Original article

Title:

The management of segmental tibial shaft fractures: a systematic review.

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Abstract

Introduction:

Segmental tibial fractures are complex injuries associated with significant soft tissue damage that are difficult to treat. This study aimed to identify the most effective method of treating segmental tibial fractures.

Method:

A PRISMA compliant systematic review was conducted. Studies investigating the management of segmental tibial fractures with intramedullary nail fixation (IMN), open reduction and internal fixation (ORIF) or circular external fixation (CEF) were included for review. The primary outcome measure was time to fracture union. Secondary outcomes were complications and functional outcome. A narrative analysis was undertaken as meta-analysis was inappropriate due to heterogeneity of the data.

Results:

Thirteen studies were eligible and included. No randomized controlled trials were identified. Fixation with an intramedullary nail provided the fastest time to union, followed by open reduction and internal fixation and then CEF. The rate of deep infection was highest after IMN (5/162 [3%]), followed by open reduction and internal fixation (2/78 [2.5%]) and CEF (1/54 [2%]). However, some studies reported particularly high rates of infection following IMN for open segmental tibial fractures. There was limited reporting of postoperative deformities. From the studies that did include such data, there was a higher rate of deformity following ORIF (8/53 [15%]), compared to IMN (13/138 [9%]), and CEF (4/44 [9%]). Three studies, not including IMN, described patient reported outcome measures with results ranging from ‘excellent’ to ‘fair’.

Discussion:

The available evidence was of poor quality, dominated by retrospective case series. This prevented statistical analysis, and precludes firm conclusions being drawn from the results available.

Conclusion:

IMN has the fastest time to fracture union, however there are concerns regarding an increased deep infection rate in open segmental tibial fractures. In this subgroup, the data suggests CEF provides the most satisfactory results. However, the available literature does not provide sufficient detail to make this statement with certainty. We recommend a randomized controlled study to further investigate this challenging problem.

Introduction

A segmental fracture is characterised by distinct fractures at two or more levels, creating one or more completely separate intercalary fragments of tubular bone [1]. In the tibia, segmental fractures are assigned the AO classification 42C2. Segmental tibial fractures are rare, accounting for between three and 12% of all tibial shaft fractures. They often result from high energy mechanisms of injury [2]. Complications are more common in comparison to simple tibial shaft fractures, particularly in terms of non-union and infection [3].

There is a wide zone of injury associated with these fractures and the soft tissue component requires specific management considerations. Compartment syndrome occurs in up to half of all cases, and over 50% of segmental tibial fractures present as open fractures [1]. The high rate of complications is thought to relate to the severe nature of the soft tissue injury, both in open and closed fractures [4]. In all cases there is periosteal stripping and disruption of the blood supply, particularly to the intercalary fragment, which disturbs fracture healing.

Non-operative treatment is generally not indicated for these fractures as the outcome is poor [5]. Surgical options include open reduction and internal fixation (ORIF), locked intramedullary nailing (IMN) and circular frame external fixation (CEF). However, there is currently clinical equipoise with no consensus on the best method [4]. To address this uncertainty, we systematically analysed the current evidence to determine what is the optimal fracture fixation method for segmental tibial fractures.

Materials and Methods

A PRISMA compliant systematic review was conducted to determine which method of fixation resulted in the shortest time to union and the fewest complications [6].

Search Strategy

We performed a systematic literature search on the 30th April 2015 to identify relevant articles. The electronic databases MEDLINE, Embase, CINAHL, Pubmed and AMED were searched through the Ovid platform from their inception to the 30th April 2015. The unpublished literature was searched from the electronic databases OpenGrey, British Library Integrated catalogue, Current Controlled Trials and the Cochrane Central Register of Controlled Trials from inception to the 30th April 2015. The MEDLINE search strategy is presented in Supplementary Table 1. This was modified for the other electronic searches.

