Follow us @BoneJointOpen

Freely available online OPEN ACCESS

BJO

GENERAL ORTHOPAEDICS

A scoping review of the outcome reporting following surgery for chronic osteomyelitis of the lower limb

J. Camilleri-Brennan,
S. James,
C. McDaid,
J. Adamson,
K. Jones,
G. O'Carroll,
Z. Akhter,
M. Eltayeb,
H. Sharma

From York Trials Unit, Univesity of York, York, UK

Aims

Chronic osteomyelitis (COM) of the lower limb in adults can be surgically managed by either limb reconstruction or amputation. This scoping review aims to map the outcomes used in studies surgically managing COM in order to aid future development of a core outcome set.

Methods

A total of 11 databases were searched. A subset of studies published between 1 October 2020 and 1 January 2011 from a larger review mapping research on limb reconstruction and limb amputation for the management of lower limb COM were eligible. All outcomes were extracted and recorded verbatim. Outcomes were grouped and categorized as per the revised Williamson and Clarke taxonomy.

Results

A total of 3,303 records were screened, of which 99 studies were included. Most studies were case series (77/99; 78%) and assessed one method of reconstruction (68/99; 69%). A total of 511 outcomes were reported, which were grouped into 58 distinct outcomes. Overall, 143/511 of all outcomes (28%) were provided with a clear, in-text definition, and 231 outcomes (45%) had details reported of how and when they were measured. The most commonly reported outcome was 'recurrence of osteomyelitis' (62; 12%). The single-most patient-reported outcome measure was 'pain'.

Conclusion

This study has highlighted significant inconsistencies in the defining, reporting, and measuring of outcomes across studies investigating surgical management for chronic osteomyelitis of the lower limb in adults. Future studies should clearly report complete details of how outcomes are defined and measured, including timing. The development of a standardized core outcome set would be of significant benefit in order to allow evidence synthesis and comparison across studies.

Cite this article: *Bone Jt Open* 2023;4-3:146–157.

Keywords: Osteomyelitis, Chronic, Lower limb, Surgery, Reconstruction, Amputation, Outcome reporting

Introduction

Chronic osteomyelitis (COM) is a long-standing (> six weeks) infection of the bone in which patients can be affected with an indolent infection for significant periods, lasting years. The estimated incidence is 21.8 cases per 100,000 person-years, with increased rates in diabetic patients.[1] Clinical features of COM are highly variable and may include long-standing pains, fever, erythema, and pus drainage through sinus tract formation.[2]

COM is typically managed with a watch-and-wait policy and acute flare-ups are managed with antibiotics. Patients with frequent or constant discharge and/or problems can be managed surgically.[3] Surgical management is usually either limb amputation or limb reconstruction. Patients undergoing either of these surgical options

Correspondence should be sent to Julian Camilleri-Brennan; email: juliancamilleribrennan@doctors.org.uk

doi: 10.1302/2633-1462.43.BJO-2022-0109.R1

Bone Jt Open 2023;4-3:146–157.

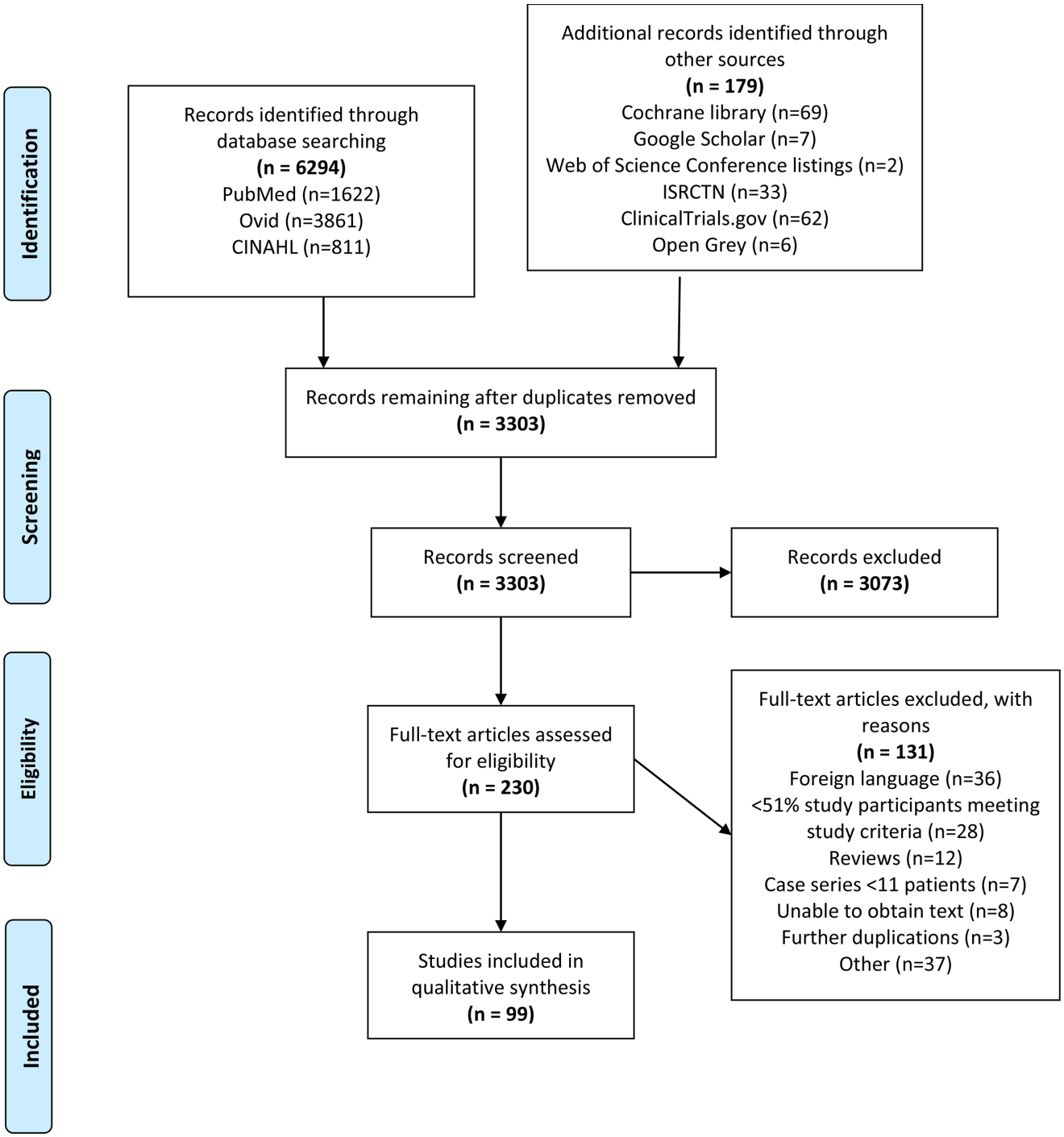

Fig. 1

PRISMA flow-chart detailing the number of records identified at each stage of the methodology.

require a long rehabilitation period and are at risk of infection recurrence. Limb reconstruction patients in addition are at risk of bony nonunion and failure of reconstruction surgery.[4]

There is a noted lack of consistency with regards to outcome reporting within the field, including the timing of outcome follow-up.[5,6] This creates challenges when making comparisons between studies and aggregating data in meta-analyses. The outcome domains being assessed, and the measurement instruments/methods used have not been systematically mapped for COM. In advance of designing our protocol, searches of PROSPERO,[7] Open Science Framework,[8] and COMET (Core Outcome Measures in Effectiveness Trials) Initiative[9] did

Table I. Characteristics of the 99 included studies.

