



**What outcomes have been reported on patients following open lower limb fracture, and how have they been measured?**

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## What outcomes have been reported on patients following open lower limb fracture, and how have they been measured?

### ABSTRACT

#### Aims

Open lower limb fracture is a life-changing injury affecting 11.5 per 100,000 adults each year and causes significant morbidity and resource demand on trauma infrastructures. This study aims to identify what, and how outcomes have been reported for people following open lower limb fracture over ten years.

#### Methods

Systematic literature searches identified all clinical studies reporting outcomes for adults following open lower limb fracture between January 2009 to July 2019. All outcomes and outcome measurement instruments were extracted verbatim. An iterative process was used to group outcome terms under standardised outcome headings categorised using an outcome taxonomy.

#### Results

Five hundred and thirty-two eligible studies were identified, reporting 1803 outcomes with 786 unique outcome terms, which collapsed to 82 standardised outcome headings. Four hundred and seventy-nine individual outcome measurement instruments were identified, including 298 outcome definitions, 27 patient and 18 clinician-reported outcome measures, and six physical performance measures. The most-reported outcome was 'bone union/healing' reported in over 50% of included studies, while health-related quality of life was only measured in 6% of included studies.

#### Conclusion

Outcomes reported for people recovering from open lower limb fracture are heterogeneous, liable to outcome reporting bias and vary widely in the definitions and the measurement tools used to collect them. Outcomes likely to be important to patients, such as quality of life and measures of physical functioning, have been neglected. This systematic review identifies the need to unify outcome measures reported on patients recovering from open lower limb fracture; this may be addressed by creating a core outcome set.

**KEYWORDS**

Open Fracture

Open Lower Limb Fracture

Core Outcome Set

Outcome

Outcome Measurement Instrument

**ARTICLE SUMMARY****Article focus**

- What outcomes have been reported in the academic literature on adult patients following open lower limb fracture over ten years?
- How have these outcomes been measured?

**Key messages**

- Existing literature on open lower limb fractures is of largely low-quality case series. It is hampered by outcome heterogeneity, wide variation in outcome definitions, use of multiple measurement tools, and infrequent collection of Patient-Reported Outcome Measures.
- This systematic review highlights significant inadequacies in outcome-reporting in the current literature on open lower limb fracture, both in terms of outcome heterogeneity and a failure to report the most important outcomes from a patient perspective.

**Strengths and Limitations**

- This systematic review provides a comprehensive overview of all outcomes and measurement instruments reported in the literature on open lower limb fracture over ten years.
- A staged search strategy demonstrated data saturation in the number of outcomes reported on patients recovering from open lower limb fracture.

## INTRODUCTION

Open lower limb fracture is a life-altering injury affecting 11.5 per 100,000 adults each year<sup>1</sup>, causing significant morbidity and mortality for patients and high resource demand on the UK trauma infrastructure<sup>1-3</sup>. Treatment is complex and multifaceted, such that an optimal treatment pathway for these devastating injuries remains unclear. Inconsistency in outcome-reporting and poor-quality studies hamper attempts to evaluate new interventions to improve function, recovery experience, and investigation into the effects of regional variation of treatment on recovery.

Advancements in medical and surgical practice have expanded the proportion of severely injured limbs that are now amenable to limb salvage and reconstruction<sup>4</sup>. Patient-centred care is a guiding principle of modern medical practice. The outcomes used in orthopaedic trauma research should reflect this, e.g., use of Patient-Reported Outcome Measures (PROMs). However, this does not appear to be reflected in the literature<sup>4,5</sup>. Scoping literature searches demonstrate that most studies reporting outcomes on patients recovering from open lower limb fracture tend to measure outcomes indicative of surgical success, e.g., objective clinical measures including bone union, alignment, and infection status. These preliminary findings are supported by Morris *et al.* 2019, who demonstrate considerable outcome heterogeneity reported in studies on closed tibial fractures<sup>5</sup>. Failure to measure patient-reported outcomes will continue to propagate a discord between the surgeon and patient perceptions of successful treatment. Inconsistency in outcome reporting in the literature hampers comparative research and the ability to produce high-level evidence to drive improvements in patient care.

## METHODS

This systematic review was registered on the Prospective Register of Systematic Reviews (XXX) and reported with the aid of the PRISMA Statement.

In a clinical trial, an outcome refers to 'what' is being measured or reported by participants, which is used to examine the effect of the intervention. An outcome measurement instrument refers to 'how' the outcome is measured. It is a tool to measure the quality or quantity of an outcome.

### Search Strategy

The EMBASE and MEDLINE bibliographic databases were searched using Ovid (Ovid Technologies, Inc 2020, Wolters Kluwer), supplemented by PsychINFO, CINHALL and Cochrane CENTRAL in the English language from January 2009 to April 20, 2017. A search

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2  
3 update was made in July 2019 of the EMBASE and MEDLINE databases (see Supplementary  
4 Material 1). 2009 was chosen as a cut off due to the publication of BOA/BAPRAS Joint  
5 Standards for Open Fracture Management<sup>6</sup>. The introduction of the Joint Standards for Open  
6 Fracture Management in 2009 was a defining milestone in the modern management of open  
7 lower limb fracture in the UK and has been widely adopted in many healthcare systems<sup>4</sup>.  
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## 10 11 12 **Study Eligibility and Data Extraction**

13  
14 Inclusion criteria were designed to maximise data capture. Any clinical study was included  
15 where outcomes were reported on more than one study participant, and 80% or greater of  
16 study participants were over the age of 16 and had an open lower limb fracture. An open lower  
17 limb fracture was defined as a break in any bone distal to the acetabulum of the hip joint where  
18 the bone is exposed to the outside environment, for example, an open fracture of the femur or  
19 below.  
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23 Systematic reviews were included as authors can specify novel outcomes (e.g., new  
24 composite outcomes derived from those reported in the literature). Study protocols were  
25 included as outcomes were described and defined a priori. Where an English-language  
26 abstract was available and reported outcomes, the article was included if the full text was non-  
27 English language. Where multiple papers were found reporting the same data, only the earliest  
28 article was included. Case reports were excluded as outcomes were only reported on  
29 individual cases. Other studies excluded were paediatric studies, laboratory studies, animal  
30 studies, expert opinions where no pooled outcomes were presented and correspondence.  
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34 All titles and abstracts were screened independently by two researchers, Author\_1 and  
35 Author\_2 or Author\_3, using Rayyan (Qatar Computing Research Institute, Doha) against  
36 eligibility criteria. Disagreements were resolved by discussion between reviewers. Full-text  
37 review and data extraction were conducted simultaneously. Author\_1 undertook full-text  
38 screening and data extraction on all shortlisted studies. A random 10% and 15% sample of  
39 full-texts were dual-screened and data-extracted by Author\_2 and Author\_3 in the primary and  
40 secondary searches, respectively. Samples from Author\_2 and Author\_3 were compared to  
41 Author\_1's for accuracy, suitability and consistency of full-text screening and data extraction.  
42 A standardised data extraction sheet was created using Google Sheets (Google, Mountain  
43 View, California) and piloted before use to allow authors to simultaneous extract data; table 1  
44 details the data fields extracted from each included study.  
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48 All outcomes were extracted verbatim with any accompanying outcome measurement  
49 instruments used, including outcome definitions/outcome measurement instruments used. All  
50 extracted outcomes and outcome measurement instruments were specified in each study's  
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3 methods or results section. Outcomes were defined where an outcome definition was provided  
4 or referenced with a citation. Where a citation defined an outcome, the outcome definition was  
5 extracted verbatim from the cited article. Where studies reported PROMs or physical  
6 performance measures without stating what outcomes they intended to measure, an  
7 overarching outcome was assigned.  
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### 11 **Categorising Outcomes and outcome measurement instruments**

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14 Verbatim outcomes were reviewed in an iterative process to devise standardised outcome  
15 headings used to group outcomes. Outcome headings were often representative of the most  
16 common outcome wording reported in the literature (see Supplementary Material 2 for a  
17 complete list of verbatim outcomes and the standardised outcome headings).  
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### 21 **Categorising outcome measurement instruments**

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24 Each outcome measurement instrument was given an overarching outcome used to group the  
25 outcome measurement instrument under a standardised outcome heading as devised in  
26 outcome extraction. Overarching outcomes for outcome measurement instruments were  
27 established using an adapted method described by Macefield *et al.* 2014 or the outcome  
28 measurement instrument definition if provided<sup>7</sup>.  
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33 All standardised outcome headings and outcome measurement instruments were organised  
34 and categorised using the Core Outcomes in Effectiveness Trials Initiative (COMET)  
35 Taxonomy of Outcomes<sup>8</sup>. The COMET Taxonomy of Outcomes is a categorisation system  
36 designed by the COMET Initiative to provide sufficient granularity and scope for classifying all  
37 medical outcomes in Core Outcome Set (COS) development. The COMET Taxonomy of  
38 Outcomes categorises outcomes into 38 outcome domains within five core areas<sup>8</sup>.  
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### 43 **Assessment Of Bias**

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45 There was no data synthesis of study effect sizes in this systematic review; therefore, no  
46 assessment of the methodological quality of the studies was conducted.  
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## 49 **RESULTS**

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51 A total of 26,988 articles were identified from a primary and updated search. After excluding  
52 duplicates and limiting date ranges, 4143 articles were shortlisted for the title and abstract  
53 review. Article screening identified 606 articles for full-text review; the article screening conflict  
54 rate between authors was less than 5%. Following a full-text review, 532 articles were included  
55 detailing outcomes reported on 429,076 participants for inclusion. Comparing duplicate full-  
56 text review and data extraction by Author\_2 and Author\_3 to Author\_1 revealed no conflicts  
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3 in studies included/excluded and no significant differences in data fields extracted. See  
4 PRISMA flowchart in Figure 1 for the study identification process and reasons for article  
5 rejection at full-text review.  
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9 There was a relatively even spread in the number of studies published between 2009 and  
10 2019. Case series and cohort studies represented 53% and 29% of all included studies,  
11 respectively, and RCTs represented 5% (29 individual studies) (see Table 2). The majority of  
12 included studies reported outcomes on between 3 and 50 participants (52% of included  
13 studies). Studies were mostly conducted from the USA, UK and China (23%, 14% and 13%  
14 of articles, respectively).  
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### 18 19 **Outcomes reported**