Study Eligibility

We aimed to identify randomized controlled trials (RCTs) and non-randomized studies reporting the surgical management of segmental tibial fractures. A broad search allowed inclusion of population characteristics, medical co-morbidities and coincidental injuries, surgical interventions and the origin of the study. Studies published in any language were included and papers were eligible irrespective of date of publication. We excluded animal or biomechanical (cadaveric or saw bone) studies.

Study Identification

Two reviewers (ZL, SM) independently reviewed the title and abstract of each study. Full text papers were ordered for those studies which met the eligibility criteria. Two reviewers (ZL, SM) then independently reviewed each full text paper against the eligibility criteria and included pertinent studies in the review. If disagreements arose between the reviewers in respect to study eligibility, data extraction or critical appraisal score, this was resolved with discussion between the two reviewers until a consensus was reached.

Data Extraction

Data was collected from each included paper by one reviewer (ZL), and verified by a second reviewer (SM). Data extracted from each paper included cohort age, gender, clinical presentation, mechanism of injury, management, complications, outcome measures and follow-up period.

Outcome Measures

The primary outcome measure was time to fracture union. Secondary outcome measures were complications and functional outcome.

Critical Appraisal

The Critical Appraisal Skills Programme (CASP) critical appraisal tool for cohort studies was used to assess the methodological quality of the included studies as this was the study design of the subsequently eligible papers [7]. Each included paper was reviewed by one reviewer (ZL) and verified by a second reviewer (SM).

Data analysis

The methodological approaches and data extracted were reviewed. There was significant study heterogeneity principally based on management strategy adopted across the studies and outcome assessments. Accordingly, it was deemed inappropriate to pool results using meta-analysis techniques. Therefore, a narrative review was deemed most appropriate and was undertaken to answer the research question. Studies were analysed by our *a priori* primary and secondary outcome measures.

Results

Search Results

Eighteen studies were reviewed in full. Five were excluded due to the use of obsolete or obscure fixation techniques (as deemed by the review team), or the investigation of multiple techniques without sufficient detail on each individual method. Therefore, 13 studies from an initial 326 were eligible for this review. This comprised a total of 366 cases. The results of the search are presented in the PRISMA flow-chart (figure 1).

Critical Appraisal Results

The critical appraisal can be found in table 1. The literature is dominated by Level IV evidence in the form of case series and poorly matched cohort studies. The methodological quality of these studies was therefore assessed using the CASP critical appraisal tool for cohort studies. The primary limitation across the majority of the studies was the limited control of confounding factors that could impact on the results, particularly given that the cohorts were small and data retrospectively collected.

Clinical Findings

Of the 13 included studies, four compared the results of multiple treatment modalities [2, 3, 8, 9], four reported the outcome of IMN alone [10-13], two ORIF alone [14, 15], and three CEF alone [4, 16, 17]. No RCTs were identified and there was significant data heterogeneity. Therefore, a narrative review of the thirteen included studies was undertaken. The findings are summarised in tables 2 and 3.

Primary outcome measure: Time to fracture union

Fixation with IMN has the fastest time to fracture union (18.5, 19.4 and 21.7 weeks) followed by ORIF (19.0 and 25.0 weeks) and CEF (25.1, 38.1 and 29.7 weeks). Teraa et al [2] reported in their mixed study that IMN patients united faster (p=0.04) than other methods, and reamed IMN faster than unreamed IMN (p = 0.031).

Secondary outcome measure: Complications

Results from studies in which the complications could be attributed to a specific modality of fixation are included here. The rate of deep infection was highest following IMN (5/162 [3%]) then ORIF (2/78 [2.5%]) and CEF (1/54 [2%]). However, some studies reported particularly high rates of infection following IMN for open segmental tibial fractures [8, 11].

There was limited reporting of postoperative deformities. From the studies that did include such data, there was a higher rate of deformity following ORIF (8/53 [15%]), compared to IMN (13/138 [9%]), and CEF (4/44 [9%]).