Year of publication	N
2020	18
2019	11
2018	11
2017	20
2016	6
2015	8
2014	6
2013	8
2012	5
2011	4
Trial protocols registered 2014, 2015	2
Study location	
China	37
USA	9
UK	8
Turkey	7
Germany	6
Italy	5
Brazil, Switzerland, France	3
Taiwan, Nigeria, South Korea, Spain	2
Japan, Poland, South Africa, Vietnam, Malaysia, Egypt, Austria, Australia	1
Multinational	2
Study design	
Case series	77
Cohort	8
Retrospective cohort	7
Randomized controlled trial	6
Retrospective case control	1
Text availability	
Full text	93
Conference proceedings	4
Randomized controlled trial registry	2
Study size, patients	
11 to 19	27
20 to 49	37
50 to 99	19
100 to 499	16
Interventions	
Reconstruction one method	68
Reconstruction vs reconstruction	29
Amputation vs reconstruction	1
Amputation	1

Table II. Outcomes as per the revised Williamson and Clarke taxonomy.[20]

Outcome domain	Outcome category	
Mortality/survival	1	Mortality/survival
Physiological/clinical	2	Blood and lymphatic system
	3	Cardiac
	4	Congenital, familial, and genetic
	5	Endocrine
	6	Ear and labyrinth
	7	Eye
	8	Gastrointestinal
	9	General
	10	Hepatobiliary
	11	Immune system
	12	Infection and infestation
	13	Injury and poisoning
	14	Metabolism and nutrition
	15	Musculoskeletal and connective tissue
	16	Neoplasms
	17	Nervous system
	18	Pregnancy, puerperium, perinatal
	19	Renal and urinary tract
	20	Reproductive system and breast
	21	Psychiatric
	22	Respiratory, thoracic, and mediastinal
	23	Skin and subcutaneous tissue
	24	Vascular
Functioning	25	Physical
	26	Social
	27	Role
	28	Emotional
	29	Cognitive
	30	Global quality of life
	31	Perceived health status
	32	Delivery of care
	33	Personal circumstances
Resource use	34	Economic
	35	Hospital
	36	Need for further intervention
	37	Societal/carer burden
Adverse events	38	Adverse events/effects

not identify any published studies that have summarized outcome reporting or developed a core outcome set, to achieve consistent reporting in studies concerning the surgical management of COM of the lower limb in adults.[10]

This paper is part of a wider scoping review, which aims to map the existing evidence on limb reconstruction and amputation for the management of COM of the lower limb.[11] This paper reports the data, addressing the specific objective of mapping the outcomes used within studies, including details of what outcomes were measured, how they were measured, and the timing of measurement, in order to aid future development of a core outcome set.

Method

A scoping review methodology was chosen to summarize evidence within this field.[12] The methodology, including full inclusion and exclusion criteria, follows a published study protocol through the Open Science Framework.[11] This study is reported according to the PRISMA-Scoping Review extension guidelines (Supplementary material table i).[13]

Inclusion and exclusion. Specifically, studies of adults (age ≥ 16 years) surgically managed for spontaneous or trauma-related lower limb COM were eligible. Studies

Table III. Most commonly reported outcomes.

Outcome reported	Outcome category	Reported, n	Definitions provided, n
OM recurrence	12. Infection and poisoning	62	18
OM eradication	12. Infection and poisoning	34	13
Bone union	15. Musculoskeletal and connective tissue	34	12
Functional status of limb	25. Physical	25	7
Wound healing complications	23. Skin and subcutaneous tissue	22	1
Complications (collective)	38. Adverse events	21	13
Time to bone union	15. Musculoskeletal and connective tissue	18	9
Limb weightbearing	25. Physical	17	8
External fixation index	15. Musculoskeletal and connective tissue	15	7
Pain	17. Nervous system	14	0

focusing on the surgical management of diabetic foot disease and peripheral vascular disease were excluded due to the distinct pathophysiology of these processes.[14] Systematic/literature reviews and meta-analyses were excluded to avoid duplication of reporting. Articles were limited to those written in English.

Search strategy. A comprehensive search strategy was formulated with assistance from a university librarian (Supplementary material ii), which was utilized for our overall scoping review on the management of lower limb chronic osteomyelitis.[11] The search strategy was applied to the following databases: MEDLINE, PubMed, EMBASE, CINAHL, PsycINFO, Cochrane Library, Open Grey, and Web of Science Conference Proceedings Index. Google Scholar was searched and limited to the first ten consecutive web-pages generated by the search, approximating to around 100 records. Additionally, ongoing and completed trials were sought using ISRCTN and clinical trials.gov.[15] At the time of searches, the World Health Organization International Clinical Trials Registry Platform was not accessible due to COVID-19. Included studies published between first January 2011 to first October 2020 were eligible, providing information on studies over a ten-year period, reflecting current use of outcome reporting in the literature.[16]

Study selection and data extraction. Search results were downloaded into Endnote (version 20; Clarivate, USA), and duplicates removed. Eligibility criteria were first applied to titles and abstracts of identified records, followed by full-text screening of potentially eligible records. Independent screening was undertaken by two reviewers (JC-B, SJ) using the Rayyan platform,[17,18] following pilot screening of the first 50 records. Discrepancies in decisions were discussed and resolved through consensus and, if necessary, through discussion with a third independent researcher (CM, HS).

An outcome was defined as a measure used to assess the effect of an intervention. All outcomes were extracted following an agreed data extraction form (Supplementary material iii), and were recorded verbatim in accordance with COMET guidance for core outcome sets.[19] Data extraction for each included study was undertaken by one reviewer (GO, KJ, ME, ZA, SJ, JC-B) and checked by a second (SJ, KJ, or GO). Disagreements on extraction were discussed and a final version agreed by consensus.

Analysis. Outcome data was categorized by outcome name and allocated to an outcome domain, following the revised Williamson and Clarke taxonomy.[20] Information was taken from the methods or results sections of the included paper. The data are reported for all included studies combined (regardless of study design) and data from randomized controlled trials (RCTs) is also reported separately.

Results

There were 3,303 records following deduplication (Figure 1). In all, 99 studies were included for data extraction (Supplementary table iv, Supplementary material v). The yearly number of included studies increased with a more recent date of publication, with studies mostly from Europe and Asia (82/99; 83%) (Table I).

The majority of studies were case series (77/99; 78%). There were 15 cohort studies, four completed RCTs, two ongoing trials identified on trial registries, and one retrospective case-control study. Most studies assessed one method of reconstruction (68/99; 69%). Two reconstructive methods were compared in 29 studies (29%), and amputation was compared to reconstruction in one study. Lower-limb amputation was the sole surgical treatment provided in one paper. The included studies represent 5,809 participants. The two ongoing trials have a combined planned sample size totalling 44 participants; 36/99 studies (36%) included mixed populations. Overall, 4,876 participants were identified as meeting this study's population eligibility criteria, though this is an approximate as in larger studies it was sometimes not possible to identify the exact number of eligible participants. Studies with mixed populations included groups with individuals aged under 16 years, upper limb reconstruction, and reconstruction for conditions other than COM.