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21 In total, 1803 individual outcomes were extracted verbatim, from which 786 unique outcome  
22 terms were identified. The 786 outcome terms were grouped under 82 standardised outcome  
23 headings, representing outcomes with the same meaning but different wording. Standardised  
24 outcome headings were then categorised using the COMET Taxonomy of Outcomes (see  
25 Supplementary Material 2 for all standardised outcome headings).  
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30 Table 3 illustrates the number and frequency of outcomes reported in the literature categorised  
31 by the outcome domains within the COMET Taxonomy of Outcomes. Supplementary Material  
32 2 gives a complete list of outcome terms reported, detailing whether they were reported as  
33 primary or secondary outcomes, the standardised outcome headings they were coded to, and  
34 categorisation using the COMET Taxonomy of Outcomes.  
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39 All outcomes reported in the literature were categorised into 18 COMET Taxonomy of  
40 Outcomes outcome domains within five core areas. The Musculoskeletal and Connective  
41 Tissue outcome domain was the most represented with 1335 outcomes (74% of all outcomes  
42 reported) and 529 unique outcome terms, which were further collapsed to 41 standardised  
43 outcome headings (see Table 3). The Musculoskeletal and Connective Tissue outcome  
44 domain consisted of outcomes representing objective clinical measures; the most reported  
45 standardised outcome heading was 'bone union or healing' consisting of 265 individual  
46 outcomes (reported in 50% of included studies), which collapsed to 76 unique outcome terms.  
47 Infection-related outcomes represented 371 outcomes and 85 unique outcome terms.  
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52 Outside the physiological/clinical core area, 330 outcomes were reported in the life impact  
53 core area. Of the 330 outcomes, 258 were reported in the physical functioning domain  
54 represented by 149 unique outcome terms. The physical functioning domain mainly consisted  
55 of outcomes centred around lower limb function and ambulation.  
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3 Of the 532 studies included, 129 (24%) stated a primary outcome. Infection was the most  
4 reported primary outcome, followed by bone union or healing in 27 (21%) and 15 (12%) studies  
5 where a primary outcome was stated, respectively.  
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### 8 **outcome measurement instruments Reported**

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11 In total, 479 individual outcome measurement instruments were identified, including 298  
12 individual outcome definitions, 27 patient and 18 clinician-reported outcome measures,  
13 respectively, and six physical performance measures. All outcome measurement instruments  
14 extracted were categorised by their overarching outcome using the COMET Taxonomy of  
15 Outcomes (see Table 3). The frequency of reporting outcome measurement instrument  
16 definitions and source text citations are detailed in Supplementary Material 3.  
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21 Of the 1803 outcomes reported, 17% were defined. Most outcome definitions were limited to  
22 outcomes categorised to the physiological/clinical core area and exclusively defined objective  
23 clinical outcomes. All individual outcome definitions were unique for wording when describing  
24 the same outcomes. For example, 'bone union or healing' was the most defined outcome. It  
25 was defined 50 times across all studies, with no identical definitions.  
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30 A total of 45 unique patient or physician reported outcome measurement instruments were  
31 used across included studies, most of which were used to measure life impact, principally  
32 physical functioning, and global Health-Related Quality of Life (HRQoL) outcomes. The  
33 physical functioning outcome domain was measured by 123 individual outcome measurement  
34 instruments, of which 29 were unique. The most used outcome measurement instrument for  
35 this domain was the Association for the Study and Application of the Methods of Ilizarov  
36 (ASAMI) criteria reported 24 times, followed by the American Orthopaedics Foot and Ankle  
37 Society (AOFAS) ankle-hindfoot scale reported 23 times.  
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44 Across all included studies, HRQoL was measured 39 times (8.1% of outcome measurement  
45 instruments identified) using eight different instruments. The most used instrument was the  
46 Short Form-36 (SF-36), followed by the EuroQol 5-Dimensions 5-Level (EQ-5D-5L) used 17  
47 and 6 times, respectively.  
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## 51 **DISCUSSION**

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53 There is widespread heterogeneity in the outcomes reported across all outcome domains,  
54 where large numbers of heterogeneous outcome terms were grouped under the same  
55 standardised outcome heading. Many different definitions were used to define the same  
56 outcomes. This is highlighted in the musculoskeletal and connective tissue outcome domain,  
57 where 239 unique outcome definitions were given with no standard texts used between studies  
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3 to define the same outcomes. These findings illustrate widespread inconsistency in outcome-  
4 reporting and little to no standardisation in outcome definitions.  
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7 Objective clinical measures such as bone union and infection represented most outcomes  
8 identified, indicating a preference by authors for outcomes relevant particularly to surgeons.  
9 This reflects reporting on outcomes important to surgeons collected as part of routine practice  
10 due to their ease of measurement despite guidance and research trends advocating for the  
11 increased measurement of life impact outcomes in the form of PROMs<sup>6</sup>. Publication of the  
12 'Standards for the Management of Open Fractures of the Lower Limb' in 2009 principally  
13 recommended the measurement of life impact outcomes in the form of the Enneking Score,  
14 which broadly assesses lower limb function in addition to the measurement of HRQoL,  
15 suggesting the Short-Study Form-36 (SF-36) or the Sickness Impact Profile (SIP) as suitable  
16 tools. Despite these recommendations made over ten years ago, few studies have reported  
17 using these scores.  
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25 There was a high degree of variation in patient and physician-reported outcome measurement  
26 instruments used to assess physical functioning. Of the 18 different outcome measurement  
27 instruments used, none were specific for measuring function following open lower limb fracture  
28 or traumatic injury. The majority were designed to measure the function of an anatomical area,  
29 generally in the context of elective orthopaedic surgery. HRQoL was measured 39 times  
30 across all studies with little consistency in the outcome measurement instruments used. A  
31 total of 8 different HRQoL measures were identified.  
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37 This systematic review was ambitious in its data capture and included many relevant studies  
38 over ten years; it is unlikely that any potentially significant outcome term or outcome  
39 measurement instrument reported in the literature will not have been captured. Listing all  
40 outcome terms and definitions verbatim and summarising source literature for each composite  
41 outcome measurement instrument identified in this study allows reviewers to trace outcomes  
42 identified in the COS back to their source. Due to the passage of time following the primary  
43 literature search, a search update was conducted. Undertaking staged systematic reviews is  
44 an accepted practice in COS development studies allowing comparison of outcome lists  
45 against each other over time to identify if data saturation has been achieved<sup>9</sup>. When comparing  
46 outcomes identified from the primary search (January 2009 to April 2017) and the search  
47 update (January 2017 to July 2019), no new standardised outcome headings were created.  
48 As such, it is unlikely that any additional new significant outcomes will have been reported  
49 since July 2019 to the point of publication of this study.  
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58 We limited the inclusion of studies to those published after 2009. This was done to ensure the  
59 review remained focused on the relevant literature and manageable whilst avoiding  
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unnecessary data extraction of potentially irrelevant literature; this approach is commensurate with COMET guidance<sup>9</sup>. However, outcomes important to stakeholders may have been reported before 2009 and have been missed. Although this is a possibility, it is unlikely, as clinically meaningful outcomes would likely have been reported over the last decade. The review was limited to studies published in the English language. However, this was mitigated by extracting outcomes from non-English-language articles reporting an English-language abstract.

The categorisation of outcomes using the COMET Taxonomy of Outcomes is subjective, and as a result, there may be conflict in the categorisation of outcomes between the outcome terms and the outcome measurement instruments used to measure them, leading to inconsistencies. While the COMET Taxonomy of Outcomes provides an excellent framework for categorising reported outcomes, it was not designed to categorise outcome measurement instruments. However, categorising outcomes and outcome measurement instruments was a method used to structure, organise, and present data to stakeholders<sup>6</sup>. Using an outcome framework such as the COMET Taxonomy of Outcomes, it is possible to see the spread of outcomes across core areas and the underlying outcome domains allowing COS developers to identify any apparent gaps in outcomes identified from the literature. Unexpected gaps, if present, may indicate that data saturation was not achieved. On interrogation of the outcomes spread across the COMET ToT outcome domains, there were no apparent areas where outcomes we may have expected to be reported were missing.

## CONCLUSION

This systematic review highlights significant inadequacies in outcome-reporting in the current body of literature on open lower limb fracture, both in terms of outcome heterogeneity and a failure to report on life impact outcomes measuring patient's functional recovery despite guidance published in 2009 advocating the use of PROMs. There was an over-reliance on objective clinical outcomes reported in the literature.

This systematic review supports the need to unify outcome collection and recognises the need for higher-quality studies in this field. Developing a COS for open lower limb fracture will provide a consensus and guidance for collecting a homogeneous set of outcomes and outcome measures that will help address current limitations identified in this field<sup>3</sup>.

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(Will appear on non-anonymised manuscript)

## FUNDING STATEMENT

1  
2  
3 (Will appear on non-anonymised manuscript)  
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5 **CONFLICTS OF INTEREST**  
6

7 Study authors have no conflict of interests to declare. A ICMJE statement from each author  
8 will follow if accepted for publication.  
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For Review Only

**REFERENCES**

1. Costa ML, Achten J, Bruce J, Tutton E, Petrou S, Lamb SE, et al. Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults **with** Severe Open Fracture of the Lower Limb: The WOLLF Randomized Clinical Trial. *JAMA* [Internet]. 2018 Jun 12;319(22):2280–8. Available from: <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2018.6452>
2. Rees S, Tutton E, Achten J, Bruce J, Costa ML. Patient experience of long-term recovery after open fracture of the lower limb: a qualitative study using interviews in a community setting. *BMJ Open* [Internet]. 2019 Oct 9;9(10):e031261. Available from: <http://bmjopen.bmj.com/lookup/doi/10.1136/bmjopen-2019-031261>
3. Walter N, Rupp M, Hierl K, Pfeifer C, Kerschbaum M, Hinterberger T, et al. Long-term patient-related quality of life after fracture-related infections of the long bones. *Bone Joint Res.* 2021;10(5):321–7.
4. Khalid AH, Oliver P, Michael K. Standards of open lower limb fracture care in the United Kingdom. *Inj.* 2021;52(3):378–83.
5. Morris R, Pallister I, Trickett RW. Measuring outcomes following tibial fracture. *Injury* [Internet]. 2019;50(2):521–33. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0020138318306909>
6. Nanchahal J, Nayagam N, Khan U, Moran C, Barrett S. Standards for the management of open fractures of the lower limb. *British Association of Plastic Reconstructive and Aesthetic Surgeons* [Internet]. British Orthopaedic Association; 2009. (British Orthopaedic Association). Available from: <https://www.boa.ac.uk/wp-content/uploads/2015/10/Standards-for-the-Management-of-Open-Fractures-of-the-Lower-Limb.pdf>
7. Macefield RC, Jacobs M, Korfage IJ, Nicklin J, Whistance RN, Brookes ST, et al. Developing core outcomes sets: methods for identifying and including patient-reported outcomes (PROs). *Trials* [Internet]. 2014 Feb 5;15(1):1–12. Available from: *Trials*
8. Ramsey I, Eckert M, Hutchinson AD, Marker J, Corsini N, Villani L, et al. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *J Clin Epidemiol* [Internet]. 2018;96(5):84–92. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0895435617305899>
9. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. *Trials* [Internet]. 2017 Jun 20;18(Suppl 3):280–50. Available from: <http://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-1978-4>

## TABLES

<b>Table 1. Data fields extracted at full-text review</b>	
<b>Study demographics</b>	<b>Study outcomes</b>
Publication date	Primary outcome identified/defined
Study title	<b>Extracted for each named outcome</b>
Journal	Primary or secondary outcome
Journal reference (volume, issue and page numbers)	Outcome wording (extracted verbatim)
Authors	Outcome definition
Language	OMI used to measure the outcome
Location (country where research was conducted)	Time points measured
Abstract	<b>Extracted for each OMI</b>
Study design (e.g. RCT, cohort, case series etc)	OMI used
Study population (e.g. proportion of participants with open fracture)	Time points measured
Number of participants	Citation of OMI, where provided
Sex distribution of participants	
Age distribution of participants	
Study inclusion and exclusion criteria	