Cases of fasciotomy for compartment syndrome were described. IMN had the highest associated rate of fasciotomy (11/162 [7%]) followed by ORIF (4/78 [5%]), and then CEF (2/54 [4%]). Other complications, such as delayed union, pseudarthrosis and wound problems have been described in several papers. Differing definitions of these terms prevented valid comparison between studies.

Secondary outcome measure: Functional results

Three studies looking at ORIF and CEF included patient reported outcome measures (PROMS). No papers reported PROMS following IMN. One study reported results for ORIF with 21/25 (84%) reported as excellent and 4/25 (16%) ‘good’ [15]. Two studies included results for CEF, with 30/41 (73%) reported as excellent, 8/41 (20%) good and 3/41 (7%) fair [16, 17].

Discussion

The findings of this review demonstrate low-quality evidence from which we can infer that with regard to the primary outcome measure, IMN has the fastest time to fracture union, followed by ORIF and then CEF. This would appear to support the use of IMN in the management of these fractures.

All studies reported complications, which is understandable due to the severity and complexity of these injuries. IMN had the highest rate of fasciotomy for compartment syndrome, followed by ORIF and CEF. However, it is not clearly stated in all studies whether these compartment syndromes were diagnosed pre- or post-operatively, and the different protocols for diagnosis and management were not specified. Therefore, it cannot be inferred that one particular method of fixation has a higher association with post-operative compartment syndrome than any other.

The data with regard to deep infections is more complex. When combining the available data from the single fixation and mixed studies, there were five deep infections in 162 IMN (3%), 2 in 78 ORIF (2.5%) and 1 in 54 patients with CEF (2%). Not all studies with mixed treatment modalities separated out the infection data according to fixation method [2]. It is also difficult to delineate from most of the studies whether these infections occurred in closed or open fractures. Teraa et al [2] reported an infection rate of 10/30 (33%) in their group of mixed patients treated with IMN or ORIF. Further detail was not provided; however, from the data available in the paper, at least six out of 24 patients who underwent IMN (25%) suffered a deep infection, which is similar to the rate of infection following IMN in open segmental tibial fractures reported by Giannoudis (3/15 [20%]) [8]. Although the overall rate of infection between IMN and ORIF are the same when results are pooled, these reports are concerning for a high risk of deep infection following IMN where the fracture is open. This analysis cannot take into account the varying severity of the soft tissue injuries in each study due to inconsistent reporting and the differing soft tissue management and prophylactic antibiotic regimen used at the different centres.

Resulting deformities (shortening and angulation) were reported in some but not all studies. Thirteen out of 138 (9%) IMN resulted in deformity, compared to eight out of 53 (15%) in those who had ORIF and four out of 44 (9%) in those treated with CEF. This would suggest a higher rate of resulting deformity following ORIF; however, the clinical significance of such deformity in terms of functional impact, cosmetic result and whether any additional surgery was required was unfortunately not further described.

Interestingly, there were significant variations in the complication rates reported between studies of the same fixation method. For example, Huang and Wu reported no cases of compartment syndromes in their studies, while Kakar reported a 10% compartment syndrome rate among IMN patients [10-12]. This may reflect the different populations studied and the spectrum of injury severity, but may also be due to the subjective nature of diagnosing compartment syndrome. Similarly, Reynders investigated ORIF and found an extensor hallucis longus (EHL) palsy in 22% of patients (which may have resulted from injury to the deep peroneal branch to EHL during percutaneous plating, or alternatively represent a missed diagnosis of compartment syndrome) and 30% required plate removal due to prominence. Meanwhile, Ma investigated a similar number of patients and reported no such complications [15]. Kakar had no deep infections in a cohort of 51 patients undergoing IMN, whereas Huang identified two deep infections in a group of 33 [11, 12]. All studies had reasonably small numbers and this may also contribute to the difficulties in interpreting data on complications.