Table IV. Outcomes reported within the physiological/clinical domain group.

Outcome category	Outcome reported	Reported, n	Definitions provided, n
2. Blood and lymphatic system	Thrombosis	1	0
3. Cardiac 4. Congenital, familial, and genetic 5. Endocrine 6. Ear and labyrinth 7. Eye 8. Gastrointestinal 9. General 10. Hepatobiliary	No outcomes reported		
Immune system	Allergic reaction	1	0
12. Infection and poisoning	OM recurrence	62	18
	OM eradication	34	13
	Pin site infection	11	0
	Other	12	3
13. Injury and poisoning 14. Metabolism and nutrition	No outcomes reported		
15. Musculoskeletal and connective tissue	Bone union	34	12
	Time to bone union	18	9
	Bone score	13	9
	External fixation index	15	7
	Structural deformity	11	5
	Fracture	10	1
	Leg length discrepancy	9	2
	Non/mal union	8	3
	Other	22	1
16. Neoplasms	No outcomes reported		
17. Nervous system	Pain	14	0
	Altered sensation	3	1
18. Pregnancy, puerperium, perinatal 19. Renal and urinary tract 20. Reproductive system and breast	No outcomes reported		
21. Psychiatric	Anxiety/depression	6	1
22. Respiratory, thoracic, and mediastinal	Pulmonary embolism	2	0
23. Skin and subcutaneous tissue	Flap survival	12	1
	Flap necrosis	7	0
	Other flap complications	6	2
	Wound healing complications	22	1
	Other	15	1
24. Vascular	Compartment syndrome	1	0
	Other	1	0

OM, osteomyelitis.

The included studies reported a total of 511 outcomes (58 distinct) outcomes. Clear, in-text definitions were provided for 143 outcomes (28%), and 231 outcomes (45%) had details reported of how and when they were measured. One included study, a conference abstract, did not report any outcomes. In the remaining studies, the number of outcomes reported ranged from 1 to 14. 68 reported outcomes (13%) were identified to be patient-reported.

Outcomes were grouped and categorized as per the revised Williamson and Clarke taxonomy (Table II).[20] More clinically applicable outcome category headings have been used within the main text. The outcomes reported in the studies mapped onto 18 of 38 categories, predominantly, physiological/clinical categories. Table III outlies the most commonly reported outcomes throughout the included studies.

Mortality/survival (category 1). 'Mortality' was reported in four studies and 'survival' in two studies. No clear time-points were reported at which these outcomes were measured, although overall follow-up periods were provided within five of the six studies that reported these outcomes.

Physiological/clinical (categories 2 to 24). This domain was the most frequently recorded (340/511; 67%) of all outcomes reported. Only four studies did not include an outcome from this domain. Outcomes within the physiological/clinical domain are summarized in Table IV.

Table V. Working definitions reported for the outcome 'eradication of infection'.

Study	In-text reported definition
Dai (2020)[21]	'As per the criteria for evaluation of the recovery of osteomyelitis of Mckee et al, within 2 years postoperatively.'
Drampalos (2020)[22]	'Recurrence of infection of the soft-tissues or bone, recurrent sinus formation, further surgery for infection or patient requiring antibiotic treatment for persisting symptoms was defined as a failure.'
Jiang (2015)[23]	'No relapse within one year.'
Lam (2019)[24]	'Control infection without the need for amputation or chronic antibiotic suppression.'
Li (2019)[25]	'Excellent if the following conditions were observed: no local swelling, heat, and pain; closed sinus tract; no local tenderness; no new focus found in the affected region through radiograph radiography; affected bone segment recovery; and wide marrow cavity. The patients were rated good if the following conditions were observed: occasional pain in local regions; no swelling, heat, and pain; no pathological features detected through radiograph radiography; and affected bone segment recovery. The patients were rated poor if the following conditions were observed: local swelling, heat, and pain; open sinus tract with seepage; and focus revealed by radiograph radiography.'
Lin (2017)[26]	'No inflamed hot pain and purulent secretion around the local focuses; the indicators of blood tests, are normal; and radiograph examination shows that infected non-union are healed.'
Lindfors (2017)[27]	'Excellent – no complications and no sign of infection within 15 days. Good – a small complication i.e. muscle flap or wound healing achieved within 15 days with some drainage. Fair – a wound showing prolonged sterile drainage or serum leakage with time to healing and less than six weeks. Poor – a temporary stable situation with sign of infection or a complication involving a reinfection.'
Marais (2015)[28]	'Remission was defined as the absence of clinical evidence of infection.'
Niikura (2016)[29]	'Patients were considered to be free of infection when they had no fever, no wound drainage, no signs of local inflammation, normal CRP (CRP) levels, ESR (ESR) < 20 mm/h, and normal white blood cell count for at least 4 weeks. Pre- and post-treatment magnetic resonance imaging and scintigraphy findings were compared, and a decrease in the extent of abnormal signals and uptake was considered to confirm the absence of infection.'
Opara (2020)[30]	'Defined by cessation of drainage and normalisation of CRP.'
Rod-Fleury (2011)[31]	'Remission was defined as complete clinical resolution of the former infection after a follow-up of two years. Mechanical sequels were allowed in the definition "remission".'
Wu (2017)[32]	'Resolution of the clinical signs of infection and normalization of ESR and CRP.'
Zhou (2020)[33]	'Absence of any signs of osteomyelitis and a completely healed wound.'

Recurrence and eradication of infection (category 12: infection and poisoning). The most commonly reported physiological/clinical outcome was 'recurrence of osteomyelitis' (162/511; 12%), with definitions provided for approximately one-third. The recurrence of COM was typically identified through utilization of a combination of radiological, biochemical and clinical assessments in 20/62 studies (32%). Follow-up periods differed significantly, across the studies, the mean follow-up range was 12 months to 11 years.

The successful clearance rate of osteomyelitis, focusing on 'eradication of infection', was reported in 34 studies, with 13 studies publishing a working definition (Table V). The mean duration of follow-up ranged from 16 months and 5.9 years. In total, 71/99 studies have reported on either recurrence or clearance of osteomyelitis. In all, 14 studies reported on both "recurrence" and "eradication" of osteomyelitis.

Bone union, structural outcomes, 'bone results', and postoperative fracture rate (category 15: musculoskeletal and connective tissue disorders). In all, 62 studies reported 140 musculoskeletal outcomes. Most commonly reported was 'bone union' 34 times, and defined on 12 occasions. Seven definitions were uniform in requiring three or four cortices to show evidence of bridging. Radiological assessment was the basis of measuring union and details of this were reported 24/34 times (71%). No uniformity was noted in the time-points at which the incidence of 'bone union' was assessed (e.g. 12-month bone union rate); however, the mean duration of follow-up ranged between 5.5 months to 11 years. 'Leg-length discrepancy (LLD)' and 'limb deformity' were reported nine and 11 times, respectively. LLD was defined twice. One study reported LLD to be present if there was a > 1.5 cm difference, in comparison to a second study that defined it as > 3 cm. 'Limb deformity' was defined in five papers. Deformity was defined if there was sagittal malignment of >5° or >7°, or frontal malalignment of >15°.

