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Measuring outcomes following tibial fracture

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ABSTRACT

Aim: The aim of this study was to determine how outcome is measured following adult tibial fracture in the modern era of functional outcome measurement and patient reported outcomes.

Methods: A systematic review of publications since 2009 was performed, looking specifically at acute, adult tibial shaft fractures. Ovid Medline, Embase, PubMed and PsycINFO databases were searched for relevant titles which were then screened by two authors with adjudication where necessary by a third. Relevant articles were reviewed in full and data was extracted concerning the study participants, study design and any measures that were used to quantify the results following fracture. The results were collated and patient reported outcome measures were assessed using the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) standards.

Results: A total of 943 titles and articles were reviewed, with 117 included for full analysis. A wide range of clinical and radiological "outcomes" were described, along with named clinician- and patient-reported outcome measures. There was considerable heterogeneity and lack of detail in the description of the simplest outcomes, such as union, infection or reoperation. Reported clinician and patient reported outcome measures are variably used. None of the identified patient reported outcome measures have been validated for use following tibial fracture.

Conclusion: We recommend definition of a core outcome set for use following tibial fracture. This will standardise outcome reporting following these injuries. Furthermore, there is need for a validated patient reported outcome measure to better assess patient important outcomes in this patient group.

Introduction

Tibial fractures – in particular open injuries – are an archetypal potentially complex lower limb injury [1,2]. Importantly they demonstrate the full range of "outcomes": From pain free union with a full range of movement; to unsuccessful salvage and subsequent amputation [3,4]. This coupled with the variety of surgical and rehabilitation strategies in regular use, presents an opportunity to improve research by accurately and consistently measuring outcome.

As modern techniques have rendered a greater proportion of severely injured lower limbs salvageable [5–7], so the measurement of surgical success has shifted from limb preservation towards a more patient focused approach.

Surgical markers of outcome – successful bony union with normal alignment, uneventful infection free soft tissue healing and the rate of revision surgery – are commonly reported [14,15] but do not measure function. This is better assessed clinically using a variety of measures such as range of movement, strength, gait and balance.

Patient Reported Outcome Measures (PROMs) have gained popularity, assessing disease severity upon diagnosis [9–12], used as thresholds to determine the necessity for surgical intervention [13] and to monitor the results following that intervention [9,10]. Many of these tools have been developed for the elective orthopaedic setting where their practice is established. Whilst tools developed specifically for elective orthopaedic patients [16–19] are validated they may be less suitable for use following trauma. Generic PROMs measuring quality of life are valid across multiple diseases [20–23] but their use to measure outcomes and recovery following injury has been disputed [24], remaining insufficiently responsive to monitor an individual's recovery [25].

Patients who have successfully completed their treatment following open tibial fractures recognise that "healing" does not always indicate recovery – *"I thought that when it healed it would be back to normal."* [8]. This highlights the discordance between surgeon related clinical outcomes and the outcomes important to patients – despite a seemingly good "surgical" outcome – no infection, united fractures and healed soft tissues– the patients can often report persistent symptoms and these symptoms can result in significant functional limitations [8,26].

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The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) defines standards that aid in appraisal of measurement tools [30]. The COSMIN checklist has been used to assess the properties of measurement instruments used in neck pain [31,32] grading each as excellent, good, fair and poor [33]. Properties assessed by the COSMIN tool include: Internal consistency (the agreement between items in a scale, suggesting the items measure the same underlying variable), test-retest reliability (whether the same person will respond in the same manner on two distinct occasions providing there has been no interval change), content validity (whether the scale comprehensively and appropriately measures the variable of interest), structural validity (whether the structure of the scale reflects the dimensionality of the variable being measured), hypothesis testing (whether the scale performs as predicted *a priori* compared with other PROMs), and responsiveness (the ability of the scale to measure interval change) [34].

This study aims to determine how clinical and patient reported outcome measures are used to report results following tibial shaft fractures.

Methods

A review of all papers reporting clinical results following tibial fractures was performed. Only papers published since 2009 were considered. This was to allow the recommendations made in the Standards [1] to be used as a guide for the gold standard reporting of outcomes. Whilst these guidelines purport solely to open lower limb fractures, as an archetypal severe lower limb injury we feel that the recommendations should apply more widely, and certainly to closed tibial fractures.

A search strategy based on the Participants, Intervention, Comparisons, Outcomes and Study Design (PICOS) technique was constructed [35] (Table 1). The strategy was designed to be maximally inclusive, retrieving as many potential articles describing clinical results following tibial shaft fracture.

Ovid Medline (1946 to date), Embase (1974 to date), PubMed (1956 to date), CINAHL (1981 to date), PsycINFO (1806 to date) and OVID Medline in-process and other non-indexed citations were searched on 19th July 2016 (Table 2). Duplicates were removed automatically using the Ovid interface (Search point #5, Table 2) and the full references were imported into a reference manager library [36]. Following a detailed review, additional duplicates of full text articles and conference abstracts that were later published in full were removed manually (Search point #6, Table 2). All titles were screened manually to include potentially relevant articles and exclude non-English full texts. If an English abstract was available and gave details of the outcome measures used, the article was included even when the full text was in a non-English language. This method was used to maximise data capture. Where doubt concerning the methodology of the article remained then full-texts were reviewed accordingly.