**Table 1. Data fields extracted at full-text review**

**Table 2. Summary characteristics and demographics of included studies**

<b>Summary characteristics and demographics of included studies</b>											
<b>Characteristic (number of studies reported)</b>											
<b>Publication year</b>	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
<b>Number of studies (532)</b>	27 (5%)	42 (8%)	51 (9%)	48 (9%)	47 (8%)	51 (9%)	58 (11%)	51 (9%)	53 (10%)	57 (11%)	47 (9%)
<b>Study design</b>	Case series	Retrospective cohort study	Prospective cohort study	Randomised controlled trial	Systematic review	Case-control	Health economic	Qualitative	Cross-sectional	Protocol	Other
<b>Number of studies (523)</b>	275 (53%)	115 (22%)	38 (7%)	26 (5%)	23 (4%)	20 (4%)	8 (2%)	7 (1%)	4 (1%)	4 (1%)	3 (1%)
<b>Number of participants (Total 429,076)</b>	1 to 10	11 to 25	26 to 50	51 to 100	101 to 200	201 to 500	501 to 1000	Greater than 1000			
<b>Number of studies (500)</b>	35 (7%)	108 (22%)	117 (23%)	94 (19%)	60 (12%)	40 (8%)	16 (3%)	30 (6%)			
<b>Top 10 journals of publication</b>	Injury	Journal of Orthopaedic Trauma	International Orthopaedics	Bone and Joint Journal	China Journal of Orthopaedics and Traumatology	Journal of Reconstructive Microsurgery	Plastic and Reconstructive Surgery	Journal of Bone and Joint Surgery	Chinese Journal of Reparative and Reconstructive Surgery	Indian Journal of Orthopaedics	
<b>Number of studies (532)</b>	56 (11%)	52 (10%)	17 (3%)	16 (3%)	12 (2%)	11 (2%)	11 (2%)	11 (2%)	10 (2%)	9 (2%)	
<b>Top 10 countries of origin</b>	USA	UK	China	India	Turkey	Pakistan	Italy	Canada	Germany	Iran	

<b>Number of studies (516)</b>	117 (23%)	71 (14%)	68 (13%)	37 (7%)	22 (4%)	18 (3%)	17 (3%)	12 (2%)	10 (2%)	9 (2%)
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1. Where the study was conducted or if over multiple countries where lead author/institution was based.

## Table 2. Summary characteristics and demographics of included studies

For Review Only

**Table 3. Outcome domains identified how they were reported in 532 studies on adult OLLF.**

Outcome domain organised by the COMET Taxonomy of Outcomes, core areas and outcome domains	Individual outcomes reported	Unique outcome terms reported	Standardised outcome headings created	Outcome Measurement Instruments (OMI)		
				Definitions stated	Individual patient/clinician-reported outcome measures or PPMs reported	Unique patient/clinician-reported outcome measures or PPMs reported
<b>Death</b>						
Mortality/survival (1)	21	7	1	3	1	1
<b>Physiological/ clinical</b>						
Blood and lymphatic system outcomes (2)	10	8	1	0	0	0
General outcomes (9)	3	2	1	0	0	0
Musculoskeletal and connective tissue outcomes (15)	1335	529	41	239	9	3
Nervous system outcomes (17)	0	0	0	0	1	1
Renal and urinary outcomes (19)	5	5	2	2	1	1
Psychiatric outcomes (21)	0	0	0	0	3	3
<b>Life Impact</b>						
Physical functioning (25)	258	149	15	0	123	29
Social functioning (26)	4	4	2	0	0	0
Role functioning (27)	17	9	2	0	0	0
Emotional functioning/wellbeing (28)	11	9	5	0	2	2
Global quality of life (30)	32	7	1	0	39	8
Perceived health status (31)	2	1	1	0	0	0
Delivery of care (32)	6	5	2	1	2	2



**Table 3. Outcome domains identified how they were reported in 532 studies on adult OLLF.**

Outcome domain organised by the COMET Taxonomy of Outcomes core	Individual outcomes	Unique outcome	Standardised outcome	Outcome Measurement Instruments (OMI)		
Resource use						
Economic (34)	24	12	1	10	0	0
Hospital (35)	70	38	6	0	0	0
Need for intervention (36)	0	0	0	10	0	0
Adverse events						
Adverse events/effects (38)	5	1	1	33	0	0

Reported outcomes are shown as the number of all outcomes reported, outcomes reported with unique terminology and the number of standardised outcome headings created within each outcome domain.

**Table 3. Outcome domains identified how they were reported in 532 studies on adult OLLF.**

## FIGURES

Figure 1. PRISMA Flow diagram

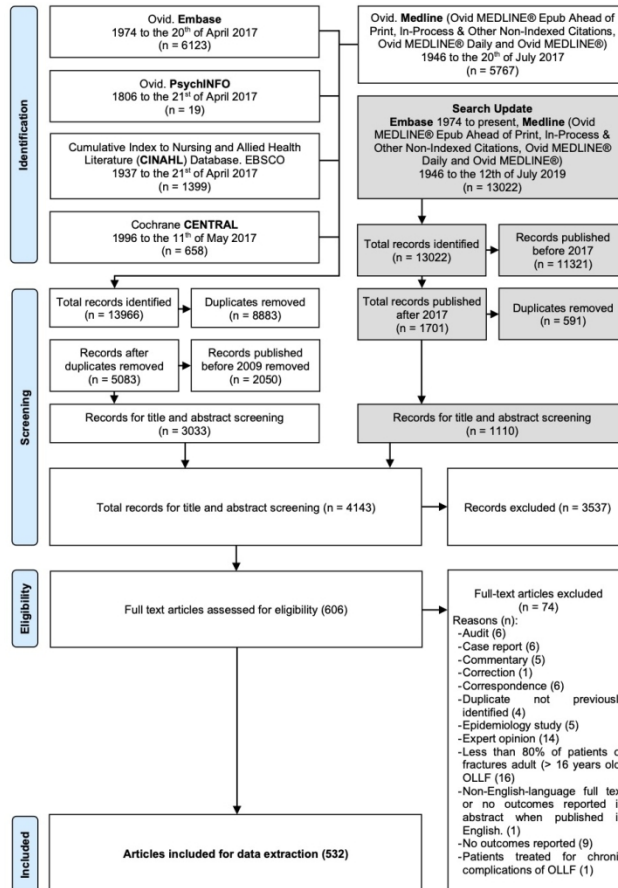


Figure 1. PRISMA Flow diagram

449x635mm (72 x 72 DPI)

1  
2  
3  
4 **What outcomes have been reported on patients following open lower limb**  
5 **fracture and how have they been measured?**  
6  
7

8 **SUPPLEMENTARY MATERIAL**  
9

10 **Supplementary material 1.** Search strategy summary, search terms used and detailed  
11 search results.  
12  
13  
14

<b>Databases searched and date ranges detailed</b>		
<b>Database</b>	<b>Date range after addition of date filters (dd/mm/yyyy)</b>	
<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: 'OR'	
	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: 'OR'	
	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 'AND' 2	
<p>MeSH - Medical Subject Heading (MeSH)</p> <p>exp – exploded MeSH heading</p> <p>* – Truncation/wildcard symbol</p> <p>ti – Title search (search for key word in article titles)</p> <p>ab – Abstract search (search for keyword in article abstracts)</p> <p>adj3 – Proximity search term (two words next to each other, in any order, up to 2 words in between)</p>		

### Primary searches

Medline (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

### Searches

### Results

1		
2		
3	1	Fractures, Open/ 5041
4		
5	2	((open or compound or severe* or mangle*) adj3 (fracture* or 10342
6		break*)).ti,ab.
7		
8	3	1 or 2 12576
9		
10	4	exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp 153269
11		knee/ or exp leg/ or exp thigh/
12		
13	5	"lower extremit*".ti,ab. 46287
14		
15	6	"lower limb*".ti,ab. 40713
16		
17	7	(leg or legs).ti,ab. 99855
18		
19	8	(foot or feet).ti,ab. 97562
20		
21	9	thigh*.ti,ab. 25165
22		
23	10	ankle*.ti,ab. 49851
24		
25	11	(hip or hips).ti,ab. 119217
26		
27	12	exp Leg Bones/ 87046
28		
29	13	knee*.ti,ab. 121914
30		
31	14	femur*.ti,ab. 45068
32		
33	15	tibia*.ti,ab. 73410
34		
35	16	patella*.ti,ab. 17803
36		
37	17	talus*.ti,ab. 4094
38		
39	18	fibula*.ti,ab. 10540
40		
41	19	calcaneus*.ti,ab. 4884
42		
43	20	navicular*.ti,ab. 2185
44		
45	21	cuneiform*.ti,ab. 1321
46		
47	22	cuboid*.ti,ab. 4749
48		
49	23	metatarsal*.ti,ab. 7996
50		
51	24	exp Foot Bones/ 16512
52		
53	25	phalan*.ti,ab. 9815
54		
55	26	Leg/ 62724
56		
57	27	(toe or toes).ti,ab. 17450
58		
59	28	exp Toes/ 11385
60		
	29	pilon*.ti,ab. 2304

1  
2  
3 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 671851  
4 18 or 17 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28  
5 or 29

6  
7  
8 31 3 and 30 **5767**  
9

10  
11 Embase 1974 to the 20<sup>th</sup> of April 2017  
12

13 **Searches**

**Results**

14  
15 1 exp open fracture/ 5640  
16  
17 2 \*open fracture/ 2603  
18  
19 3 ((open or compound or severe\* or mangle\*) adj3 (fracture\* or  
20 break\*)).ti,ab. 11677  
21  
22 4 1 or 3 13474  
23  
24 5 exp lower limb/ 352703  
25  
26 6 \*lower limb/ 843  
27  
28 7 exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp 357372  
29 knee/ or exp leg/ or exp thigh/  
30  
31 8 exp leg/ 295179  
32  
33 9 exp foot/ 56040  
34  
35 10 exp knee/ 91003  
36  
37 11 exp hip/ 73237  
38  
39 12 exp femur/ 87374  
40  
41 13 exp tibia/ 43709  
42  
43 14 exp fibula/ 8840  
44  
45 15 exp ankle/ 40546  
46  
47 16 exp talus/ 5334  
48  
49 17 exp calcaneus/ 8506  
50  
51 18 exp navicular bone/ 156  
52  
53 19 exp cuneiform bone/ 71  
54  
55 20 exp cuboid bone/ 46  
56  
57 21 exp metatarsal bone/ 6527  
58  
59 22 exp toe phalanx/ 264  
60  
23 exp foot bone/ 20513