Thirteen studies reported on a composite outcome, 'bone score/results'. Eight defined this according to a scoring system including bone union, limb deformity, regenerative quality, limb shortening and infection. This was measured clinically and radiologically and graded as excellent, good, fair, and poor.[34,35] Four studies defined 'bone score/results' as per the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria, using the same categorizations.[34,35] One study reported on a modified radiological bone score,[36] based on secondary fracture dislocation, radiological signs of bone infection, implant-related complication, bone consolidation and the surgeon's intraoperative evaluation of stability following implant removal. The mean follow-up for these studies ranged from 13.5 months to 63 months.

Ten studies reported on fracture formation postoperatively. Four of these studies reported the tools used in identifying postoperative fracture formation. The

Table VI. Details of reported composite scoring systems assessing limb function.

Composite scoring system reported	Papers reported, author (yr)	Brief summary of components (as reported)	Summary reported?, n (%)	Outcome defined, n (%)	Mean follow-up (range)
Association for the Study and Application of Methods of Ilizarov[34,35]	Yushan et al (2020)[37] Tong et al (2017)[38] Sigmund et al (2020)[39] Shahid et al (2013)[40] El-Sayed et al (2014)[41]	Joint stiffness, presence of reflex sympathetic dystrophy, limping, physical activity, requiring amputation.	100%	4/5 (80)	15 to 38 months
Paley et al[34,35]	Sen et al (2020)[42] Eralp et al (2012)[43] Eralp et al (2016)[44] Ju et al (2018)[45] Wang et al (2017)[46] Tetsworth et al (2017)[47] Qin et al (2018)[48] Zhang et al (2016)[49]	Observable limp, joint stiffness, dystrophy, pain and inactivity.	4/8 (50)	0 (0)	14 to 63 months
American Orthopaedic Foot and Ankle Score[50]	Shahid et al (2013)[40] Kirienko et al (2013)[51] Zhiju et al (2018)[52]	Function, pain and alignment.	1/3 (33)	2/3 (66)	15 months to 6 years
Lower Limb Functional Scale questionnaire[53]	Wu et al (2017)[32] Yang et al (2013)[54]	20 questions rating ability to perform tasks such as housework, shopping and aspects of mobilizing.	100%	0 (0)	12 to 30 months
Enneking scoring system[55]	Li et al (2019)[25] Liu et al (2015)[56]	Limb pain, activity function, self-perception, brace application, walking ability and gait change.	1/2 (50)	0 (0)	1.9 years
Modified Merchant Dietz score[57]	Schröter et al (2016)[58]	Ability to perform tasks e.g. housework. Freedom of pain at rest and mobilizing. Abnormalities to gait such as limping. Range of motion of knee.	100%	1/1 (100)	2 to 8 years
Kofoed Ankle score[59]	Dai et al (2020)[21]	Not reported	0%	0 (0)	2 years
Hospital for Special Surgery Knee Scale[60]	Zhiju et al (2018)[52]	Not reported	0%	1/1 (100)	Not reported
Shahcheraghi and Bayatpoor[61]	Deng et al (2014)[62]	Functional status, range of motion of the knee and ankle, presence of infection, shortening and pain.	100%	0 (0)	22.6 months

range of mean follow-up in these studies was from 5.5 months to 65 months.

Pain (category 17: nervous system). 'Pain' was the most frequently reported patient-reported outcome measure (PROM; 13 studies), however, was never formally defined, and largely non-specific regarding the location and circumstances during which pain was assessed. For example, questions included 'pain that reduced activity or impaired sleep' or 'pain of the leg after activity'. Only one study specified pain at the donor site of bone grafting. A visual analogue scale was the most commonly used measure (four papers) – two papers recorded pre- and postoperative pain (timeframe not reported); one evaluated pain at five time-points (day before surgery, then one, four, eight, and 12 weeks postoperatively); and the last did not specify reporting intervals, but described a mean follow-up of 62 weeks. Two further measurement tools were noted: one paper used a numeric rating scale to assess residual pain on mobilizing a minimum of two years postoperatively, and another used a non-validated physician-led patient survey asking about the need for narcotics, at least one year following frame removal.

Depression and anxiety (category 21: psychiatric). Five different studies explored changes to mental health following surgery for COM. 'Anxiety' was assessed three times using a self-rated anxiety scale, with no further details provided. One study compared pre- and postoperative anxiety and depression scores (mean follow-up 18.9 months). 'Depression' was reported in another study, which defined patients as those who required psychological support and antidepressant medication. In another study, the revised symptom checklist 90-item questionnaire (SCL-90-R) was used to determine general psychological changes in patients at four time-points (perioperatively, two months after the docking site was connected, when the external fixation device was removed, and two months after the removal of the device).

Flap and wound complications (category 23: skin and subcutaneous tissues). 'Flap/graft survival' was reported within 12 studies. One study that reported specifically 'partial flap loss' defined this as < 20% of the flap. 'Flap/graft necrosis' was reported in seven studies with no definitions provided. Mean follow-up ranged from 16 months to 11 years. A total of 22 outcomes that related to complications to wound healing were reported by 14 studies. This included wound infection, haematoma and seroma formation, wound breakdown, and delays to wound healing. One study defined the outcome, specifically wound infection, based on the colour and odour of the wound and absence of pus secretion.

Functioning (categories 25 to 33). Outcomes were reported across four of the nine functioning categories. No studies reported on the emotional or cognitive impact of surgery.

Limb function (category 25: physical). Ambulation was reported 17 times across 15 studies including ambulation with or without mobility aides (7/17; 41%), full weightbearing (4/17; 24%), painful or pain-free mobilizing (3/17; 18%), and non-specific ability to walk or to weightbear (3/17; 18%). Definitions were provided for 47% (8/17) of the outcomes, but did not specify conditions e.g. distance assessed. Non-validated patient questionnaires were

Table VII. Primary and secondary outcomes reported within randomized control trial studies (published and unpublished).

Author (yr)	Primary outcome	Secondary outcomes				
Finelli et al (2019)[64]	Relapse of COM What? When? How?	Pain What? When? How?	Comparative costing What? When? How?			
Huang et al (2018)[65]		Pain What? When? How?	OM recurrence What? When? How?	Time to drain removal What? When? How?	Total effectiveness rate What? When? How?	Improvement of inflammatory markers What? When? How?
Zhiju et al (2018)[52]		Knee and ankle joint function What? When? How?	Wound recovery time What? When? How?	Wound infection What? When? How?	Treatment effectiveness What? When? How?	
Hernigou et al (2018)[66]		Bone union What? When? How?	Recurrence of infection What? When? How?	Mean graft resorption What? When? How?	Number of surgical procedures What? When? How?	Normaliation of inflammatory markers What? When? How?
Borens et al (in press)[67]	i) Device absorption What? When? How? ii)Bone ingrowth What? When? How?	Bone healing What? When? How?	Infection recurrence What? When? How?			
Microbion (in press)[68]	Adverse events What? When? How?	Treatment failures What? When? How?	Treatment failures in antibiotic-resistant infections What? When? How?			