Table 1
Search strategy and search terms using PICOS analysis.

	Definition	Main search terms Subject heading (/) and free text terms
Participants	Persons with tibial shaft fracture	Tibia Fracture Shaft / diaphysis
Intervention	Not applicable	
Comparisons	Not applicable	
Outcomes	Any measured outcome	Outcome
Study Design	All included	

Table 2
Detailed search methodology.

Search number	Search term	Retrieved Titles	
#1	tibia.mp	108493	
#2	fracture.mp	468715	
#3	outcome.mp	3309828	
#4	shaft.mp	36734	
#5	diaphysis.mp	11548	
#6	#4 OR #5 (shaft OR diaphysis)	47,236	
#7	#1 AND #6 (tibia AND shaft/diaphysis)	7733	
#8	#2 AND #3 AND #7	938	
#9	De-duplicate (automatic)	−177	761
	De-duplicate (manual)	−2	759
#10	Exclude publication prior to 2009	−417	342

Inclusion was determined by two authors independently. Where disagreement occurred, the third author decided on inclusion.

As no consideration was to be given to the actual results described by each study merely the outcome measure that was utilised, no limit was placed on the methodology of the articles. Review articles that did not report original results, instead summarising results of previous studies and case series of less than 5 patients were not included. However, the references of these articles were reviewed separately to ensure no articles had been missed by the original search strategy. Retrieved articles were assessed for their use of any measure of perceived outcome at any point within the study.

Data extraction was performed independently by two authors. All retrieved articles reported some results concerning tibial fracture, though the precise nature of these results was often unclear from the methodology. Frequently articles reported results in a heterogeneous patient population. Acute injuries, mal- or non-unions and salvage, following both open and closed injuries, were often considered together and these articles were included for review. Isolated reports concerning non-union surgery were excluded.

Data concerning the study design and participants was collected in addition to the assessment of clinical outcome and methods used, and the use of any named “outcome measures”. Specific searches were then performed to identify relevant validation studies in tibial shaft fracture cohorts.

Titles, abstracts and full texts were reviewed to determine the relevance of the article and then reviewed in full text to allow the COSMIN checklist items to be assessed in line with the COSMIN manual [33]. The checklist provides a 4-point score (excellent, good, fair and poor) for each component of the checklist [33]. The “Measurement Error” and “Cross-Cultural Validity” measurement properties defined by the COSMIN group [33,34] were not considered as part of this review. In line with the COSMIN opinion that gold standard measurement do not (cannot) exist for patient reported outcomes (unless a shorter version of a PROM is being validated against its longer counterpart), “Criterion Validity” was not considered for any of the identified validation studies. This was true even when the study claimed to have assessed criterion validity. In these cases, the study was scored appropriately for “Hypotheses Testing”. Where there was doubt concerning the most suitable response due to poor clarification within the text, the more favourable response was selected. To maximise the potential score achievable, no studies were downgraded due to “other methodological flaws”. Rather than present a specific COSMIN checklist for each validation study, the summary score is stated for each PROM assessed.

Results

In total, 312 articles were reviewed (Fig. 1) with 168 being excluded on the title and abstract alone. Thus 144 articles were