1		
2		
3	24	exp toe/ 14142
4		
5	25	"lower extremit*" .ti,ab. 59556
6		
7	26	"lower limb*" .ti,ab. 56681
8		
9	27	(leg or legs).ti,ab. 127677
10		
11	28	(foot or feet).ti,ab. 123942
12		
13	29	exp thigh/ 22631
14		
15	30	thigh* .ti,ab. 33234
16		
17	31	ankle* .ti,ab. 64262
18		
19	32	(hip or hips).ti,ab. 151631
20		
21	33	knee* .ti,ab. 151705
22		
23	34	femur* .ti,ab. 56709
24		
25	35	tibia* .ti,ab. 88356
26		
27	36	patella* .ti,ab. 20358
28		
29	37	exp patella/ 10542
30		
31	38	talus* .ti,ab. 4676
32		
33	39	fibula* .ti,ab. 12385
34		
35	40	calcaneus* .ti,ab. 5616
36		
37	41	navicular* .ti,ab. 2451
38		
39	42	cuneiform* .ti,ab. 1452
40		
41	43	cuboid* .ti,ab. 5378
42		
43	44	metatarsal* .ti,ab. 9363
44		
45	45	phalan* .ti,ab. 11785
46		
47	46	(toe or toes).ti,ab. 22731
48		
49	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 822119
50		
51		
52	48	4 and 47 6123
53		
54		
55		PsychINFO 1806 to the 21st of April 2017
56		
57	<b>Searches</b>	<b>Results</b>
58		
59		
60		

1		
2		
3	1	180
4		
5		
6	2	4
7		
8	3	180
9		
10	4	1788
11		
12	5	2401
13		
14	6	9136
15		
16	7	9141
17		
18	8	794
19		
20	9	2117
21		
22	10	5023
23		
24	11	3769
25		
26	12	325
27		
28	13	1703
29		
30	14	237
31		
32	15	11
33		
34	16	84
35		
36	17	35
37		
38	18	8
39		
40	19	107
41		
42	20	26
43		
44	21	46
45		
46	22	215
47		
48	23	1226
49		
50	24	44
51		
52	25	1456
53		
54	26	954
55		
56	27	412
57		
58	28	641
59		
60	29	32034



30 3 and 29

19

Cumulative Index to Nursing and Allied Health Literature (CINAHL)  
Database. EBSCO 1937 to the 21<sup>st</sup> of 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	1399
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")	

1		
2		
3	S27	TI hip
4		
5	S28	AB hip
6		
7	S29	(MH "Femur+")
8		
9	S30	TI femur
10		
11	S31	AB femur
12		
13	S32	(MH "Knee")
14		
15	S33	TI knee
16		
17	S34	AB knee
18		
19	S35	(MH "Patella")
20		
21	S36	TI patella
22		
23	S37	AB patella
24		
25	S38	"tibial plateau"
26		
27	S39	TI tibial plateau
28		
29	S40	AB tibial plateau
30		
31	S41	(MH "Tibia")
32		
33	S42	TI tibia
34		
35	S43	AB tibia
36		
37	S44	(MH "Fibula")
38		
39	S45	TI fibula
40		
41	S46	AB fibula
42		
43	S47	(MH "Ankle")
44		
45	S48	TI ankle
46		
47	S49	AB ankle
48		
49	S50	(MH "Talus")
50		
51	S51	TI talus
52		
53	S52	AB talus
54		
55	S53	(MH "Calcaneus")
56		
57	S54	TI calcaneus
58		
59	S55	AB calcaneus
60		
	S56	(MH "Tarsal Bones") OR "navicular"

1			
2			
3	S57	TI navicular	
4			
5	S58	AB navicular	
6			
7	S59	"cuboid"	
8			
9	S60	TI cuboid	
10			
11	S61	AB cuboid	
12			
13	S62	"cuneiform"	
14			
15	S63	TI cuneiform	
16			
17	S64	AB cuneiform	
18			
19	S65	(MH "Metatarsal Bones")	
20			
21	S66	TI metatarsal	
22	S67	AB metatarsal	1534
23			
24	S68	"phalanx"	
25			
26	S69	TI phalanx	
27			
28	S70	AB phalanx	
29			
30	S71	(MH "Foot") OR (MH "Foot Bones")	
31			
32	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	130012
33			
34			
35			
36			
37			
38			
39			
40			
41			
42	S73	S6 AND S72	1399
43			
44			
45		Cochrane CENTRAL 1996 to the 11 <sup>th</sup> of May 2017	
46			
47		<b>Searches</b>	<b>Results</b>
48	#1	open fracture*:ti,ab,kw (Word variations have been searched)	1485
49	#2	MeSH descriptor: [Fractures, Open] explode all trees	101
50	#3	#1 or #2	1485
51	#4	lower limb:ti,ab,kw (Word variations have been searched)	6146
52	#6	MeSH descriptor: [Thigh] explode all trees	413
53	#7	MeSH descriptor: [Hip] explode all trees	369
54			
55			
56			
57			
58			
59			
60			

1		
2		
3	#8	MeSH descriptor: [Femur] explode all trees 1170
4		
5	#9	MeSH descriptor: [Knee] explode all trees 690
6		
7	#10	MeSH descriptor: [Tibia] explode all trees 512
8		
9	#11	MeSH descriptor: [Leg] explode all trees 2865
10		
11	#12	MeSH descriptor: [Ankle] explode all trees 443
12		
13	#13	MeSH descriptor: [Foot] explode all trees 1450
14		
15	#14	MeSH descriptor: [Leg Bones] explode all trees 1845
16		
17	#15	MeSH descriptor: [Foot Bones] explode all trees 266
18		
19	#16	hip:ti,ab,kw (Word variations have been searched) 13792
20		
21	#17	femur:ti,ab,kw (Word variations have been searched) 3889
22		
23	#18	knee:ti,ab,kw (Word variations have been searched) 16216
24		
25	#19	fibula:ti,ab,kw (Word variations have been searched) 185
26		
27	#20	MeSH descriptor: [Fibula] explode all trees 72
28		
29	#21	MeSH descriptor: [Patella] explode all trees 296
30		
31	#22	patella:ti,ab,kw (Word variations have been searched) 742
32		
33	#23	tibia:ti,ab,kw (Word variations have been searched) 1503
34		
35	#24	ankle:ti,ab,kw (Word variations have been searched) 5560
36		
37	#25	MeSH descriptor: [Foot Bones] explode all trees 266
38		
39	#26	"talus":ti,ab,kw (Word variations have been searched) 73
40		
41	#27	MeSH descriptor: [Talus] explode all trees 33
42		
43	#28	MeSH descriptor: [Calcaneus] explode all trees 150
44		
45	#29	Calcaneus:ti,ab,kw (Word variations have been searched) 309
46		
47	#30	navicular:ti,ab,kw (Word variations have been searched) 36
48		
49	#31	cuboid:ti,ab,kw (Word variations have been searched) 10
50		
51	#32	cuneiform:ti,ab,kw (Word variations have been searched) 8
52		
53	#33	MeSH descriptor: [Metatarsal Bones] explode all trees 62
54		
55	#34	metatarsal:ti,ab,kw (Word variations have been searched) 260
56		
57	#35	MeSH descriptor: [Tarsal Bones] explode all trees 196
58		
59	#36	phalan*:ti,ab,kw (Word variations have been searched) 174
60		
	#37	toe or toes:ti,ab,kw (Word variations have been searched) 813

1  
2  
3 #38 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 **42552**  
4 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or  
5 #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32  
6 or #33 or #34 or #35 or #36 or #37  
7  
8

9 **Search update**

10  
11 Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed  
12 Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to the 12th of July  
13 2019  
14

Searches	Results
1 Fractures, Open/	8995
2 ((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	24342
3 1 or 2	27936
4 exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	524638
6 "lower limb*".ti,ab.	113075
7 (leg or legs).ti,ab.	253197
8 (foot or feet).ti,ab.	247500
9 thigh*.ti,ab.	66484
10 ankle*.ti,ab.	130736
11 (hip or hips).ti,ab.	307815
12 exp Leg Bones/	192500
13 knee*.ti,ab.	316636
14 femur*.ti,ab.	113307
15 tibia*.ti,ab.	181369
16 patella*.ti,ab.	42426
17 talus*.ti,ab.	9619
18 fibula*.ti,ab.	25838
19 calcaneus*.ti,ab.	11324
20 navicular*.ti,ab.	4897
21 cuneiform*.ti,ab.	2977
22 cuboid*.ti,ab.	11131
23 metatarsal*.ti,ab.	18957

24	exp Foot Bones/	36140
25	phalan*.ti,ab.	23221
26	Leg/	133989
27	(toe or toes).ti,ab.	44724
28	exp Toes/	25104
29	pilon*.ti,ab.	5338
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	1696412
31	3 and 30	<b>13022</b>

Embase 1974 to the 12th of July 2019

### Searches

### Results

1	Fractures, Open/	8995
2	((open or compound or severe* or mangle*) adj3 (fracture* or break*)).ti,ab.	24342
3	1 or 2	27936
4	exp lower extremity/ or exp buttocks/ or exp foot/ or exp hip/ or exp knee/ or exp leg/ or exp thigh/	524638
6	"lower limb*".ti,ab.	113075
7	(leg or legs).ti,ab.	253197
8	(foot or feet).ti,ab.	247500
9	thigh*.ti,ab.	66484
10	ankle*.ti,ab.	130736
11	(hip or hips).ti,ab.	307815
12	exp Leg Bones/	192500
13	knee*.ti,ab.	316636
14	femur*.ti,ab.	113307
15	tibia*.ti,ab.	181369
16	patella*.ti,ab.	42426
17	talus*.ti,ab.	9619
18	fibula*.ti,ab.	25838
19	calcaneus*.ti,ab.	11324

1		
2		
3	20	navicular*.ti,ab. 4897
4		
5	21	cuneiform*.ti,ab. 2977
6		
7	22	cuboid*.ti,ab. 11131
8		
9	23	metatarsal*.ti,ab. 18957
10		
11	24	exp Foot Bones/ 36140
12		
13	25	phalan*.ti,ab. 23221
14		
15	26	Leg/ 133989
16		
17	27	(toe or toes).ti,ab. 44724
18		
19	28	exp Toes/ 25104
20		
21	29	pilon*.ti,ab. 5338
22		
23	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 1696412
24		18 or 17 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or
25		29
26	31	3 and 30 13022
27		
28	32	limit 31 to last 2 years 1701
29		
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**Supplementary Material 2.** List of verbatim outcomes, and frequency of reporting. Grouped by standardised outcome headings, outcome domains and core areas using the COMET Taxonomy of Outcomes.