'What?' - has a definition been reported?
'When?' - have details of outcome measurement timings been reported?
'How?' - have details of how the outcome has been measured been reported?
An underlined phrase reflects that this outcome detail has been reported within the study.

utilised for three outcomes ('ambulation with supportive device', 'ability to walk', and, 'ability to weightbear').

'Limping' on mobilizing was reported in two studies (no definitions provided). One study measured this with a non-validated patient questionnaire (mean follow-up was 22.6 months, and 3.9 years).

'Joint movement' was reported by ten studies. This was defined only once, and was based on the maximum angulation of the joint achieved on movement. The movement of the knee joint was reported in seven studies, ankle in three, and hip in two. Few details were provided on how 'joint movement' was assessed, but two studies reported details to suggest a clinical assessment was performed. The mean duration of follow-up ranged from 17.8 months to 96 months.

In all, 24 studies reported on 25 outcomes concerning the functional status of the limb; 17/25 (76%) of these outcomes were defined, and measurement was based on various scoring systems to assess functional status (Table VI).

Return to daily activities (category 26: social). 'Return to work/sport' was reported by six studies two of which provided a definition. One study reported the use of a non-referenced standardized questionnaire, which 'determined implant removal, return to work and daily (sports) activity, ability of weightbearing, and reoccurrence of osteomyelitis with required additional surgery' with a mean follow-up of 23 months.

Seven studies reported on 'activities of daily living (ADL)'. Three different definitions were provided. One study focused on the lack of symptoms and signs of infection that interfered with the ability to perform ADLs, while another focused on the interference of pain limiting ADLs. Two studies reported the use of a 'daily living scale'; however, no citation or details of the scale were provided. One study used the self-reported lower limb functional scale.[53]

Quality of life (category 30). One study reported on quality of life using the 36-Item Short Form survey (SF-36) before and after surgery (mean follow-up 18.9 months).

Care provision (category 32: delivery of care). 'Treatment success' was reported seven times and has been included within this outcome group as definitions were often multifocal. For example, one study defined success as functional bone reconstruction with no infection recurrence. Another defined success as radiologically confirmed bone union with soft-tissue cover. A further study simply defined it as 'complete healing' in comparison to a different paper that based the definition on pain relief, lack of symptoms and signs, improved radiological findings, and improved inflammatory markers. All outcomes were defined. The mean duration of follow-up varied significantly between 19 to 64 months. Four studies reported on the use of radiology to determine treatment success (including one report of MRI).

Five studies measured 'patient satisfaction', the focus of which varied across studies. One paper measured satisfaction with pursuing limb salvage over amputation (very satisfied, satisfied, unsatisfied). Another paper recorded satisfaction with treatment and whether they would undergo limb salvage again (yes/no) using a non-validated, unreferenced, patient questionnaire (mean follow-up 3.9 years). A further paper also measured patient satisfaction with a non-validated self-reported

questionnaire, prior to discharge, containing questions on satisfaction with the functional and aesthetic outcome of the reconstruction, flap and donor site. Patient outcome satisfaction was assessed with a seven-point Likert-rating scale (dissatisfied to very satisfied) in a separate study.

Resource utilization (categories 34 to 37). Outcomes were reported across three of the four 'resource utilization' outcome domains. No outcomes were identified that reported on societal care (category 37).

Costs of treatment (category 34: economic). One study compared the total costs of delivering each treatment arm of the study. A summary of costs was provided with no measurement details provided.

Hospital stay (category 35: hospital). 'Hospital length of stay' was reported nine times and was the most commonly reported outcome within this category. 'Hospital readmission' and 'ITU admission' were reported once but no timeframe was provided.

Need for further surgery (category 36: need for further intervention). 'Number of surgical procedures' was reported by six studies. No definitions were provided, and no explicit timeframe was reported, although the range of mean follow-up was between 15 months to 7.5 years. 'Need for reoperation' was reported by a further 12 studies. One paper defined this as additional surgeries following frame removal, however no other definitions/criteria were provided. The mean follow-up of studies varied, ranging from just under a year to over ten years. 'Amputation rate' was reported on eight occasions.

Category 38: adverse events. One study reported on 'systemic reactions'. No definition or measurement tools were described. 'Complications' was reported 21 times, by 19 different studies, relating to postoperative surgical complications. The Paley classification system[63] for complications was used in four papers.

Randomized controlled trials. Four published RCTs and two ongoing RCTs identified from trial registries were included. One study was due to be completed in 2017; however, this status had not been updated on the registry at the time of the searches. The other study was due to be completed in 2018, and results were posted to the registry in September 2021.

One of the four completed RCTs had an explicitly reported primary outcome, which was the two-year remission rate of COM. This was clearly defined and methods of measurement detailed. There was no clearly reported primary outcome within the remaining completed RCTs. In total, 17 outcomes were reported across the four published RCTs. The outcomes within these trials reflect the outcomes reported by other study designs (Table VII).

Only 5/17 of the reported outcomes (29%) had all aspects fully reported (definition, time of measurement, method of measurement). Two studies did not provide a definition for 'pain' and did not specify the timeframe of 'postoperative' measurement of pain. One study did not report on how costings to compare treatment arms were obtained and another did not define 'recurrence of infection'. Two studies did not encompass what determined an improvement of inflammatory markers.

Seven outcomes have been documented within the two RCT protocols. Details on the timing of outcome measurement were provided for all outcomes. However, the outcomes documented by one RCT registration record had no details provided on the methods used to measure outcome data.

Discussion

The outcomes reported in 99 studies for a ten-year period from 2011 to 2020 were mapped against the revised Williamson and Clarke taxonomy.[20] The review has highlighted significant disparities in the outcomes utilized and the methods of defining and measuring outcomes across studies of surgical reconstruction and amputation for COM. Almost all studies (96%) reported an outcome from the physiological/clinical domain; however, no single outcome was common across the included studies. Furthermore, outcomes were rarely defined (143/511; 28%), and there was a lack of definition consistency within individual outcomes. For example, for the outcome of infection eradication, Niikura et al[29] required radiological evidence, whereas Lam et al[69] based this on the need for amputation or chronic antibiotic usage. A more recent study by McNally et al,[70] published after our search end date, defined failure of eradication as positive cultures from biopsies, recurrent sinus formation, need for further surgery or antibiotics for infection. Standardization of outcome definitions and methods of collection would be of benefit to overcome this problem. The timing of outcome assessment also varied substantially. Our findings echo those found in research with other surgical populations. A recent systematic review of outcome reporting following incisional hernia surgery identified no single outcome that was reported in all included studies.[71] This was a similar finding following surgery for colorectal cancer[72] and lower limb amputation.[73] Furthermore, there was great heterogeneity in the list of outcomes used within studies.

This study has identified the most commonly reported outcomes within the literature which can be used to guide a Delphi consensus involving clinicians and patients in the formation of a core outcome set. A core outcome set will contribute to improving consistency in the use of outcomes allowing more direct comparisons across studies and ensuring that the most important outcomes to patients are considered.