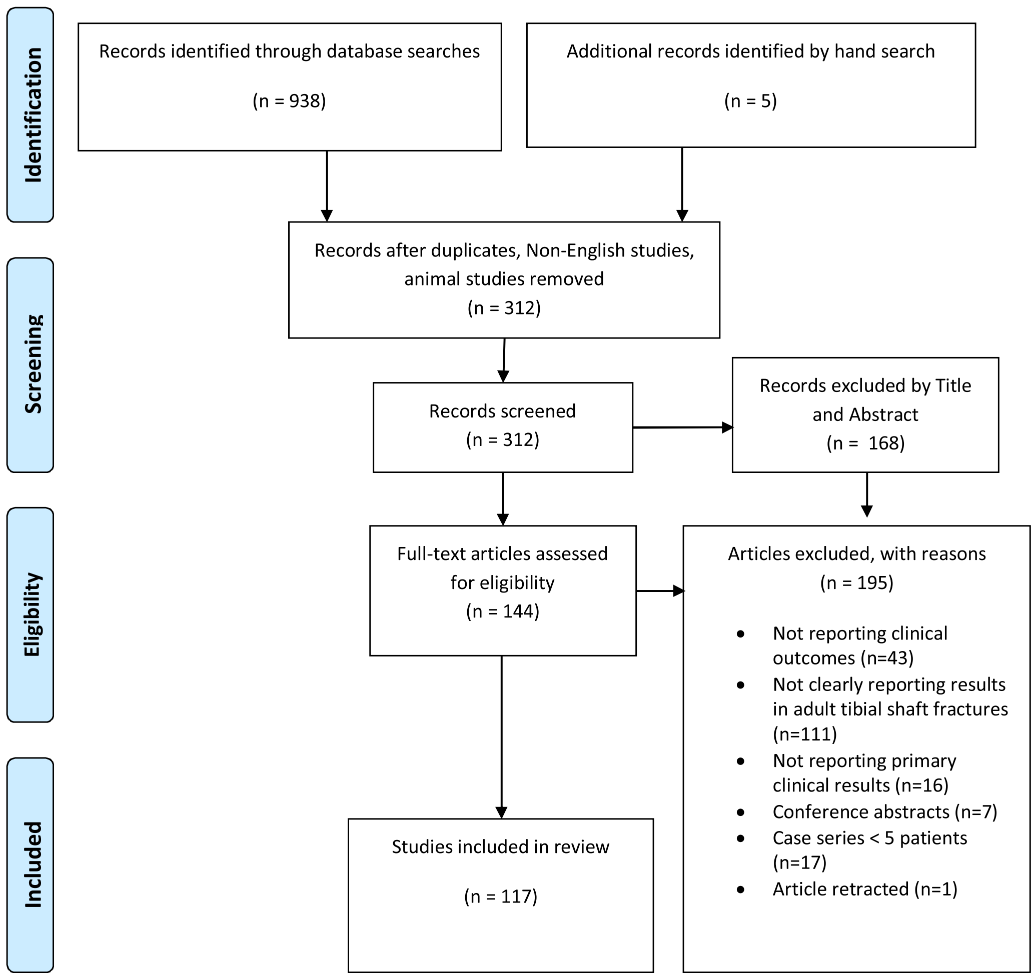

Fig. 1. Flow chart of article screening and inclusion.

reviewed in full, subsequently discarding 27. A total of 117 articles were included for data extraction. There were 65 case series, 31 comparative trials and 21 randomised or pseudorandomised trials.

Union

The majority of articles reported union with reference to clinical and radiological parameters. Ten articles reported union as part of either the Association for the Study and Application of the Methods of Ilizarov (ASAMI) or Johner and Wruhs clinician scores [37–46] (described below in Clinician Reported Measures). Many others reported "union" assessed by clinical and radiographic means [37,47–116]. However, rarely were the precise methods of determination described, nor the exact timing. Three articles specifically reported time to union but contained no specific description of how this was determined [51,59,70].

Regarding radiographic union, three articles specifically reported using the Radiographic Union Scale for Tibia (RUST) [117,118] as a determinant of radiographic union [66,69,119]. Further articles described radiographic union in isolation [53,119–126] or clinical union in isolation, defined as full painless weight-bearing [127].

Clinical parameters

In addition to union, the majority of articles reported objective clinical parameters. Knee and ankle range of movement were specifically reported in 25 [37,40,41,45,51,68,74,76,80,81,83,84,86,89,90,93,94,98,110,112,114,124,128–130] and 17 [37,39–41,45,51,68,74,80,81,84,90,98,112,124,128] articles respectively. Those articles using the Johner and Wruhs criteria [40–46] also made assessments of range of movement at both the knee and ankle. Usually, minimal details were given regarding the exact method of measurement.

Similarly, leg length discrepancy was described in 14 articles [40,43,58,61,90,92,100,102,108,112,114,124,130,131] with 3 additional articles reporting leg length as a component of the ASAMI score [37–39].

Radiological alignment was also described by those articles reporting the ASAMI or Johner and Wruhs criteria [37–46]. It was also specifically reported by 34 articles [47,51,53,58,61,63,74–76,80,84,85,88,90,92,94,96,98–102,106,108–112,114,129,131–134].

Simple binary complications were reported frequently, as was the rate of reoperation (Table 3). Few papers accurately defined the diagnosis of infection, nor quantified its severity. Often, it was reported alongside reoperation. Similarly, the need for fasciotomy – specifically reported as a separate measure in three articles [111,135,136] was often considered within the reoperation rate, along with surgery for delayed or non-union or other acute complications and removal of metalwork. Papers reporting mortality either reported this as part of long-term loss to follow-up [47,59,65]; as a primary or secondary outcome [58,60,129,137–139]; or describing general outcomes in polytraumatised patients [57,140,141].

Table 3
Number of articles reporting specific complications.

Complication	Reported by n articles
Infection	63
Reoperation (any reason)	54
Limb salvage rate	11
Mortality	12

A single paper examined the use of opioid use post-operatively [142].

Recognised "outcome measures" were widely used with articles reporting a variety of clinician based and patient reported outcomes (Table 4).

Clinician reported measures

The Association for the Study and Application of the Methods of Ilizarov (ASAMI) score [143]

The ASAMI score was originally described in 1989 as a measure of outcome in a series of 25 patients with tibial non-union treated with an Ilizarov ring fixator [143]. The score had scales for bony outcome – describing union, presence of infection, deformity greater than 7° and leg length discrepancy – and function – describing limp, equinus contracture at the ankle, soft tissue dystrophy, pain and inactivity either at work or activities of daily living. Results were considered separately for bone and function as excellent, good, fair or poor, depending on the presence of each of the variables.