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	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 system outcomes (2)	Venous thromboembolism	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 (9)	Systemic sepsis or bacteraemia	3	0	3	2	Bacteraemia	2
							The risk for sepsis	1
	Musculoskeletal and connective tissue outcomes (15)	Adverse events of orthopaedic intervention	5	2	3	5	A major complication	1
							Achilles tendon contracture	1
							Adverse events	1
							Bleeding haematoma	1
							Orthopaedic complications	1



Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported					
		Complications and post-operative complications	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					
							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 failure	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										

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Pin site loosening	3	1	2	2	Pin loosening	2
							Pin site loosening	1
		Time in external fixator	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
							Bone union rates	2

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							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
							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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported				
							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
											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					

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							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-union	53	2	51	9	Delayed or nonunion	1
		Non-union					Fracture non-union	1
		Non-union					Non-union and delayed union rate	1
		Non-union					Non-union rate	1
		Non-union					Nonunion/non-union	42
		Non-union					Nonunion rates	2
		Non-union					Nonunions	1
		Non-union					Rate of non-union	1
		Non-union					Rate on non-union	1
		Osteonecrosis	5	1	4	5	Avascular necrosis	1
		Osteonecrosis					Necrosis of tibial segment	1
		Osteonecrosis					Osteonecrosis	1
		Osteonecrosis					Posttraumatic osteonecrosis	1
		Osteonecrosis					Radiographic osteoarthritis	1

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Pseudoarthrosis	2	0	2	2	Pseudoarthrosis	1
							Rate of Atrophic pseudoarthrosis	1
		Compartment syndrome	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
							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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported					
		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
		Flap infection	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
		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 arthritis	5	4	1	5	Implant sepsis	1					
												Knee sepsis	1
												Occurrence of ipsilateral knee sepsis	1
												Septic joint	1
							Superficial infection	1					

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Superficial or wound infection	41	1	40	13	Infection superficial Local wound infection Percentage of wound infection Postoperative superficial infection Soft tissue infection Superficial incisional infection Superficial infection Superficial infections Superficial wound infection Surface infection Wound infection Wound infection rate Wound infection rates	1 1 1 1 2 1 20 2 1 1 1 8 1 1
		Laboratory tests	4	0	4	4	Histological analysis of muscle tissue IL-6 level Infection cultures Positive CRP level	1 1 1 1
		Leg length or leg shortening	25	0	25	13	Bone shortening Leg length Leg length discrepancy Leg length ratio Leg length shortening Limb length discrepancy Limb length shortening Limb shortening Limb-length discrepancy Mean lengthening distance Rate of shortening Shortening Shortening deformity	2 1 6 1 3 1 1 2 1 1 2 3 1
		Microbiology cultures	17	1	16	15	Bacteria isolated Bacterial culture Causative organisms of infection Clostridium difficile infection Culture result Drug resistant microbiology Infectious pathogen causing infection and antibiotic resistance Microbiological profile of deep infection Microbiology cultures Pathogen cultured Positive culture Specific pathogen on culture	1 1 1 1 1 1 1 1 1 1 1 1



Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							Time taken to negative culture	1
							Wound culture	3
							Wound culture results	1
		Wound cultures	13	1	12	5	Positive wound culture	1
							Wound culture	9
							Wound culture result	1
							Wound cultures	1
							Wound cultures from infected cases	1
		Numbness and loss of sensation	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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							Pain free	1
							Pain on walking	2
							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 use for pain	1	0	1	1	Pain medication use	1
		Plastics intervention e.g. flap or graft	2	0	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	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
F			51	4	47	17	Complete flap loss	1

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		lap failure or					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
		Graft or flap necrosis	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	
						Unplanned, clinically important reoperations	1	
		Z	7	0	7	7	Frequency of debridement	1

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Number of debridements					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 of reoperations	1
							Rate of secondary surgeries	1
							Re-operation rates	3
							Reoperation	2
							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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							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 and dehiscence	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
							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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported	
		Wound necrosis	14	1	13	9	Wound healing	17	
							Wound healing problem	1	
							Wound healing problems	4	
							Wound healing time	1	
							Wound infection	1	
							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						
		Wound necrosis	1						
		Renal and urinary outcomes (19)	Acute Kidney Injury	4	2	2	4	Acute kidney injury	1
								Aki	1
								AKI rate	1
								Improvement in renal function	1
		Renal failure	1	0	1	1	Renal failure	1	
Life impact	Physical functioning (25)	Ability to climb stairs	2	0	2	2	Ability to climb stairs	1	
							Climbing stairs	1	
		Ability to do activities of daily living	4	0	4	4	Ability to resume activities of daily living	1	
							Activities of daily living	1	
							Regain of walking and adls	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	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						

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							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
		Ankle function	16	0	16	7	Ankle and foot function	1
		Ankle function					Ankle function	8
		Ankle function					Ankle functional outcome	1
		Ankle function					Ankle joint function	1
		Ankle function					Foot and ankle function	3
		Ankle function					Functional outcome	1
		Ankle function					Knee functionality	1
		Foot function	7	0	7	4	Ankle and foot function	1
		Foot function					Foot and ankle function	3
		Foot function					Foot function	2
		Foot function					Foot functional outcomes	1
		Knee function	12	0	12	7	Additional functional assessment	1
		Knee function					Functional outcome	1
		Knee function					Knee function	5
		Knee function					Knee functional results	1
		Knee function					Knee range of movement	2
		Knee function					Knee Society scoring	1
		Knee function					Ligament integrity of knees	1

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Shoulder function	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	
	Use of crutches						1	
	Walking speed						1	
	Walking ability	1						
	Walking without assistance	1						
	Weight bearing	2	0	2	2	Ability to fully weight bear pain free	1	
						Time to weight bearing	1	
	Weight bearing status and time to weight bear	14	0	14	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						



Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
		Movement, range of movement and stiffness	25	0	25	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
		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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
							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 and fitness	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
		Wearing shoes	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 employment	1	0	1	1	Return to work
	Role functioning (27)	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

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported	
Emotional functioning and wellbeing (28)	Appearance	Aesthetic outcome	5	0	5	3	Aesthetic outcome	2	
		Cosmetic outcome					Cosmetic outcome	1	
		Scar quality					Scar quality	2	
	Donor site appearance	Donor site appearance	1	0	1	1	Donor site appearance	1	
		Mood	1	0	1	1	Mood		
	Worry and anxiety	Worry and anxiety	1	0	1	1	Fear	1	
		Stress	Physical and mental stress	3	1	2	3	Physical and mental stress	1
			Post-traumatic stress					Post-traumatic stress	1
	Stress						Stress	1	
	Global quality of life (30)	Quality of life	General health status	32	0	32	7	General health status	1
			General Health/quality of life					General Health/quality of life	1
			Health related quality of life					Health related quality of life	9
			Health-related quality of life					Health-related quality of life	3
			Preference-based health-related quality-of-life outcomes					Preference-based health-related quality-of-life outcomes	1
			Quality of life					Quality of life	7
Perceived health status (31)	Subjective assessment of success	Quality of life and physical function	2	0	2	1	Quality of life and physical function	1	
		Subjective assessment of success					Subjective assessment of success	2	
Delivery of care (32)	Communication	Whether the leaflets were used to improve communication with other healthcare professionals.	1	0	1	1	Whether the leaflets were used to improve communication with other healthcare professionals.	1	

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported
Resource use		Patient satisfaction	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 (34)	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
							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-admission
	Number of secondary surgical admissions	1						
	Rates of readmission	1						
	Readmissions	1						
	Re-hospitalisation rates at 1 year	1						
	Length of hospital stay	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 (LOS)	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							

Core Area	Outcome domain (domain number)	Standardised outcome heading	Number of times reported	Primary outcome	Secondary outcome	Number of unique outcome terms	Verbatim outcomes	Number of times reported		
		Length of ICU stay	6	0	6	5	Total duration of hospitalisation	1		
							ICU length of stay	2		
							ICU LOS	1		
							ITU length of stay	1		
							Length of ICU stay	1		
							Length of stay in ICU	1		
		Number of emergency department	1	0	1	1	1	Number of emergency department attendances	1	
		Number of outpatient	5	0	5	4		Number of clinic visits	1	
								Outpatient appointments	2	
								Outpatient attendances	1	
								Total number of outpatient visits	1	
		Number of primary care encounters	1	0	1	1	1	Primary care encounters	1	
		Adverse events	Adverse events or effects (38)	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</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 (antero posterior 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> <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</li> </ol>	50

Name	Description of OMI including definitions	Frequency of reporting
	<p>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.</p> <p>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. 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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <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>	

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Name	Description of OMI including definitions	Frequency of reporting
	<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 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</p>	



Name	Description of OMI including definitions	Frequency of reporting
	<p>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> <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</p>	

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Name	Description of OMI including definitions	Frequency of reporting
	<p>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> <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 pro- longed period of immobilization or with operative débridement 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).11–14 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.15 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 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>	

Name	Description of OMI including definitions	Frequency of reporting
	<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 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>	

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Name	Description of OMI's including definitions	Frequency of reporting
	<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>	
<b>Definitions of clinical union</b>	<ol style="list-style-type: none"> <li>1. Clinical union where patients were able to walk without pain.</li> <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>	6
<b>Definitions of malunion</b>	<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> </ol>	20

Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <li data-bbox="573 320 1839 379">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 data-bbox="573 411 1783 470">4. Malunion or malalignment defined as an angular or rotational deformity exceeding 5° or shortening exceeding 15 mm.</li> <li data-bbox="573 502 1861 624">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 cavitory metaphyseal defect. All patients had a minimum 3-month follow-up.</li> <li data-bbox="573 655 1832 715">6. Malalignment (or malunion) was defined as angulation or rotational deformity of 5 or more, compared to the uninjured leg.</li> <li data-bbox="573 746 1816 805">7. As more than 5 degrees or varus/valgus, more than 10 degrees of anterior/posterior angulation, more than 15 degrees of rotation or shortening of more than 1 cm.</li> <li data-bbox="573 837 1861 927">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.</li> <li data-bbox="573 959 842 991">9. &gt; 5deg angulation.</li> <li data-bbox="573 1023 1861 1082">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.</li> <li data-bbox="573 1114 1749 1145">11. Malalignment was evaluated as varus/valgus angulation greater than 7 degrees on radiographs.</li> <li data-bbox="573 1177 1447 1209">12. Deformity was defined as angulation, when there was &gt; 5° angulation.</li> <li data-bbox="573 1241 1760 1300">13. Angular malalignment (.5 degrees of sagittal or coronal angulation referenced in contralateral leg radiographs, if non-injured).</li> <li data-bbox="573 1332 1570 1364">14. Shortening was defined as &gt; 10 mm shortening compared to the unaffected side.</li> </ol>	

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Name	Description of OMI including definitions	Frequency of reporting
	<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 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>	
<b>Definitions of non-union</b>	<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 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.</li> <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> </ol>	16

Name	Description of OMI definitions	Frequency of reporting
	<p>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.</p> <p>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</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 (eg, 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.</p> <p>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</p> <p>13. Time to union was defined by the radiographic union score in the tibia (RUST) score at 6 months.</p> <p>14. Defined as absence of a bridging callus across a fracture site after the expected time interval for that injury (usually 10 months)</p> <p>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, 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.</p>	

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Name	Description of OMI including definitions	Frequency of reporting
	16. Nonunion was defined as painful fracture with inadequate healing of the fracture 6 months after injury and requiring revision surgery to achieve union.	
<b>Definitions of radiographic bone union</b>	<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 removal of external fixation [26]. Callus volume was evaluated by CT scan at 12 months, and compared to the pre-grafting CT scan.</li> <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> </ol>	33



Name	Description of OMI including definitions	Frequency of reporting
	<p>11. Presence of bridging calluses on 2+ cortices.</p> <p>12. Presence of callus.</p> <p>13. Defined as complete union of the cortices with sufficient callus support and continuity of the medullary canal on both anteroposterior and lateral radiographs.</p> <p>14. Three or more of four cortices had bridging callus in anteroposterior and lateral views.</p> <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>	

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Name	Description of OMI including definitions	Frequency of reporting
	<p>23. Bridging callus across three of four cortices on orthogonal radiographs evaluated by one investigator at each site.</p> <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> <p>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.</p>	

Name	Description of OMI including definitions	Frequency of reporting
<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> <li>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.</li> </ol>	5
<b>External fixation index (EFI)<sup>2</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> </ol>	31