Surgical interventions for lower limb COM can leave a patient with significant rehabilitation needs and, in some cases, the requirement for lower limb amputation. Despite this potential impact on the patient,

PROMs only represented a minority (68/511; 13%) of outcomes reported. Quality of life, functional status, mental health, and patient satisfaction are outcomes that are likely to be important to patients and their limited use may reflect surgeon and researcher priorities in studies. Additionally, reporting of definitions and methods of measurement were particularly poor for PROMs and it was often unclear whether a standardized validated tool had been used. Although the specific focus of this review was not quality of reporting we observed that in three of the four reports of RCTs the primary outcome was not explicit. Additionally, while extracting the data we observed that there were inconsistencies in methods and results sections in some studies with outcomes appearing in the results which had not been stated in the methods and vice versa.

This study has provided a comprehensive overview of outcome reporting. The application of our search strategy to multiple databases has resulted in a broad search of the available evidence and has allowed the mapping of the body of literature available. Duplicate screening and checked extraction ensured thorough and accurate data extraction. Furthermore, outcomes were mapped against a published outcome framework. Although the search strategy was comprehensive, some relevant studies may have been missed if they did not use the term osteomyelitis in the title or abstract. However, it is unlikely that any additional studies would add to the variation and change the conclusions of this review. In addition, due to a large number of records identified using the original plan of an unrestricted search start date and any primary study design,[11] the parameters of the search strategy had to be restricted to those published in the past ten years, although the majority of these papers were published in the most recent five years. Studies with fewer than 11 participants and studies in which 50% or more participants did not meet our inclusion criteria were also excluded. Studies written in languages other than English were also excluded. Inclusion of these studies may have resulted in identification of other outcomes which have not been represented in this study. Finally, due to papers reporting on mixed populations, this study has not distinguished between COM and fracture-related infection, which has a recently published consensus definition.[74] This study is limited to the surgical management of chronic osteomyelitis and studies focusing only on medical management have been excluded.

In conclusion, this study has highlighted significant inconsistencies in the reporting, defining and measuring of outcomes across studies investigating surgical management for COM of the lower leg in adults. There was very limited use of PROMs. Future study designs should explicitly report the definition, measurement and timing of outcomes. The development of a standardized core outcome set, through Delphi consensus, would be of significant benefit in order to allow comparison across studies investigating surgical treatments for lower limb COM. This should be informed by patient perspectives in addition to researchers and healthcare professionals.

Take home message

- This study has identified inconsistencies in the reporting of outcomes in studies focusing on the surgical management of lower limb chronic osteomyelitis.
- Future studies should ensure details of outcomes, such as the definitions and timing of the outcomes, are provided.
- The development of a standardized core outcome set would allow evidence synthesis and comparison across multiple studies.

Supplementary material

PRISMA ScR checklist; search strategy (PubMed/MEDLINE), data extraction sheet, table showing list of included 99 studies, and reference list of included studies.

References

1. **Kremers HM**, **Nwojo ME**, **Ransom JE**, **Wood-Wentz CM**, **Melton LJ**, **Huddleston PM**. Trends in the epidemiology of osteomyelitis: a population-based study, 1969 to 2009. *J Bone Joint Surg Am*. 2015;97-A(10):837–845.
2. **Panteli M**, **Giannoudis PV**. Chronic osteomyelitis: what the surgeon needs to know. *EFORT Open Rev*. 2016;1(5):128–135.
3. **Barakat A**, **Schilling WHK**, **Sharma S**, **Guryel E**, **Freeman R**. Chronic osteomyelitis: a review on current concepts and trends in treatment. *Orthopaedics and Trauma*. 2019;33(3):181–187.
4. **Wettstein R**, **Schürch R**, **Banic A**, **Erni D**, **Harder Y**. Review of 197 consecutive free flap reconstructions in the lower extremity. *J Plast Reconstr Aesthet Surg*. 2008;61(7):772–776.
5. **Pincher B**, **Fenton C**, **Jeyapalan R**, **Barlow G**, **Sharma HK**. A systematic review of the single-stage treatment of chronic osteomyelitis. *J Orthop Surg Res*. 2019;14(1):393.
6. **Egeler SA**, **de Jong T**, **Luijsterburg AJM**, **Mureau MAM**. Long-term patient-reported outcomes following free flap lower extremity reconstruction for traumatic injuries. *Plast Reconstr Surg*. 2018;141(3):773–783.
7. **No authors listed**. National Institute for Health Research. https://www.crd.york.ac.uk/prospero/ (date last accessed 6 January 2023).
8. **No authors listed**. Open Science Framework. https://osf.io/ (date last accessed 6 January 2023).
9. **No authors listeed**. COMET Initiative. https://www.comet-initiative.org/Studies (date last accessed 6 January 2023).
10. **Tunis SR**, **Clarke M**, **Gorst SL**, **et al**. Improving the relevance and consistency of outcomes in comparative effectiveness research. *J Comp Eff Res*. 2016;5(2):193–205.
11. **Camilleri-Brennan J**, **James S**, **Pincher B**, **et al**. Protocol: A scoping review on the surgical management of chronic osteomyelitis of the lower limb. Open Science Framework. https://osf.io/epgdu/ (date last accessed 6 January 2023).
12. **Munn Z**, **Peters MDJ**, **Stern C**, **Tufanaru C**, **McArthur A**, **Aromataris E**. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.
13. **Tricco AC**, **Lillie E**, **Zarin W**, **et al**. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467–473.
14. **Clemens MW**, **Attinger CE**. Functional reconstruction of the diabetic foot. *Semin Plast Surg*. 2010;24(1):43–56.
15. **No authors listed**. US National Library of Medicine ClinicalTrials.gov. https://clinicaltrials.gov (date last accessed 6 January 2023).
16. **Spiegelberg B**, **Parratt T**, **Dheerendra SK**, **Khan WS**, **Jennings R**, **Marsh DR**. Ilizarov principles of deformity correction. *Ann R Coll Surg Engl*. 2010;92(2):101–105.
17. **Ouzzani M**, **Hammady H**, **Fedorowicz Z**, **Elmagarmid A**. Rayyan-a web and mobile app for systematic reviews. *Syst Rev*. 2016;5(1):210.