The scale was subsequently modified by El-Rosasy in 2007 [144] (Table 5), widening the definition of contracture to both the knee and ankle, lowering the threshold for deformity and including patient satisfaction. Results were considered satisfactory or unsatisfactory.

The original ASAMI criteria was used in 2 articles [37,38] with Atef et al [39] using the El-Rosasy modification.

Iowa ankle and Iowa knee scores [145]

The Iowa scores for the knee and ankle were initially reported together in a cohort of tibial fractures [145] and have been used together [63,92,132] and as the ankle score in isolation [113].

Table 4
Distribution of named outcome measures used in the retrieved articles.

	Outcome Measure	Reported by n articles
Clinician Reported Measures	ASAMI	3
	Iowa ankle	4
	Iowa knee	3
	Johner & Wruhs	7
	Kalstrom & Olerud	2
	Olerud & Molander	5
Patient Reported Generic Health Measures	EQ5D	2
	MFA / SMFA	2 / 3
	SF-36 / RAND36 / SF-12	11 / 1 / 2
	SIP	1
Location/Disease specific PROMs	AAOSLLQ	1
	FADI	1
	FFI	1
	KOOS	2
	LEFS	3
	LEM	1
	Lysholm	6
	Tegner	1
Other	SPOC	1

Table 5
El-Rosasy modification of the Paley score [144].

Parameter	Satisfactory	Unsatisfactory
Bony union	United	Non-united
Residual deformity	Less than 5°	More than 5°
Residual leg-length discrepancy	Less than 2.5 cm	More than 2.5 cm
Recurrent infection	No more infection	Bone and/or soft-tissue infection
Soft-tissue healing	No exposed bone	Soft-tissue defect remaining
Permanent joint contracture	Less than 5°	More than 5°
Persistent pain	No or mild pain	Moderate or incapacitating pain
Return to previous work	Yes	Has to change job
Patient satisfaction	Satisfied	Not satisfied

The knee score describes function across 11 activities of daily living, freedom from pain, gait, absence of deformity or stability and range of movement. Whilst describing the same domains except deformity/stability, the ankle score scores each component differently with alternate descriptors used.

Both scores have been subsequently validated in tibial shaft fractures against the physical component of the SF-36 generic health measure, with correlation coefficients reported of .55 (ankle) and .57 (knee). [146].

Johner & Wruhs [147]

This combined clinician and patient based score (Table 6) was originally used by the authors to augment their report on the classification and outcomes of tibial shaft fractures. Details concerning the process of development are not described [147]. There were demonstrable differences in the scores between open and closed injuries as well as a greater number of poor results in comminuted fractures. No further validation studies were identified.

The score is widely used [40–46] likely due to its relative simplicity and incorporation of clinical factors at both the knee and ankle joints.

Karlstrom and Olerud [148–150]

Cekic et al. [119] report using the score as described in 1974 [149] but originally described in 1972 [148]. Zhen et al [112] reported using the version as described in 1983 but this was also originally described in 1972.

Further confusion arises as Karlstrom and Olerud described two similar clinician based outcome measures for use in the lower limb [148,151]. The 1972 version is described in Table 7.

Zhen et al. report a summated score in their results although the descriptions published by Karlstrom and Olerud [148–152] do not describe a numeric summation.

Olerud and Molander ankle (OMA) score [153]

The OMA score was developed as a clinician based measure describing outcome in 9 domains: pain, stiffness, swelling, stair-climbing, running, jumping, squatting, (mobility) supports and work, activities of daily life. Details concerning the process of development are not described but it was validated against a visual analogue score of the patients' perception of ankle function and correlated well with this. There were also statistically significant differences in the OMA score depending on the ankle range of loaded dorsiflexion, presence of osteoarthritis and the presence of dislocation or incongruence [153]. No validation in tibial fracture patients was identified.

The OMA score was commonly used in articles describing the use of ring external fixation [63,68,99,132] as well as the impact of mal-rotation following intramedullary nailing [134].

Table 6
Johner and Wruhs criteria [147].

	Excellent	Good	Fair	Poor
Non-union, osteitis, amputation	None	None	None	Yes
Neurovascular disturbances	None	Minimal	Moderate	Severe
Deformity				
Varus/valgus	None	0°–5°	6°–10°	>10°
Anteversion/recurvatum	0°–5°	6°–10°	11°–20°	>20°
Rotation	0°–5°	6°–10°	11°–20°	>20°
Shortening	0–5 mm	6–10 mm	11–20 mm	>20 mm
Mobility				
Knee	Normal	>80%	>75%	<75%
Ankle	Normal	>75%	>50%	<50%
Subtalar joint	>75%	>50%	<50%	
Pain	None	Occasional	Moderate	Severe
Gait	Normal	Normal	Insignificant limp	Significant limp
Strenuous activities	Possible	Limited	Severely limited	Impossible

Table 7
The Karlstrom and Olerud score [148].