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Name	Description of OMI including definitions	Frequency of reporting
	<ol style="list-style-type: none"> <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> <li>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.</li> <li>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.</li> <li>9. Deep wound infections required surgical debridement for a purulent wound or osteomyelitis and were treated with intravenous antibiotics for at least several weeks.</li> </ol>	

Name	Description of OMI including definitions	Frequency of reporting
	<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> <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 (eg, 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>	

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Name	Description of OMI's including definitions	Frequency of reporting
	<p>21. Deep infection was defined as infection requiring surgical debridement with positive deep tissue or bone cultures.</p> <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 dehiscd, 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 sur- gery, 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 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>	

Name	Description of OMI's including definitions	Frequency of reporting
	<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>	
<b>Definitions of deep Wound Infection</b>	<p>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/17pscnosinfdef_current.pdf">http://www.cdc.gov/nhsn/pdfs/pscmanual/17pscnosinfdef_current.pdf</a>. Cited 8 July 2013</p> <p>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.</p> <p>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.</p> <p>4. Deep soft tissue infection was defined as any soft tissue infection characterized by redness, warmth, swelling, or purulence that required operative intervention.</p> <p>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</p>	5
<b>Definitions of infected implant</b>	<p>1. Any chronic wound in the vicinity of the implant, including intermittently draining sinuses.</p>	1
<b>Definitions of Infection</b>	<p>1. Laboratory culture results and presence of clinical infection.</p> <p>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.</p>	45

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Name	Description of OMI's including definitions	Frequency of reporting
	<p>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.</p> <p>4. Wound infection or osteomyelitis treated within the first three months after the injury.</p> <p>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. 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).</p> <p>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 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>	



Name	Description of OMI definitions	Frequency of reporting
	<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> <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</li> </ul> </p>	

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Name	Description of OMI including definitions	Frequency of reporting
	<p>examination, during reoperation, or by histopathologic or radiologic examination. 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 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> <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</p>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>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. 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>	

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Name	Description of OMI including definitions	Frequency of reporting
	<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> <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 (eg, 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>	

Name	Description of OMI including definitions	Frequency of reporting
	<p>37. Infection was diagnosed according to the criteria of Willenegger and Roth. 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> <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

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Name	Description of OMI's including definitions	Frequency of reporting
<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 increase in inflammatory markers [increased body temperature &gt; 38°C and white blood count (WBC) &gt; 12,000], with or without radiological evidence.</li> <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>	11
<b>Definitions of pin site infection</b>	<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>	4

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> <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> </ol>	11

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Name	Description of OMI including definitions	Frequency of reporting
	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  10. Superficial infection was defined as infection superficial to fascia, treated with local wound care and/or oral antibiotics.  11. As defined by the surveillance definitions of Center of Disease Control and Prevention	
<b>Pain outcome measurement instruments</b>		
<b>Brief Pain Inventory (BPI)<sup>3</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: 1. pain other than every day kind of pains 2. location of pain (shading diagram) 3. worst pain in the last 24-hours 4. least worst pain in the last 24-hours 5. Pain on average 6. Pain right now 7. treatments/medications for pain 8. relief of pain from treatment/medication 9. pain interference in the last 24 hours (general activity, mood, walking ability, normal work, relations with other people, sleep, enjoyment of life)	2
<b>Visual Analogue Scale (VAS)<sup>4</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>5</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>		



Name	Description of OMI including definitions	Frequency of reporting
<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>6</sup></b>	Physician reported OMI assessing acute kidney injury Assessment areas: <ol style="list-style-type: none"> <li>1. Risk of kidney injury</li> <li>2. Injury to kidney</li> <li>3. Failure of kidney</li> <li>4. Loss of kidney function</li> <li>5. End-stage kidney disease</li> </ol>	1
<b>4. Psychiatric outcome measurement instruments (21)</b>		
<b>Depression outcome measurement instruments</b>		
<b>Patient Health Questionnaire (PHQ-9)<sup>7</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>		
<b>Post-traumatic Stress Disorder (PTSD) Checklist<sup>8</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)</b>	Patient and clinical reported outcome measurement instrument. Response domains include: <ol style="list-style-type: none"> <li>1. pain</li> <li>2. functional limitation on recreational and daily activities</li> <li>3. maximum walking distance in blocks</li> </ol>	23

Name	Description of OMI including definitions	Frequency of reporting
<b>ankle-hindfoot scale<sup>9</sup></b>	4. walking ability on different surfaces 5. Gait abnormality 6. Sagittal motion 7. hindfoot motion 8. ankle -hindfoot stability 9. Alignment	
<b>Association for the Study and Application of the Methods of Ilizarov (ASAMI) criteria<sup>10</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 doors flexion, reflex sympathetic dystrophy, pain, amputation, employment and return to activities of daily living)	24
<b>Chen grading system<sup>11</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
<b>Disability Rating Index (DRI)<sup>12,13</sup></b>	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<sup>14</sup></b>	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

Name	Description of OMI including definitions	Frequency of reporting
	3. the problem's impact on social activities, work, sleep, and self-image (4 items)	
<b>Enneking score</b> <sup>15</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>16</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>17</sup>	Physician reported outcome measurement instrument assessing functional outcome following open lower limb fractures in the following domains: 1. pain 2. range of motion 3. ability to return to normal work	1
<b>Hamlyn Mobility Score (HMS)</b> <sup>18</sup>	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: 1. use of mobility aids 2. participation in work and leisure activities 3. satisfaction with walking 4. pain	1
<b>Hospital for Special Surgery (HSS) knee scoring system</b> <sup>19,20</sup>	Physician reported outcome measurement instrument to assess outcome after knee replacement surgery. The HSS knee score assesses 7 domains: 1. pain (rest pain, support required because of pain) 2. stability (measured as total varus-valgus arc, extension) 3. motion (measured as total passive arc) 4. quadriceps strength (measured as a percentage of normal for age and gender) 5. subtractions (for extension lag, flexion contracture, fixed varus or valgus deformity)	1

Name	Description of OMI including definitions	Frequency of reporting
<b>Iowa ankle-evaluation rating system<sup>21</sup></b>	Physician reported outcome measurement instrument assessing the function of the ankle. Domains assessed include: 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) 2. pain 3. gait 4. range of motion	5
<b>Johner-Wruhs evaluation<sup>22</sup></b>	Physician reported outcome measurement instrument assessing surgical outcome following a tibial fracture. Domains assessed: 1. bone union, osteitis or amputation 2. neurovascular disturbances 3. bone deformity 4. range of motion 5. pain 6. gait 7. Participation in strenuous activities	10
<b>Lower Extremity Functional Scale (LEFS)<sup>23</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>24</sup></b>	Patient-reported outcome measurement instrument to assess knee function. It assess 8 domains including: 1. limp 2. walking support 3. pain 4. instability 5. locking 6. swelling 7. stair-climbing 8. squatting	1
<b>Maryland foot score (MFS)<sup>25</sup></b>	Patient and Physician reported outcome measurement instrument to assess foot injuries. Domains include: 1. pain 2. function (gait, distance walked, stability, support, limp and wearing shoes)	3

Name	Description of OMI including definitions	Frequency of reporting
<b>Mazur ankle function evaluation</b> <sup>26</sup>	Patient and physician reported outcome measurement instrument to assess ankle function over 12 response items in 2 domains: 1. pain 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)	1
<b>Musculoskeletal Function Assessment (MFA)</b> <sup>27-29</sup>	Patient-reported outcome measurement instrument assessing musculoskeletal function consisting of 100 response items over the following domains: 1. mobility 2. hand and fine motor 3. housework 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	1
<b>Neer knee score</b> <sup>30,31</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>32</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>33,34</sup>	Objective physical performance measurement instrument to assess physical performance by measuring the time	1

Name	Description of OMI including definitions	Frequency of reporting
	taken to ascend and descend a flight of stairs consisting of 14 steps.	
<b>Timed up and go test</b> <sup>35</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>36</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>37</sup>	Patient-reported outcome measurement instrument assessing symptoms after ankle fracture in 9 domains: <ol style="list-style-type: none"> <li>1. pain</li> <li>2. stiffness</li> <li>3. swelling</li> <li>4. stair climbing</li> <li>5. running</li> <li>6. jumping</li> <li>7. squatting</li> <li>8. supports</li> <li>9. work and activities of daily living</li> </ol>	1
<b>Paley Criteria</b> <sup>38-40</sup>	Physician reported outcome measurement instrument assessing bone and functional outcomes of the lower leg. Domains assessed: <ol style="list-style-type: none"> <li>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)</li> <li>2. Function (pain free, walking, joint stiffness, talocrural or subtalar motion, use of analgesia, and activities of daily living)</li> </ol>	12
<b>Sanders knee score</b> <sup>41,42</sup>	Physician reported outcome measurement instrument assessing knee function following distal femoral fracture assessing the following domains: <ol style="list-style-type: none"> <li>1. Range of movement</li> <li>2. Pain</li> <li>3. Deformity</li> <li>4. walking ability (walking and stair climbing)</li> <li>5. return to work (employment/return to pre-injury functioning)</li> </ol>	1

Name	Description of OMI including definitions	Frequency of reporting
<b>Severn scale scoring system by Puno et al<sup>43</sup></b>	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
<b>Short Musculoskeletal Function Assessment Questionnaire (SMFA)<sup>44</sup></b>	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<sup>45</sup></b>	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)<sup>46,47</sup></b>	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<sup>48</sup></b>	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	1

Name	Description of OMI including definitions	Frequency of reporting
	novel instrument only cited in this study	
<b>Vancouver scar scale</b> <sup>49</sup>	Physician reported OMI to assess scare 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>		
<b>EuroQol 5-Dimensions 3-Level (EQ-5D-3L)</b> <sup>50</sup>	The EQ-5D-3L descriptive system comprises the following five dimensions: 1. mobility 2. self-care 3. usual activities 4. pain/discomfort 5. anxiety/depression 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.	2
<b>EuroQol 5-Dimensions 5-Level (EQ-5D-5L)</b> <sup>51</sup>	Patient-reported outcome measurement instrument. The descriptive system comprises five dimensions: 1. mobility 2. self-care 3. usual activities 4. pain/discomfort 5. anxiety/depression 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.	6
<b>Short Form-12 (SF-12)</b> <sup>52</sup>	Patient-reported outcome measurement instrument. Assessing the following domains: 1. physical functioning 2. role-physical 3. bodily pain 4. general health 5. vitality	5



Name	Description of OMI including definitions	Frequency of reporting
	6. social functioning 7. role-emotional 8. mental Health	
<b>Short Form-36 (SF-36)<sup>53</sup></b>	Patient-reported outcome measurement instrument. Assessing the following domains: 1. physical functioning 2. role-physical 3. bodily pain 4. general health 5. vitality 6. social functioning 7. role-emotional 8. mental Health	17
<b>Short Form-6 Dimensions (SF-6D)<sup>54</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>55,56</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