18. **No authors listed**. Rayyan - a web and mobile app for systematic reviews. https://rayyan.qcri.org/welcome (date last accessed 6 January 2023).
19. **Williamson PR**, **Altman DG**, **Bagley H**, **et al**. The COMET Handbook: version 1.0. *Trials*. 2017;18(Suppl 3):280.
20. **Dodd S**, **Clarke M**, **Becker L**, **Mavergames C**, **Fish R**, **Williamson PR**. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *J Clin Epidemiol*. 2018;96:84–92.
21. **Dai C**, **Huang K**, **Ma G**. Efficacy of one-stage operation on the traumatic osteomyelitis in middle and distal tibia: A retrospective analysis of 68 cases. *Acta Medica Mediterranea*. 2020;36(3):1881–1886.
22. **Drampalos E**, **Mohammad HR**, **Pillai A**. Augmented debridement for implant related chronic osteomyelitis with an absorbable, gentamycin loaded calcium sulfate/hydroxyapatite biocomposite. *Journal of Orthopaedics*. 2020;17:173–179.
23. **Jiang N**, **Ma YF**, **Jiang Y**, **et al**. Clinical characteristics and treatment of extremity chronic osteomyelitis in southern china: A retrospective analysis of 394 consecutive patient. *Medicine (Baltimore)*. 2015;94(42):e1874.
24. **Lam A**, **Richardson SS**, **Buksbaum J**, **et al**. Chronic osteomyelitis of the tibia and ankle treated with limb salvage reconstruction. *J Bone Jt Infect*. 2019;4(6):306–313.
25. **Li J**, **Zhang H**, **Qi B**, **et al**. Outcomes of vacuum sealing drainage treatment combined with skin flap transplantation and antibiotic bone cement on chronic tibia osteomyelitis: A case series study. *Med Sci Monit*. 2019;25:5343–5349.
26. **Lin B**, **Huang K**, **Yu H**. Surgical treatment for 76 patients with posttraumatic osteomyelitis of the tibia. *Biomedical Research (India)*. 2017;28(8):3585–3588.
27. **Lindfors N**, **Geurts J**, **Drago L**, **et al**. Antibacterial bioactive glass S53P4 for chronic bone infections - A multinational study. *Adv Exp Med Biol*. 2017;971:81–92.
28. **Marais LC**, **Ferreira N**, **Aldous C**, **et al**. A modified staging system for chronic osteomyelitis. *J Orthop*. 2015;12:184–192.
29. **Niikura T**, **Lee SY**, **Iwakura T**, **Sakai Y**, **Kuroda R**, **Kurosaka M**. Antibiotic-impregnated calcium phosphate cement as part of a comprehensive treatment for patients with established orthopaedic infection. *J Orthop Sci*. 2016;21(4):539–545.
30. **Opara KO**, **Nwagbara IC**. The use of sural island musculo fasciocutaneous flap, in the management of chronic osteomyelitis of the tibia. *Niger J Clin Pract*. 2018;21(6):698–702.
31. **Rod-Fleury T**, **Dunkel N**, **Assal M**, **et al**. Duration of post-surgical antibiotic therapy for adult chronic osteomyelitis: A single-centre experience. *Int Orthop*. 2011;35(11):1725–1731.
32. **Wu H**, **Shen J**, **Yu X**, **et al**. Two stage management of Cierny-Mader type IV chronic osteomyelitis of the long bones. *Injury*. 2017;48(2):511–518.
33. **Zhou CH**, **Ren Y**, **Ali A**, **et al**. Single-stage treatment of chronic localized tibial osteomyelitis with local debridement and antibiotic-loaded calcium sulfate implantation: a retrospective study of 42 patients. *J Orthop Surg Res*. 2020;15(1).
34. **Paley D**, **Catagni MA**, **Argnani F**, **Villa A**, **Bijnedetti GB**, **Cattaneo R**. Ilizarov treatment of tibial nonunions with bone loss. *Clin Orthop Relat Res*. 1989;241(amp;NA):146–165.
35. **Paley D**, **Maar DC**. Ilizarov bone transport treatment for tibial defects. *J Orthop Trauma*. 2000;14(2):76–85.
36. **Bahrs C**, **Oehm J**, **Rolauffs B**, **et al**. T-plate osteosynthesis - an obsolete osteosynthesis procedure for proximal humeral fractures? middle-term clinical and radiological results. *Z Orthop Unfall*. 2007;145(2):186–194.
37. **Yushan M**, **Ren P**, **Abula A**, **et al**. Bifocal or trifocal (double-level) bone transport using unilateral rail system in the treatment of large tibial defects caused by infection: A retrospective study. *Orthop Surg*. 2020;12(1):184–193.
38. **Tong K**, **Zhong Z**, **Peng Y**, **et al**. Masquelet technique versus Ilizarov bone transport for reconstruction of lower extremity bone defects following posttraumatic osteomyelitis. *Injury*. 2017;48(7):1616–1622.
39. **Sigmund IK**, **Ferguson J**, **Govaert GAM**, **et al**. Comparison of ilizarov bifocal, acute shortening and relengthening with bone transport in the treatment of infected, segmental defects of the tibia. *Journal of Clinical Medicine*. 2020;9(2).
40. **Shahid M**, **Hussain A**, **Bridgeman P**, **et al**. Clinical outcomes of the ilizarov method after an infected tibial non union. *Arch Trauma Res*. 2013;2(2):71–75.
41. **El-Sayed MMH**, **Gaballah S**, **Hosny G**, **et al**. Management of infected nonunion of the femur in adults using the ilizarov technique. *Eur J Orthop Surg Traumatol*. 2014;5(3):285–291.
42. **Sen C**, **Akgul T**, **Tetsworth KD**, **et al**. Combined technique for the treatment of infected nonunions of the distal femur with bone loss: short supracondylar nail-augmented acute shortening/ lengthening. *J Orthop Trauma*. 2020;34(9):476–481.
43. **Eralp L**, **Kocaoglu M**, **Polat G**, **et al**. A comparison of external fixation alone or combined with intramedullary nailing in the treatment of segmental tibial defects. *Acta Orthopaedica Belgica*. 2012;78(5):652–659.
44. **Eralp L**, **Kocaoglu M**, **Celiktas M**, **et al**. Is acute compression and distraction superior to segmental bone transport techniques in chronic tibial osteomyelitis? comparison of distraction osteogenesis techniques. *Acta orthopaedica Belgica*. 2016;82(3):599–609.
45. **Ju J**, **Li L**, **Zhou R**, **et al**. Combined application of latissimus dorsi myocutaneous flap and iliac bone flap in the treatment of chronic osteomyelitis of the lower extremity. *J Orthop Surg Res*. 2018;13(1):117.
46. **Wang Y**, **Jiang H**, **Deng Z**, **et al**. Comparison of monolateral external fixation and internal fixation for skeletal stabilisation in the management of small tibial bone defects following successful treatment of chronic osteomyelitis. *Biomed Res Int*. 2017;2017:1–8.
47. **Tetsworth K**, **Paley D**, **Sen C**, **et al**. Bone transport versus acute shortening for the management of infected tibial non-unions with bone defects. *Injury*. 2017;48(10):2276–2284.
48. **Qin C**, **Xu L**, **Liao J**, **et al**. Management of osteomyelitis-induced massive tibial bone defect by monolateral external fixator combined with antibiotics-impregnated calcium sulphate: A retrospective study. *Biomed Res Int*. ;2018:1–8. n.d.
49. **Zhang S**, **Wang H**, **Zhao J**, **et al**. Treatment of post-traumatic chronic osteomyelitis of lower limbs by bone transport technique using mono-lateral external fixator: follow-up study of 18 cases. *J Orthop Sci*. 2016;21(4):493–499.
50. **D'souza JJ**. American orthopedic foot-and-ankle society score, where are we now?: A narrative review of quality of life measures in foot and ankle surgery. *Open Access Maced J Med Sci*. 2020;8(F):133–136.
51. **Kirienko A**, **Peccati A**, **Arnaldi E**, **et al**. Ankle arthrodesis and leg lengthening in the tibial distal defect. *J Orthopaed Traumatol*. 2013;14(Suppl 1):S47–S82.
52. **Zhiju W**, **Binfeng W**, **Hui L**, **et al**. Clinical effects of antibiotic-impregnated cement on the treatment of traumatic shinbone osteomyelitis. *Acta Medica Mediterranea*. 2018;34(4):1101–1104.
53. **Binkley JM**, **Stratford PW**, **Lott SA**, **Riddle DL**. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther*. 1999;79(4):371–383.
54. **Yang C**, **Geng S**, **Fu C**, **et al**. A minimally invasive modified reverse sural adipofascial flap for treating posttraumatic distal tibial and calcaneal osteomyelitis. *International Journal of Lower Extremity Wounds*. 2013;12(4):279–285.
55. **Enneking WF**, **Dunham W**, **Gebhardt MC**, **Malawar M**, **Pritchard DJ**. A system for the functional evaluation of reconstructive procedures after surgical treatment of tumors of the musculoskeletal system. *Clin Orthop Relat Res*. 1993;286:241.
56. **Liu Y**, **Song J**, **Xu LL**, **et al**. Vascularized fibular graft combined with vacuum assisted closure in the reconstruction of tibial defects. *Afr J Tradit Complement Altern Med*. 2015;12(6):27–32.
57. **Merchant TC**, **Dietz FR**. Long-term follow-up after fractures of the tibial and fibular shafts. *J Bone Joint Surg Am*. 1989;71-A(4):599–606.
58. **Schröter S**, **Ateschrang A**, **Flesch I**, **et al**. First mid-term results after cancellous allograft vitalized with autologous bone marrow for infected femoral non-union. *Wien Klin Wochenschr*. 2016;128(21):827–836.
59. **Naal FD**, **Impellizzeri FM**, **Rippstein PF**. Which are the most frequently used outcome instruments in studies on total ankle arthroplasty? *Clin Orthop Relat Res*. 2010;468(3):815–826.
60. **Bach CM**, **Nogler M**, **Steingruber IE**, **et al**. Scoring systems in total knee arthroplasty. *Clin Orthop Relat Res*. 2002;399:184–196.
61. **Shahcheraghi GH**, **Bayatpoor A**. Infected tibial nonunion. *Can J Surg*. 1994;37(3):209–213.
62. **Deng Z**, **Cai L**, **Jin W**, **et al**. One-stage reconstruction with open bone grafting and vacuum-assisted closure for infected tibial non-union. *Arch Med Sci*. 2014;10(4):764–772.
63. **Paley D**. Problems, obstacles, and complications of limb lengthening by the Ilizarov technique. *Clin Orthop Relat Res*. 1990;250(amp;NA):81.
64. **Finelli CA**, **dos Reis FB**, **Fernandes HA**, **et al**. Intramedullary reaming modality for management of postoperative long bone infection: a prospective randomized controlled trial in 44 patients. *Patient Saf Surg*. 2019;13(1).
65. **Huang K**, **Lin B**, **Guo Q**, **et al**. Research on the clinical efficacy of the combination of chinese traditional medicine and western medicine on the chronic traumatic tibial osteomyelitis. *Pak J Pharm Sci*. 2018;31(6):2841-5.
66. **Hernigou P**, **Dubory A**, **Homma Y**, **et al**. Single-stage treatment of infected tibial non-unions and osteomyelitis with bone marrow granulocytes precursors protecting bone graft. *Int Orthop*. 2018;42(10):2443–2450.
67. Bethesda (MD): National Library of Medicine (US). Identifier NCT02128256, CERAMENT; 1 May 2014, https://clinicaltrials.gov/ct2/show/NCT02128256