		A	B	C
Subjective	Ankle joint symptoms	0 or negligible	Moderate. Some functional reduction	Severe. Clear functional reduction
	Aching or pain in fracture area	0 or slight symptoms on exertion	Moderate symptoms	Severe symptoms. Pain at rest
	Difficulty in walking	0	Mild subjective symptoms	Severe symptoms. Limp
	Work and sports	Unchanged activities	Works as before. Finished with some sport	Stopped working because of injury
Objective	Skin condition	Normal	Slightly discoloured	Ulcer or fistula, persistent infection
	Deformity	0	Slight, not noticeable	Considerable, noticeable shortening > 1 cm
	Muscular atrophy	0 – 1 cm	1 – 2 cm	>2 cm
	Swelling	0 – 1 cm	1 – 2 cm	>2 cm
	Movement of ankle joint, dorsi- and platar-flexion	Limitation 0 or <5°	Limitation 5-10°	Limitation > 10°

Patient reported generic health measures

EuroQol-5D (and EuroQol-6D)

The EuroQol Group was established in 1987 with the purpose of developing a standardised, non-disease specific instrument for describing and valuing health-related quality of life [154[Online] http://www.euroqol.org/ [Accessed 21/05/2015]]. From the outset the EuroQol group have focussed on simplicity and the cross country use of the derived tool, allowing it to describe the full spectrum of health from best to worst, including death.

The EQ-5D describes 5 health domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [155]. Each domain can be classified as one of three groups: no problem, some or moderate problems and extreme problems. In addition, there are 2 further separate health states defined: unconsciousness and death (although these are not included for obvious reasons in the self-reporting version of the tool). Thus a total of 245 separate states can be defined by the tool, despite its apparent simplicity, giving it good discriminatory power. The modern score also includes a 20 cm visual analogue scale for self-reporting of the participants own “health state”.

The EQ-5D has been used in many studies across a wide range of clinical areas, primarily oncology, musculoskeletal, cardiovascular, respiratory and mental health [155]. It is currently being used as a secondary outcome measure in the WOLLF trial [156] along with the SF-12. The tool has been validated for use in many disease states, though notably not specifically in tibial fractures or lower limb trauma [154 [Online] http://www.euroqol.org/ [Accessed 21/05/2015]]. However, it’s wide use and established country specific population norms make it a useful generic measurement tool.

The EQ-5D has been used to describe results in open [63] and closed [132] tibial fractures as well as the “full spectrum” of tibial injury including closed tibial fractures, fasciotomy without underlying fracture, Gustilo-Anderson grade IIIB and IIIC open fractures and early amputation following severe injury [4].

Whilst the use of EQ-5D has been validated across multiple disease states, there is little evidence or prospective validation for its use in tibial fracture.

Short form-36 (SF-36) and variations (RAND-36, SF-12)

The SF-36 was developed following a 2 year study into clinical outcomes in chronic health conditions in over 22,000 patients, and has been quoted as being the most widely evaluated generic patient assessed health outcome measure in a bibliographic study of the growth of quality of life measures [28]. Coupled with its alternate and shortened versions (RAND-36 using a different scoring algorithm [157] and the SF-12) it was the most widely used measure, being used in 14 of the articles [73,76,92,99,100,107,113,119,120,129,158–161].

The SF-36 consists of 11 questions asking about 36 items across 8 domains and is available in over 170 languages. Each domain is scored independently between 0 and 100, with the assumption that each question carries the same weight. The scores can be directly transformed into a scale between 0 and 100; a score of 0 is complete disability and 100 is no disability. These allow presentation of the sub-scale scores for each of the domains. The sub-scales can be combined to give the overall physical component summary (PCS) and mental component summary (MCS). Population normals for the PCS and MCS have been calculated with the average healthy adult scoring 50 and normalised scores facilitate direct comparisons across disease states in the average adult population.

The SF-36 and SF-12 remain commonly used measures in current trauma research [28,162].

Musculoskeletal function assessment (MFA) and short musculoskeletal function assessment (SMFA)

The MFA was developed to provide a comprehensive tool to measure functioning across all musculoskeletal conditions for research purposes [163]. The SMFA was later developed to facilitate use in clinical studies [164]. Both tools are described for use in research rather than clinical monitoring due to their length and relative burden of use [163,164] – an accepted disadvantage of comprehensive tools. The development of the MFA was performed using data derived directly from interviews with 135 patients (including limb fractures, but not specifically stating tibial fracture) and 12 clinicians. Both the MFA and SMFA have been shown to have good internal consistency [163,164]. The SMFA was also shown to be valid against physician grading of functioning across a wide range of musculoskeletal pathologies. As expected due to its relative ease of use, the SMFA was used marginally more [59,75,159] than the MFA [130,165].

