic tissue.</p> <p>13. Total or partial necrosis of the transferred tissue.</p> <p>14. Intraoperative flap thrombosis was defined as recurrent venous or arterial thrombosis occurring during the primary flap procedure. Postoperative flap thrombosis was defined as any thrombotic event requiring emergent take-back for flap salvage following the conclusion of the primary flap procedure. Take-backs for the planned debridement.</p> <p>15. Partial flap failure was defined as those requiring additional surgical procedure(s) related to wound breakdown or need for flap debridement during the first 3 months after free-flap coverage.</p>	



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