The economic implications of each method of fixation must also be considered. No studies reported direct data on the length of hospital stay. However, information regarding the delay to definitive treatment was described in some studies. This may be used as an indicator of increased cost, as well as inconvenience to the patient. For IMN fixation, one study [11] reported a mean 12 (range 3 to 103) day delay, and a second study [10] described the delay as approximately one week. Two studies [16, 17] reported a delay of 23 days (range 4 to 35) and 14 days (range 4 to 36) respectively for CEF, and two studies [14, 15] reported delays of 23 days (range 4 to 35) and 'six to 12 weeks' for ORIF. From the data available, IMN offers the quickest time to definitive fixation. However, no studies offer direct comparative data, hence inconsistencies between management protocols may be adversely affecting these results.

Three studies included patient reported outcome measures (PROMS) in their data with results ranging from excellent to fair. In Foster's study [4], those patients with an AO 42C2 fracture also had encouraging results with SF-12 physical and mental scores at a mean of 46 and 51 respectively, which is around average for the normal population - this is surprisingly high following severe injury and prolonged treatment in external fixation. These injuries are associated with high levels of morbidity, and it is positive that patients tend to be happy with their outcomes, when scored. Foster [4] commented that several patients volunteered that they had developed a more positive outlook on life having survived major injury with a lower limb intact. Unfortunately, no scoring data were available for any of the studies investigating IMN. The results of these PROMS overall are encouraging, but the lack of such data following IMN is concerning.

There are limitations to this analysis. The use of 'time to union' as the primary outcome measure may be criticized. To be completely accurate this would require daily radiographs, which is not practical or reasonable and was not performed in any of the papers. A better end point would be to categorize the time to union within a time scale, for example the numbers of patients with fractures healed by three, six, nine, twelve months etc.; however, the dataset available does not provide the detail required for this level of analysis. The studies were all case series, with variable materials and methods which could lead to bias. However, it does appear that the findings could be extrapolated to the wider population as the included studies largely reported similar basic demographics, with regard to mean age and a dominance of male patients, and there was a higher proportion of open compared to closed fractures, which is in keeping with the existing epidemiological data available for these injuries [1].

The significance of the results is tempered by the standard of the studies available, which are largely retrospective case series, with limited information on soft tissue injury severity and management, and poor delineation between the results in closed injuries as compared to open fractures. Some papers exhibited selection bias by excluding those with more severe soft tissue components to their injuries, such as Wu and Shih who excluded Gustilo-Anderson grade IIIb fractures. The functional outcome and quality of life following IMN compared to ORIF and CEF has also not been adequately studied.

Conclusion

From the evidence available, reamed IMN provides the fastest time to fracture union and the shortest time from injury to definitive fixation in the treatment of these fractures, and should probably be the treatment of choice in the sub-group of closed segmental tibial fractures. However, there appears to be an elevated risk of deep infection with IMN compared to ORIF and CEF, particularly in open fractures, and therefore we suggest that IMN is a high risk operative strategy for open segmental tibial fractures. From the evidence available, this appears to be a sub-group of patients in whom CEF provides the best results.

Well-designed multi-centre RCTs to assess patient reported outcomes and complication rates following different modalities of fixation in both closed and open segmental tibial fractures are needed, so that a consensus agreement can be made as to the optimal management of these complex injuries.

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Table 1: Results of the Critical Appraisal Skills Programme (CASP) questionnaire for Cohort Studies for each included paper

Study	**1**	**2**	**3**	**4**	**5a**	**5b**	**6a**	**6b**	**7**	**8**	**9**
Beardi	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Foster	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Giannoudis	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Giotakis	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Huang	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Kakar	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Kim	Y	Y	Y	N	N	N	N	Y	Y	Y	Y
Ma	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Ozturkmen	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Reynders	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Rommens	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y
Teraa	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Wu	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y