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Name	Description of OMI including definitions	Frequency of reporting
<b>Veterans Affairs System of Rating Disabilities</b> <sup>57</sup>	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
<b>Veterans RAND 12 Item Health Survey (VR-12)</b> <sup>16</sup>	Patient-reported outcome measurement instrument assesses domains: 1. general health perceptions 2. physical functioning 3. role physical 4. role emotional 5. bodily pain 6. vitality/mental health 7. social functioning 8. change physical 9. change emotional	1
<b>4. Delivery of care outcome measurement instruments (32)</b>		
<b>Satisfaction outcome measurement instruments</b>		
<b>Definitions of satisfaction</b>	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.	1
<b>The Patient Satisfaction Questionnaire Short Form (PSQ-18)</b> <sup>58</sup>	Patient-reported outcome measurement instrument assessing satisfaction in the following domains: 1. general satisfaction 2. technical quality 3. interpersonal manner 4. communication 5. financial aspects 6. time spent with doctor 7. accessibility and convenience	1
<b>Visual Analogue</b>	Patient-reported outcome measurement instruments assessing satisfaction on a continuous scale (0-100mm).	1

Name	Description of OMI including definitions	Frequency of reporting
<b>Scale for satisfaction<sup>59</sup></b>	Novel score only used in citing study.	
<b>4. Resource use outcome measurement instruments</b>		
<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 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.</li> </ol>	10

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Name	Description of OMI including definitions	Frequency of reporting
	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.  10. Real income received for service provision as determined per HRG remuneration.	
<b>2. Need for intervention outcome measurement instruments (36)</b>		
<b>Definitions of reoperation</b>	1. All unplanned operations deemed clinically important.  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  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.  4. An operation to revise or augment fracture fixation after arriving to a Level V facility.  5. The third evaluation factor of the psychosocial evolution of the patients was represented by the number of later readmissions for secondary surgical interventions.  6. Reoperation was defined as at least one surgical procedure following the index procedure.  7. Metal work exchange or reinsertion, joint fusion, bone resection and bone grafting) in addition to the routine.  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.  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.	10

Name	Description of OMI including definitions	Frequency of reporting
<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 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.</li> <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> </ol>	18

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Name	Description of OMI including definitions	Frequency of reporting
	<p>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.</p> <p>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.</p> <p>8. We recorded complications requiring reoperation.</p> <p>9. Pseudoarthrosis, chronic osteitis and angular deformities of over 10 degrees</p> <p>10. All complications and surgical interventions related to the open fracture will be recorded.</p> <p>11. Neurovascular injury be- cause 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 <math>\square</math>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 HCUP CCS 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>	

Name	Description of OMI including definitions	Frequency of reporting
	<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>	
<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>

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Name	Description of OMI's 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>	

**References**

1. Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. J Clin Epidemiol [Internet]. 1994;47(11):1245–51. Available from: <https://linkinghub.elsevier.com/retrieve/pii/0895435694901295>

2. Niekerk AH van, Birkholtz FF, Lange P de, Tetsworth K, Hohmann E. Circular external fixation and cemented PMMA spacers for the treatment of complex tibial fractures and infected nonunions with segmental bone loss. J ORTHOP SURG [Internet]. 2017;25(2). Available from: <http://journals.sagepub.com/doi/10.1177/2309499017716242>

3. Keller S, Bann CM, Dodd SL, Schein J, Mendoza TR, Cleeland CS. Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. Clin J Pain [Internet]. 2004;20(5):309–18. Available from: <http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00002508-200409000-00005>



- 1  
2  
3 4. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and  
4 experimental pain. *Pain* [Internet]. 1983;17(1):45–56. Available from:  
5 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=6226917&retmode=ref&cmd=prlinks>  
6
- 7 5. Compston A. Aids to the investigation of peripheral nerve injuries. Medical Research Council: Nerve Injuries Research Committee. His  
8 Majesty's Stationery Office: 1942; pp. 48 (iii) and 74 figures and 7 diagrams; with aids to the examination of the peripheral nervous system. By  
9 Michael O'Brien for the Guarantors of Brain. Saunders Elsevier: 2010; pp. [8] 64 and 94 Figures. *Brain* [Internet]. 2010;133(10):2838–44.  
10 Available from: <https://academic.oup.com/brain/article-lookup/doi/10.1093/brain/awq270>  
11
- 12 6. Hocine A, Defrance P, Lalmand J, Delcour C, Biston P, Piagnerelli M. Predictive value of the RIFLE urine output criteria on contrast-induced  
13 nephropathy in critically ill patients. *BMC Nephrol* [Internet]. 2016 Mar 28;17(1):36–9. Available from:  
14 <http://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-016-0243-5>  
15
- 16 7. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* [Internet].  
17 2001;16(9):606–13. Available from: <http://link.springer.com/10.1046/j.1525-1497.2001.016009606.x>  
18
- 19 8. Blanchard EB, Jones-Alexander J, Buckley TC, Forneris CA. Psychometric properties of the PTSD Checklist (PCL). *Behav Res Ther*  
20 [Internet]. 1996;34(8):669–73. Available from: <https://linkinghub.elsevier.com/retrieve/pii/0005796796000332>  
21
- 22 9. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux,  
23 and lesser toes. *Foot Ankle Int* [Internet]. 1994;15(7):349–53. Available from: <http://journals.sagepub.com/doi/10.1177/107110079401500701>  
24
- 25 10. Inam M, Saeed M, Khan I, Durrani A, Satar A, Arif M. Outcome of ilizarov fixator in tibial non-union. *JPMA J Pak Med Assoc* [Internet].  
26 2015;65(11):S94–9. Available from:  
27 [http://gateway.webofknowledge.com/gateway/Gateway.cgi?GWVersion=2&SrcAuth=mekentosj&SrcApp=Papers&DestLinkType=FullRecord&](http://gateway.webofknowledge.com/gateway/Gateway.cgi?GWVersion=2&SrcAuth=mekentosj&SrcApp=Papers&DestLinkType=FullRecord&DestApp=WOS&KeyUT=000467464600024)  
28 [DestApp=WOS&KeyUT=000467464600024](http://gateway.webofknowledge.com/gateway/Gateway.cgi?GWVersion=2&SrcAuth=mekentosj&SrcApp=Papers&DestLinkType=FullRecord&DestApp=WOS&KeyUT=000467464600024)  
29
- 30 11. Parmaksizoglu F, Koprulu AS, Unal MB, Cansu E. Early or delayed limb lengthening after acute shortening in the treatment of traumatic  
31 below-knee amputations and Gustilo and Anderson type IIIC open tibial fractures: The results of a case series. *Journal of Bone and Joint*  
32 *Surgery - Series B* [Internet]. 2010 Nov 1;92 B(11):1563–7. Available from: [http://online.boneandjoint.org.uk/doi/10.1302/0301-](http://online.boneandjoint.org.uk/doi/10.1302/0301-620X.92B11.23500)  
33 [620X.92B11.23500](http://online.boneandjoint.org.uk/doi/10.1302/0301-620X.92B11.23500)  
34  
35  
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- 1  
2  
3 12. Salén BA, Spangfort EV, Nygren AL, Nordemar R. The Disability Rating Index: an instrument for the assessment of disability in clinical  
4 settings. *J Clin Epidemiol* [Internet]. 1994;47(12):1423–35. Available from:  
5 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=7730851&retmode=ref&cmd=prlinks>  
6
- 7 13. Parsons H, Bruce J, Achten J, Costa ML, Parsons NR. Measurement properties of the Disability Rating Index in patients undergoing hip  
8 replacement. *Rheumatology (Oxford)* [Internet]. 2015;54(1):64–71. Available from:  
9 <http://www.rheumatology.oxfordjournals.org/cgi/doi/10.1093/rheumatology/keu293>  
10
- 11 14. Gummesson C, Atroshi I, Ekdahl C. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: longitudinal construct  
12 validity and measuring self-rated health change after surgery. *BMC Musculoskelet Disord* [Internet]. 2003 Jun 16;4(1):602–6. Available from:  
13 <http://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/1471-2474-4-11>  
14
- 15 15. Wada T, Kawai A, Ihara K, Sasaki M, Sonoda T, Imaeda T, et al. Construct validity of the Enneking score for measuring function in patients  
16 with malignant or aggressive benign tumours of the upper limb. *Journal of Bone and Joint Surgery - Series B* [Internet]. 2007 May 1;89(5):659–  
17 63. Available from: <http://online.boneandjoint.org.uk/doi/10.1302/0301-620X.89B5.18498>  
18
- 19 16. Selim AJ, Rogers W, Fleishman JA, Qian SX, Fincke BG, Rothendler JA, et al. Updated U.S. population standard for the Veterans RAND  
20 12-item Health Survey (VR-12). *Quality of Life Research* [Internet]. 2009 Feb 1;18(1):43–52. Available from:  
21 <http://link.springer.com/10.1007/s11136-008-9418-2>  
22
- 23 17. Tu Y, Lin C, Su J, Hsu D, Chen R. Unreamed interlocking nail versus external fixator for open type III tibia fractures. *Journal of trauma*  
24 [Internet]. 1995;39:361–7. Available from: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/179/CN-00118179/frame.html>  
25
- 26 18. Kwasnicki RM, Hettiaratchy S, Jarchi D, Nightingale C, Wordsworth M, Simmons J, et al. Assessing Functional Mobility After Lower Limb  
27 Reconstruction A Psychometric Evaluation of a Sensor-based Mobility Score. *Ann Surg* [Internet]. 2015;261(4):800–6. Available from:  
28 <http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00000658-201504000-00027>  
29
- 30 19. Hofmann AA, Tkach TK, Evanich CJ, Camargo MP, Zhang Y. Patellar component medialization in total knee arthroplasty. *J*  
31 *ARTHROPLASTY* [Internet]. 1997;12(2):155–60. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0883540397900619>  
32
- 33 20. Evanich CJ, Tkach TK, Glinski S von, Camargo MP, Hofmann AA. 6- to 10-year experience using countersunk metal-backed patellas. *J*  
34 *ARTHROPLASTY* [Internet]. 1997;12(2):149–54. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0883540397900607>  
35  
36  
37  
38  
39  
40  
41  
42  
43  
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- 1  
2  
3 21. MERCHANT TC, DIETZ FR. Long-Term Follow-Up After Fractures of the Tibial and Fibular Shafts. *The Journal of Bone & Joint Surgery*  
4 [Internet]. 1989;71A(4):599–606. Available from: <http://Insights.ovid.com/crossref?an=00004623-198971040-00016>  
5
- 6 22. Johner R, Wruhs O. Classification of tibial shaft fractures and correlation with results after rigid internal fixation. *Clin Orthop Relat Res*  
7 [Internet]. 1983;(178):7–25. Available from:  
8 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=6883870&retmode=ref&cmd=prlinks>  
9
- 10 23. Binkley JM, Stratford PW, Lott SA, Riddle DL, Network TNAORR. The Lower Extremity Functional Scale (LEFS): Scale Development,  
11 Measurement Properties, and Clinical Application. *Physical Therapy* [Internet]. 1999 Apr 1;79(4):371–83. Available from:  
12 <http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00005650-198903001-00007>  
13  
14
- 15 24. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res* [Internet]. 1985;(198):43–9.  
16 Available from: <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=4028566&retmode=ref&cmd=prlinks>  
17
- 18 25. Sanders R, Fortin P, DiPasquale T, Walling A. Operative treatment in 120 displaced intraarticular calcaneal fractures. Results using a  
19 prognostic computed tomography scan classification. *Clin Orthop Relat Res* [Internet]. 1993;(290):87–95. Available from:  
20 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=8472475&retmode=ref&cmd=prlinks>  
21  
22
- 23 26. Mazur JM, Schwartz E, Simon SR. Ankle arthrodesis. Long-term follow-up with gait analysis. *The Journal of Bone & Joint Surgery*  
24 [Internet]. 1979;61(7):964–75. Available from:  
25 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=489661&retmode=ref&cmd=prlinks>  
26
- 27 27. Martin DP, Engelberg R, Agel J, Snapp D, Swiontkowski MF. Development of a musculoskeletal extremity health status instrument: the  
28 Musculoskeletal Function Assessment instrument. *J Orthop Res* [Internet]. 1996;14(2):173–81. Available from:  
29 <http://doi.wiley.com/10.1002/jor.1100140203>  
30
- 31 28. Engelberg R, Martin DP, Agel J, Swiontkowski MF. Musculoskeletal function assessment: reference values for patient and non-patient  
32 samples. *J Orthop Res* [Internet]. 1999;17(1):101–9. Available from: <http://doi.wiley.com/10.1002/jor.1100170116>  
33  
34
- 35 29. Engelberg R, Martin DP, Agel J, Obremsky W, Coronado G, Swiontkowski MF. Musculoskeletal Function Assessment instrument: criterion  
36 and construct validity. *J Orthop Res* [Internet]. 1996;14(2):182–92. Available from: <http://doi.wiley.com/10.1002/jor.1100140204>  
37
- 38 30. Schmidt-Rohlfing B, Pfeifer R, Kaneshige J, Hofman M, Knobe M, Sellei R, et al. Scoring systems for outcome after knee injuries. *Injury*  
39 [Internet]. 2011 Mar 1;42(3):271–5. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0020138310008077>  
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31. Neer CS, Grantham SA, Shelton ML. Supracondylar fracture of the adult femur. A study of one hundred and ten cases. *J Bone Joint Surg Am* [Internet]. 1967 Jun 1;49(4):591–613. Available from: <https://www.scopus.com/inward/record.uri?partnerID=HzOxMe3b&scp=0014094733&origin=inward>
32. BALKE B. A simple field test for the assessment of physical fitness. *Rep Civ Aeromed Res Inst US* [Internet]. 1963 Apr 1;53:1–8. Available from: <https://www.scopus.com/inward/record.uri?partnerID=HzOxMe3b&scp=34250778035&origin=inward>
33. Nightingale EJ, Pourkazemi F, Hiller CE. Systematic review of timed stair tests. *J Rehabil Res Dev* [Internet]. 2014;51(3):335–50. Available from: <http://www.rehab.research.va.gov/jour/2014/513/pdf/JRRD-2013-06-0148.pdf>
34. Zaino CA, Marchese VG, Westcott SL. Timed up and down stairs test: Preliminary reliability and validity of a new measure of functional mobility. *Pediatr Phys Ther* [Internet]. 2004 Jun 1;16(2):90–8. Available from: <https://insights.ovid.com/crossref?an=00001577-200401620-00003>
35. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the timed up and go test. *Physical Therapy* [Internet]. 2000 Sep 23;80(9):896–903. Available from: <https://www.scopus.com/inward/record.uri?partnerID=HzOxMe3b&scp=0033822729&origin=inward>
36. Hallstrand TS, Boitano LJ, Johnson WC, Spada CA, Hayes JG, Raghu G. The timed walk test as a measure of severity and survival in idiopathic pulmonary fibrosis. *Eur Respir J* [Internet]. 2005;25(1):96–103. Available from: <http://erj.ersjournals.com/cgi/doi/10.1183/09031936.04.00137203>
37. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg* [Internet]. 1984 Sep 1;103(3):190–4. Available from: <http://link.springer.com/10.1007/BF00435553>
38. Paley D, Maar DC. Ilizarov bone transport treatment for tibial defects. *J Orthop Trauma* [Internet]. 2000;14(2):76–85. Available from: <https://insights.ovid.com/crossref?an=00005131-200002000-00002>
39. Paley D, Catagni MA, Argnani F, Villa A, Benedetti GB, Cattaneo R. Ilizarov treatment of tibial nonunions with bone loss. *Clin Orthop Relat Res* [Internet]. 1989 Jan 1;(241):146–65. Available from: <https://www.scopus.com/inward/record.uri?partnerID=HzOxMe3b&scp=0024514814&origin=inward>