Sickness impact profile (SIP)

The SIP was developed in 1975 as a behaviourally based measure of sickness-related dysfunction [27]. It has been used to describe outcome in a single retrieved article [130]. The SIP was developed using a qualitative process, where unhealthy individuals, their carers, health care professionals and healthy individuals provided statements describing sickness related changes in behaviour [27]. These statements were refined into 14 categories and piloted in 246 patients and non-patients across all levels of medical care. The SIP was shown to be a comprehensive descriptor of dysfunction. Due to its comprehensive nature the length of the tool, makes it unwieldy for some patients [27].

The SIP was used by the LEAP study group [166–168], highlighting that demographic and socioeconomic factors had a significant impact on measurable outcome following severe lower limb trauma [169]. Despite this widespread usage, the SIP has not been formally validated for use in severe lower limb trauma or open tibial fracture.

Visual analogue scale (VAS) for pain

The VAS is an analogue measure often used to determine pain, but can also be used for satisfaction or other variables. It is usually considered as a point along a line from 0 to 10, but different end-points can be used. The line should be drawn for the respondent and measure 10 or 20 cm long [170]. It must be made clear to the respondent that a point along the line should be marked, rather than a corresponding integer (which would approximate a numerical rating scale instead). The Numerical Rating Scale (NRS) is considered as an integer between 0 and 10, essentially an 11-point scale [170]. Often VAS and NRS are used interchangeably and serve to grade the variable of interest in a (pseudo) nominal fashion [170].

VAS and NRS measures are widely used for their ease of use and understanding [74,86,89,98,119,124,129,171,172].

The VAS has been shown to be particularly susceptible to scale recalibration, the phenomenon whereby respondents reprioritise and introduce measurement bias through adaptation [173] and has not been specifically validated in the tibial fracture population.

Location/disease specific PROMs

The combined COSMIN checklist scores for each of the measures are summarised in Table 8.

American academy of orthopaedic surgeons lower limb core scale (AAOSLLCS)

The AAOS scores (including the Lower Limb Core Scale and scores for the hip, knee and sports injuries) share the same basic structure and were developed together to provide a higher level of region specificity and symptom definition, useful in both measuring outcomes and assisting in clinical decision making [18]. The development and validation study [18] explained the iterative process behind the development of these scores, stating that the items were generated by a group of interested stakeholders at the Sponsored meeting of the AAOS and the Council of Musculoskeletal Specialty Societies in Tarpon Springs, Florida in April 1994. Generated items were grouped and refined during the meeting leading to the development of a broad scale. This was subdivided depending on the joint or body region of interest, with different modules being used in the hip and knee, foot and ankle and lower limb core scales. Whilst the scale was thought to have good validity as a result of the construction process of the tool, the calculation of the test-retest reliability (thought to be good to excellent for all of the scores [18]) is invalid. The authors used a Pearson correlation coefficient which does not guarantee agreement – an argument previously highlighted in hip and knee outcome measure development [174,175]. A further criticism of this validation study, is the emphasis within the paper on the good correlations between the newly developed scores (all based on the same core dataset of items) and the core lower limb scale. This emphasises the problem of vicious circle cross-validation studies [176].

No articles validating the use of the AAOSLLCS were identified in tibial fracture patients so its generalisability in these patients is poor. One identified article used the AAOSLLCS as an outcome measure [113].

Foot and Ankle Disability Index (FADI)

The Foot and Ankle Disability Index (FADI) was a former version of the Foot and Ankle Ability Measure (FAAM), including four items

Table 8
COSMIN checklist items for the outcomes measures identified.

COSMIN Checklist Item [validation reference]	Internal Consistency	Reliability	Content Validity	Structural Validity	Hypothesis Testing	Responsiveness
AAOSLLCS [17, 231]	Poor	Poor	Poor	Poor	Fair	Poor
FADI [180]	N/A	Fair	N/A	N/A	Fair	Fair
FFI [182,193,194]	Poor	Poor	Poor	N/A	Good	Fair
KOOS [10,197,198]	Poor	Poor	Fair	N/A	Poor	Poor
LEFS [203-207, 232-235]	Good	Excellent	Good	Good	Good	Good
LEM [208,209]	Fair	Good	Good	N/A	Good	Good
Lysholm [213,214]	N/A	N/A	N/A	N/A	Poor	N/A
Tegner [214]	N/A	N/A	N/A	N/A	Poor	N/A

concerning pain and a single item concerning sleep that were later excluded following factor analysis [177–179]. The original description of the index is only available as a conference abstract [177], but the same authors have published on the FADI subsequent to this [179]. The FADI was used in a single retrieved article [108]. Hale and Hertel [180] investigated the FADI in patients with chronic ankle instability. No specific validation studies have been performed in tibial fractures. The FADI has subsequently superseded by the FAAM [179,181].

Foot Function Index (FFI)

The FFI was developed in 1991 [182]. The original description was in patients with rheumatoid arthritis, with the 23 items selected by an expert panel consisting of a rheumatologist, two physiotherapists and a podiatrist [182]. There was no patient involvement in the development of the index and adequate content validity was not adequately considered [182]. That the index did not consider the psychosocial aspects of foot and ankle pathology or the wider quality of life aspects has been later criticised [183] and this ultimately lead to the development of a revised version – the FFI-R [184]. One identified article cites the use of the FFI [165]. Whilst published following its revision in 2006, it does not use the revised index.