Table 2: Results from mixed treatment studies

	Fixation modality	Number of cases	Age (years)	Male: female	Open: closed	Mean time to union (weeks)	Complications
Giannoudis	**IMN**	16	38.9	25:2	12:4	40	2 deep infection** 4 superficial infection 2 compartment syndrome 1 amputation 1 exchange nail 2 converted to CEF 1 application of LISS plate and bone graft for delayed union
	EF	8, of which 4 converted to tibial nail			7:1		2 deep infection (1 after conversion to IMN)** 1 superficial infection 1 amputation 4 converted to tibial nail 1 converted to CEF 2 malunions
	ORIF	2			0:2		1 compartment syndrome 1 superficial infection
	Plaster	1			0:1		1 malunion
Teraa	**IMN**	17	47	22:8	17:13	34	10 deep infection 21 delayed union 4 non union 1 amputation 17 secondary procedure***
	ORIF	3					
	EF	5					
Beardi	**IMN**	16	44	21:5	10:16	49	9 pseudarthrosis 1 delayed union 10 secondary procedure
	ORIF	5					2 axial malalignment 2 secondary procedure
	EF	5					3 pseudarthrosis 2 deep infection 5 secondary procedure
Rommens	**ORIF**	23	37	37:3*	26:15	34	5 wound problems 2 pseudarthrosis 2 pseudarthrosis with failure 1 deep infection 2 refracture 1 malunion
	EF	18					5 wound problems 2 pseudarthrosis 2 septic pseudarthrosis 1 refracture 1 delayed union 1 malunion

IMN = Intramedullary Nail; EF = External Fixation; ORIF = Open Reduction and Internal Fixation; Cons = Conservative Management; LISS = Less Invasive Stabilisation System
NS = not stated
* 40 patients, 41 cases (one bilateral)

** all deep infections occurred in open fractures
*** complications not separated by fixation modality within the paper

Table 3: Results from single fixation method studies

Author and fixation modality		Number of cases	Mean patient age in years (range)	Male : Female	Open : Closed	Mean Fracture union (weeks)**	Complications
Huang	**IMN**	33	56 (18-79)	29:4	24:9	18.5 (12-34)	2 deep infections 1 shortening >1.5cm 1 angulation 12°
Kakar		62 (only 51 followed up)	44 (16-90)	42:20	46:5	21.7	6 compartment syndrome 3 chronic pain 1 superficial infection 2 shortening >1cm 3 angulation >5°
Kim		4	38 (19-52)	4:0	NR	NR	1 delayed union
Wu		42	32 (18-54)	31:7	32:10	19.4 (SD 6.9)	1 delayed union 6 angulation <5° 26 nail removal
Ma	**ORIF**	25	38 (15-67	15:10	22:3	25 (12-46)	3 superficial infection 2 shortening >1cm 3 angulation >5°
Reynders		23	34 (17-72)	21:2	23:0	19 (10-44)	3 compartment syndrome 13 fasciotomies 2 non union 1 deep infection 1 angulation 8° 7 plate removal 5 EHL palsy
Giotakis	**CEF**	20	47 (25-79)	15:5	15:5	25.1 (10-80)	1 compartment syndrome 2 non-union 3 angulation >5° 1 shortening 1.5 cm 1 deep infection
Ozturkmen		24	38 (22-66)	19:5	17:0	38.1 (10-80)	1 compartment syndrome 13 superficial infection 1 excision middle segment of bone 1 non union
Foster*		10	48	NS	3:7	29.7 (16-41)	2 delayed union

IMN = Intramedullary nail; ORIF = Open Reduction and Internal Fixation; CEF = Circular External Fixation; NR= Not Reported
* study of 40 complex tibial fractures, 10 of which were segmental
** ‘time to union’ converted from months to weeks in some cases to aid clarity

Supplementary Table 1: MEDLINE search strategy.

	Search Term
1	Tibial/
2	Fracture/
3	Segment.tw.
4	Complex.tw.
5	AND/1-4