- 1  
2  
3 40. Ferchaud F, Rony L, Ducellier F, Cronier P, Steiger V, Hubert L, et al. Reconstruction of large diaphyseal bone defect by simplified bone  
4 transport over nail technique: A 7-case series. *Orthop Traumatol Surg Res* [Internet]. 2017 Nov 1;103(7):1131–6. Available from:  
5 <http://dx.doi.org/10.1016/j.otsr.2017.05.016>  
6
- 7 41. Sanders R, Swiontkowski M, Rosen H, Helfet D. Double-plating of comminuted, unstable fractures of the distal part of the femur. *The*  
8 *Journal of Bone & Joint Surgery* [Internet]. 1991;73(3):341–6. Available from:  
9 <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=2002071&retmode=ref&cmd=prlinks>  
10
- 11 42. Jain D, Arora R, Garg R, Mahindra P, Selhi HS. Functional outcome of open distal femoral fractures managed with lateral locking plates. *Int*  
12 *Orthop* [Internet]. 2019 May 24;25:S8-9. Available from: <http://link.springer.com/10.1007/s00264-019-04347-5>  
13
- 14 43. M PR, L GS, L HS, D S, J H, M TT. Functional outcome of patients with salvageable limbs with grades III-B and III-C open fractures of the  
15 tibia [Internet]. 1996. Available from: <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed4&NEWS=N&AN=1997012498>  
16
- 17 44. Swiontkowski MF, Engelberg R, Martin DP, Agel J. Short musculoskeletal function assessment questionnaire: validity, reliability, and  
18 responsiveness. *The Journal of Bone & Joint Surgery* [Internet]. 1999;81(9):1245–60. Available from:  
19 <https://insights.ovid.com/crossref?an=00004623-199909000-00006>  
20
- 21 45. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res* [Internet].  
22 1989;(248):13–4. Available from: <http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=2805470&retmode=ref&cmd=prlinks>  
23
- 24 46. Stüber J, Zech S, Bay R, Qazzaz A, Richter M. Normative data of the Visual Analogue Scale Foot and Ankle (VAS FA) for pathological  
25 conditions. *Foot and Ankle Surgery* [Internet]. 2011 Sep 1;17(3):166–72. Available from:  
26 <https://www.sciencedirect.com/science/article/pii/S1268773110000718?via%3Dihub>  
27
- 28 47. Richter M, Zech S, Geerling J, Frink M, Knobloch K, Krettek C. A new foot and ankle outcome score: Questionnaire based, subjective,  
29 Visual-Analogue-Scale, validated and computerized. *Foot and Ankle Surgery* [Internet]. 2006 Nov 7;12(4):191–9. Available from:  
30 <https://linkinghub.elsevier.com/retrieve/pii/S1268773106000373>  
31
- 32 48. O'Toole RV, Castillo RC, Pollak AN, MacKenzie EJ, Bosse MJ. Surgeons and their patients disagree regarding cosmetic and overall  
33 outcomes after surgery for high-energy lower extremity trauma. *J Orthop Trauma* [Internet]. 2009 Nov 1;23(10):716–23. Available from:  
34 <https://insights.ovid.com/crossref?an=00005131-200911000-00005>  
35  
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2  
3 49. Baryza MJ, Baryza GA. The vancouver scar scale: An administration tool and its interrater reliability. *Journal of Burn Care and Rehabilitation* [Internet]. 1995 Jan 1;16(5):535–8. Available from: <https://insights.ovid.com/crossref?an=00004630-199509000-00013>
- 4  
5  
6 50. Hout B van, Janssen MF, Feng Y-S, Kohlmann T, Busschbach J, Golicki D, et al. Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. *Value Health* [Internet]. 2012;15(5):708–15. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S1098301512000587>
- 7  
8  
9  
10  
11 51. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* [Internet]. 2011;20(10):1727–36. Available from: <http://link.springer.com/10.1007/s11136-011-9903-x>
- 12  
13  
14 52. Jenkinson C, Layte R, Jenkinson D, Lawrence K, Petersen S, Paice C, et al. A shorter form health survey: can the SF-12 replicate results from the SF-36 in longitudinal studies? *J Public Health Med* [Internet]. 1997;19(2):179–86. Available from: <https://academic.oup.com/jpubhealth/article-lookup/doi/10.1093/oxfordjournals.pubmed.a024606>
- 15  
16  
17  
18 53. Jenkinson C, Coulter A, Wright L. Short form 36 (SF 36) health survey questionnaire: Normative data for adults of working age. *Br Med J* [Internet]. 1993 Jan 1;306(6890):1437–40. Available from: <http://www.bmj.com/cgi/doi/10.1136/bmj.306.6890.1437>
- 19  
20  
21  
22 54. Obradovic M, Lal A, Liedgens H. Validity and responsiveness of EuroQol-5 dimension (EQ-5D) versus Short Form-6 dimension (SF-6D) questionnaire in chronic pain. *Health Qual Life Outcomes* [Internet]. 2013 Jul 1;11(1):110–9. Available from: <http://hqlo.biomedcentral.com/articles/10.1186/1477-7525-11-110>
- 23  
24  
25  
26 55. Bergner M, Bobbitt RA, Carter WB, Gilson BS. The Sickness Impact Profile: development and final revision of a health status measure. *Medical Care* [Internet]. 1981;19(8):787–805. Available from: <https://insights.ovid.com/crossref?an=00005650-198108000-00001>
- 27  
28  
29  
30 56. Post MW, Bruin A de, Witte L de, Schrijvers A. The SIP68: a measure of health-related functional status in rehabilitation medicine. *Arch Phys Med Rehabil* [Internet]. 1996;77(5):440–5. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0003999396900313>
- 31  
32  
33 57. McGear M, Ford MA, McCutchen SR, Barnes DK. A 21st century system for evaluating veterans for disability benefits [Internet]. *A 21st Century System for Evaluating Veterans for Disability Benefits*; 2007. (A 21st Century System for Evaluating Veterans for Disability Benefits). Available from: <http://www.nap.edu/catalog/11885>
- 34  
35  
36  
37 58. Thayaparan AJ, Mahdi E. The Patient Satisfaction Questionnaire Short Form (PSQ-18) as an adaptable, reliable, and validated tool for use in various settings. *Med Educ Online* [Internet]. 2013 Jul 23;18(1):21747. Available from: <https://www.tandfonline.com/doi/full/10.3402/meo.v18i0.21747>
- 38  
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43  
44  
45  
46

1  
2  
3 59. Frisvoll C, Clarke-Jenssen J, Madsen JE, Flugsrud G, Frihagen F, Andreassen GS, et al. Long-term outcomes after high-energy open tibial  
4 fractures: Is a salvaged limb superior to prosthesis in terms of physical function and quality of life? Eur j orthop surg traumatol [Internet].  
5 2019;29(4):899–906. Available from: <http://link.springer.com/10.1007/s00590-019-02382-x>  
6  
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