The FFI has been widely used as a "gold standard" for the validation or development of other instruments [181,185–192]. However, only 2 specific validation studies were retrieved, each concentrating on cross cultural validity [193,194].

No validation studies specific to tibial fractures were identified. A single article considered patients with foot or ankle fractures during validation [194]. It has been recognised that whilst the FFI is a "validated outcome scale", its validation is largely specific to rheumatoid arthritis patients and the revised tool is yet to be widely adopted [195].

Knee Injury and Osteoarthritis Outcome Score (KOOS)

The KOOS was used in two articles [108,196]. Roos et al. originally described the score in 1998 [11] and have since published a review of the score development, validation and usage [197]. The score was developed from items identified during a literature review and by an expert panel, which included an undisclosed number of patients with knee problems [11,197]. Since its original description the score has been investigated further [197,198]. The majority of the original descriptive work and subsequent studies have been performed in patients with intra-articular non-fracture knee pathology [197]. All of the validation studies demonstrated sound methodology but small sample sizes and poor handling of missing value data (Table 8). No validation has been reported in tibial fractures.

Lower extremity functional scale (LEFS)

The LEFS was developed in 1991 as an easy to administer score applicable to a wide range of patients with orthopaedic pathology affecting their lower limbs [12]. It was used in three identified studies [114,120,134]. In addition, the LEFS is often used as a criterion in the validation of other lower limb functional measures [199–202]. A total of nine validation studies were identified assessing the measurement properties of the LEFS.

The combined COSMIN checklist scores range from good to excellent. Some of the studies reviewed fracture patients specifically. Cacchio et al. reported the use of LEFS in 27 lower limb fracture patients [203]; Hou et al. noted 67 of their cohort had sustained a lower limb fracture [204]; Pereira et al. identified that 10 of the 100 patients who completed the Brazilian version of the LEFS had sustained a tibial fracture [205]; and Alnahdi et al. assessed the validity of the Arabic version in 116 patients, of whom 11 had sustained a lower limb fracture [206]. Interestingly, Negahban et al. actively excluded patients if they had sustained a fracture [207]. However, if only the fracture patients were considered in the validation studies, all would score poorly on the COSMIN checklist.

Lower extremity measure (LEM) (modification of the Toronto extremity salvage score (TESS))

The LEM was a modification [208] of the Toronto Extremity Salvage Score which was itself developed to overcome perceived deficiencies in the Enneking score [29], later termed the Musculoskeletal Tumour Society Rating Score [209]. The initial TESS items were generated by an expert panel of surgeons, nurses, physiotherapists and occupational therapists. Jaglal et al. modified the TESS to the Lower Extremity Measure (LEM) during their thorough review of measures assessing physical function in patients with hip fracture [208].

The LEM was used in a single article describing the outcomes in patients treated with plating [85]. The only validation study concerning the LEM was the original descriptive article [208]. Whilst the LEM and TESS differ in the exact wording on items used, both the original TESS description and the LEM description have been considered together for the COSMIN checklist items.

The TESS/LEM is frequently used as a criterion in validation studies of novel measures in orthopaedic oncology patients [210–212]. No validation has been performed in traumatic fracture patients.

Lysholm knee scale

The Lysholm Knee Scale (often termed the Lysholm score) was used in 6 articles [76,86,89,110,113,129].

The score was originally described in 1982 as a method of assessing function following ligamentous injuries to the knee [213]. Lysholm later co-authored a review of scoring systems around the knee describing a novel activity rating scale – the Tegner activity scale [214] – which is often reported with the Lysholm Knee Scale [86].

The Lysholm Knee Scale was based upon items obtained from the knee scoring system described by Larson [215], with an additional item added to describe feelings of instability [213]. Items concerning pain and function were both expanded to give a final maximum score of 100. Lysholm and Gillquist did not perform any psychometric validation of their score – this was not common practice at the time – but did test their new score against the Larson score and a subjective measure of the patients' own assessment of their knee function. Tegner and Lysholm performed a similar hypothesis testing of their combined scores in 1985 [214]. Unfortunately the methodology was disadvantaged by a poor assessment of the properties of the comparator instruments (Table 8).

No additional validation studies of the Lysholm Knee Scale specifically performed in the tibia were identified. However, the score has been widely used and validated in knee ligament injuries [216–218].

Tegner activity scale

The Tegner Activity Scale was developed to be used alongside the Lysholm Knee Scale [214]. It describes the activity level from disability and subsequent sick leave through to participation in competitive sports at an international or elite level [214]. No additional validation studies performed in tibial fracture patients were identified. The Tegner Activity Scale was in a single article [86] alongside the Lysholm Knee Scale.