68. Bethesda (MD): National Library of Medicine (US). Identifier NCT02436876, Study to assess safety and clinical activity of local MBN-101 in treatment of infected bone sites.28 April 2015, ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/record/NCT02436876

69. **Lam A**, **Richardson SS**, **Buksbaum J**, **et al**. Chronic osteomyelitis of the tibia and ankle treated with limb salvage reconstruction. *J Bone Jt Infect*. 2019;4(6):306–313.

70. **McNally MA**, **Ferguson JY**, **Scarborough M**, **Ramsden A**, **Stubbs DA**, **Atkins BL**. Mid- to long-term results of single-stage surgery for patients with chronic osteomyelitis using a bioabsorbable gentamicin-loaded ceramic carrier. *Bone Joint J*. 2022;104-B(9):1095–1100.

71. **Harji D**, **Thomas C**, **Antoniou SA**, **et al**. A systematic review of outcome reporting in incisional hernia surgery. *BJS Open*. 2021;5(2):zrab006.

72. **Whistance RN**, **Forsythe RO**, **McNair AGK**, **et al**. A systematic review of outcome reporting in colorectal cancer surgery. *Colorectal Dis*. 2013;15(10):e548–60.

73. **Ambler GK**, **Brookes-Howell L**, **Jones JAR**, **et al**. Development of core outcome sets for people undergoing major lower limb amputation for complications of peripheral vascular disease. *Eur J Vasc Endovasc Surg*. 2020;60(5):730–738.

74. **Metsemakers WJ**, **Morgenstern M**, **McNally MA**, **et al**. Fracture-related infection: A consensus on definition from an international expert group. *Injury*. 2018;49(3):505–510.

Author information:
- J. Camilleri-Brennan, BMedSci(Hons), MRCS(Ed), General Surgery Trainee
- S. James, MSc, Research Fellow
- C. McDaid, PhD, Reader in Trials, York Trials Unit
- J. Adamson, PhD, Mary Kinross Trust & Royal College of Surgeons Chair in Surgical Trials and Health Sciences
- K. Jones, PhD, Research Fellow
- G. O'Carroll, PhD, Research Fellow
- Z. Akhter, MSc, Research Fellow
  York Trials Unit, University of York, York, UK.
- M. Eltayeb, BSc(Hons), MRCS(Eng), Orthopaedic Surgery Trainee, Hull Limb Reconstruction & Bone Infection Unit, Hull University Teaching Hospitals, Hull, UK.
- H. Sharma, FRCS (Orth), MS (Orth), M Ch (Orth), FRCS (Glas.), FRCS (Lon.), Professor in Trauma & Orthopaedics University of Hull, Consultant Orthopaedic Surgeon, York Trials Unit, University of York, York, UK; Hull Limb Reconstruction & Bone Infection Unit, Hull University Teaching Hospitals, Hull, UK.

Author contributions:
- J. Camilleri-Brennan: Conceptualization, Visualization, Investigation, Validation, Writing – original draft, Writing – review & editing.
- S. James: Conceptualization, Visualization, Investigation, Writing – original draft, Writing – review & editing.
- C. McDaid: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- J. Adamson: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- K. Jones: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- G. O'Carroll: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- Z. Akhter: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- M. Eltayeb: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.
- H. Sharma: Conceptualization, Visualization, Formal analysis, Writing – original draft, Writing – review & editing.

Funding statement:
- The author(s) received no financial or material support for the research, authorship, and/or publication of this article.

ICMJE COI statement:
- The authors confirm that they have no conflicts of interest to declare.

Acknowledgements:
- We would like to acknowledge Mr David Brown, University of York librarian, for his help with the literature search strategy.

Ethical review statement:
- Ethical approval was not required for this study.

Open access funding
- The authors report that they received open access funding for this manuscript from Hull University Teaching Hospitals NHS Trust, UK.