Other scales

Somatic pre-occupation and coping (SPOC) questionnaire

The SPOC questionnaire was used in a single study which was also the development and validation paper [158]. As this tool does not measure outcome of a tibial fracture, moreover the pre-existing beliefs of the patient which appear to influence true functional outcome, this tool has not been considered further.

Discussion

A number of clinical, radiological and patient reported measures have been used to assess outcome and function following tibial fracture.

Broadly, they can be split into generic measures which excel at measuring the outcome across a population or disparate group of patients; more specific location or disease specific measures, more suitable for measuring effects in individuals [26]; and clinical factors, which may be more widely accepted by clinicians when considering change in practice [219,220]. In assessing outcome following tibial injury, it is unlikely that these groups should be considered mutually exclusive.

Clinical parameters are in widespread use and inform decision making in our everyday practice [220]. However, there is no widely accepted set of outcomes that should be collected routinely, as demonstrated by the variability of measurements used in this study. Despite this, the reliance on clinical parameters is clear. In order to inform or change practice, clinicians will often revert to outcomes they consider familiar and provide "surgical gain" [219].

There is a requirement for greater adoption of the standardised measurement of clinical variables, such as union, range of movement and alignment. Methods and timeframe for determining successful union should be clearly stated, and a standardised assessment of wound healing and scar formation should be validated in this patient cohort. These variables will remain essential in measuring outcome following tibial fracture surgery and changing clinical practice.

Generic PROMs have usually been developed following extensive study and have been tested in a number of different populations and diseases [155,221–224]. Due to the broad scope of these measures – some suggest every health state from death to perfect health can be defined accurately [155] – different measures may perform differently in certain scenarios and may even underestimate the impact in trauma patients [225]. Beaton et al. showed this variability in performance in workers with musculoskeletal problems [226]. McHorney and Tarlov criticised some of the usage of their own tool (they contributed to the development of the SF-36) by demonstrating that 5 health measures (including the SF-36 and Nottingham Health Profile) were inadequate to describe or monitor the changes as experienced by an individual [227]. However, the generic measures assist in placing the outcome of the injury in the wider context [228]. Recent recommendations have suggested the use of generic measures supplemented by injury specific measures to measure injury related disability [26].

The clinician and patient reported tools identified in current use have not been validated in tibial fracture patients. The few patient reported tools that have been partly validated in this population have not been adequately tested in line with the recommendations made by Mokkink et al. in the COSMIN checklist [229]. Thus the use of these tools can be criticised on this basis alone. Furthermore, many of the tools have been specifically developed for other conditions, or to monitor the function of either the knee or ankle joints. The tool recommended by the Standards for Management of Open Lower Limb Injury is the Enneking score [1,29,209]. Whilst there are similarities in the treatment regimens and surgical techniques in lower limb oncology and lower limb trauma, the differences are stark and this tool has not found widespread usage and has not been validated.

The reasons behind the lack of an appropriate patient reported tool for use following tibial injury are unclear. Although the routinely used tools may define a *de facto* standard by their regular use in the literature, they have insufficient or inappropriate field testing to support this.

The complexity of tibial injury patterns, as well as the broad patient demographic who suffer these injuries, presents challenges to the global measurement of outcome. A young, active female will likely have a different view of recovery and outcome when compared to an elderly, immobile, dependent male with multiple comorbidities despite suffering an identical open distal third tibial fracture. By commencing the development of a patient reported outcome measure with qualitative data derived from a spectrum of tibial fracture patients [8], some of these issues may be addressed.

This is a thorough review of the literature concerning tibial shaft fractures, but excluding plateau and pilon injuries. This was to minimise potential noise caused by large numbers of joint specific measures adopted by the knee and ankle clinicians. However, numerous knee and ankle specific clinical parameters and patient reported measures were identified in the review, corresponding with the knock-on effects on these joints following shaft injury.

The date limitation was selected to be pragmatic. Prior to the publication of the Standards for the management of open fractures of the lower limb [1] there was no accepted guidance on how to measure outcome following tibial shaft injury. Whilst this guidance is specific for open injuries, the importance of combined measurement of clinical and patient important factors was clearly stated. By reviewing papers published after this guidance, we hoped to ensure the most up-to-date and relevant picture of outcomes reporting. This is particularly relevant given the increasing interest and apparent importance placed upon patient reported measures. It is possible that some methods of measuring outcome have not been included in this review if published prior to this date. However, the importance of these could be questioned if they have not been re-used more recently.

Conclusion

None of the identified outcome measures have been specifically developed to assess function or patient reported outcome following tibial fracture. To date, there is no validated functional outcome measure for specific use in tibial fractures [230] and the best way to monitor the results, outcome, recovery and impact of treatment in these patients remains elusive. A novel patient centred tool capable of measuring recovery in tibial fracture patients is required. Simple determinants of outcome, such as need for additional surgery, should be stratified to better describe surgery for fasciotomy, non-union or infection versus surgery to remove prominent metalwork or address cosmetic issues around soft tissue reconstruction. In addition, a core outcome set, considering clinical, radiological and functional measures should be developed to standardise the reported of outcome following tibial fracture.

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