The “Road to Union” protocol for the reconstruction of isolated complex high-energy tibial trauma

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Abstract

Introduction:

The purpose of this study was to describe a standardized staged approach, "The Road to Union", for the reconstruction of isolated complex tibial trauma , both acute and chronic in nature.

Methods:

This retrospective study included all patients treated for complex tibial trauma at a specialized limb reconstruction centre, including acute open fracture as well as infected and aseptic non-unions. This standardized approach includes eight specific steps, employed in sequence. The time in external fixation (EFT), the external fixation index (EFI), and the distraction consolidation index (DCI) were the primary outcome measures. The relationship between EFI and DCI was assessed using Pearson's moment correlations.

Results:

Thirty-two patients with a mean age of 34.7±14.2 years were included; 12 were treated for complex open tibial fractures with bone loss, 13 for infected non-unions, and 6 for aseptic non-union. The mean bone defect was 66±32mm. The total EFT was 42.5±14.8 weeks; the EFI measured 51.9±25.3 days/cm, and the DCI measured 48.3±21.4 days/cm. Union was achieved in 29 out of 32 patients (91%), and there was a strong and significant relationship between EFI and DCI ($r=0.92$, $p=0.0001$) measurements. Pin site infections were observed in 11 patients, and 3 patients had persistent non-union. Three patients underwent delayed amputations when reconstructive procedures were unable to achieve union.

Conclusion:

The findings of this study demonstrate that a standardized staged treatment protocol of debridement, circular external fixation, soft-tissue management, distraction osteogenesis, and functional rehabilitation can result in a high rate of union in cases of complex tibial trauma, both acute and chronic in nature.

Keywords:

Tibial Fractures; complex trauma; bone loss; nonunion; infection; bone transport; limb reconstruction

Level of evidence

Level IV; case series

Introduction

The tibia is one of the most commonly injured long bones [1,2], and its superficial location leaves it more susceptible to severe open fractures with bone loss [3,4]. The reported incidence of tibial shaft fractures varies from 8.1 to 37.0 per 100,000 patients, with males having the highest incidence [5]. Larsen reported that 21% of these injuries were caused by high-energy trauma, but only 17% sustained more complex AO C type fractures.

Surgical management of these high-energy traumatic injuries remains a major clinical challenge [4]. Thorough debridement of devitalized bone, appropriate soft tissue coverage, and early stabilization are the most successful strategies for reducing complications, and increasing the chances for bony union [2,4,6] Several authors have suggested that the use of a tensioned wire circular external fixator has distinct advantages over intramedullary nailing for the most severe open injuries [3,4,7]. These devices allow more specific intra-operative reduction and correction of residual multi-planar deformities and by manipulating and adjusting struts and other components the reduction can be further modified post-operatively, potentially reducing the need to return to the operating room [7]. However, despite these advantages this technique is associated with a number of disadvantages and possible complications. In a systematic review by Dickson, et al. the superficial infection rate was 30.9%, which was significantly higher compared to the 3% rate reported with IM nailing [3]. In contrast time to union, risk of deep infection, and reoperation rates were all significantly lower with external fixation [3].

Soft tissue management is often the most critical factor to achieve satisfactory clinical outcomes [2]. Aggressive debridement of all involved highly contaminated or necrotic bone and soft tissue, is vitally important in the early treatment phase [8]. The timing of plastic surgical flap coverage is still controversial [8], although most, studies have demonstrated higher flap survival and lower infection rates when there is early intervention [9-12].

The final outcome of complex tibial fractures is influenced by many variables including the mechanism of injury, patient factors, and both initial and definitive management. These different factors require a structured approach to achieve the best possible outcomes while reducing complication rates [13,14]. Cognizant of its importance, the British Association of Plastic, Reconstructive and Aesthetic surgeons (BAPRAS) and the British Orthopaedic Association together introduced guidelines to improve the management of complex tibial fractures in 1997 [13]. Surprisingly, several authors have reported that awareness of and adherence to these recommended standards was poor, with no significant changes noted in the last decade [13-15].

Adopting many of the above principles, a standardized approach has evolved at our institution that we consider the “Road to Union”. The purpose of this study was to describe in detail our current treatment protocol for managing complex tibial fractures, including both acute open injuries as well as late presentations of either infected or non-infected non-unions. The secondary purpose was to establish the relationships between the external fixator index (EFI) and the distraction consolidation index (DCI), with respect to various clinical parameters. We hypothesized that use of a standard treatment protocol would result in a consistently high rate of success, with bone union and resolution of infection if present.

Methods

Patient Identification and Data Collection

This study was conducted as a retrospective cohort study. All patients were identified from the departmental database who were treated for complex open tibial fractures or infected or non-infected non-unions at a specialized limb reconstruction unit and trauma centre between 2007 and 2015. Prior approval to conduct this review was obtained from the Institutional Review Board and Human Research Ethics Committee. Patients were included if they were aged between 16 and 60 years, sustained acute traumatic Grade II/III open tibial shaft fractures, complex closed AO type C tibial shaft fractures, or presented with an infected or non-infected tibial non-union, and were followed up for a minimum of 12 months. The following exclusion criteria were applied: history of previous ipsilateral tibial fractures, contralateral lower extremity fractures, polytrauma, chest or abdominal trauma, and closed head injuries.

Patient Management Using the "Road to Union" Protocol

Surgical treatment of complex traumatic tibial pathology adhered to a standardized protocol that has been divided into eight defined steps, described in detail below. The management of open fractures, infected cases whether united or not, and cases with bone loss requiring limb reconstruction and lengthening followed all eight steps. In patients who sustained closed injuries without bone loss, the first two steps were generally omitted.

Step 1: Debridement, PMMA spacer as the Masquelet technique, and provisional stabilisation with external fixation.

Initial debridement followed established principles, with resection of all necrotic and non-perfused tissue until healthy bleeding margins were observed [11,16]. Definition of involved non-viable tissue was determined by its clinical appearance, as judged by individual surgeons. Despite its subjective nature, this is consistent with prior publications, and remains the best method currently available [11,16,17]. In open fractures, or in non-unions with significant bone loss, an antibiotic impregnated cement spacer (Palacos®, Zimmer, Warsaw, Indiana USA) was inserted into the bone defect for local antibiotic delivery and to preserve space for subsequent definitive osseous reconstruction [16]. These spacers were provisionally shaped outside the body to limit thermal damage, but were inserted prior to curing completely to allow modification of the spacer slightly to achieve overlap with the bone ends [18].

Prophylactic or therapeutic fasciotomies were routinely performed when clinically indicated. Finally, temporary external fixation was applied to stabilize the fracture.

Step 2: Soft tissue coverage and wound closure

When necessary, additional debridement was performed and wound cover was generally provided within 48-72 hours of presentation to the unit by an experienced plastic and reconstructive surgeon. Soft tissue coverage was usually obtained with a vascularized free flap. For smaller defects an antero-lateral thigh flap (ALTF) was used, and for larger defects a latissimus dorsi free flap was typically employed. This step included a latency period to allow the flap to mature and the soft tissues to stabilize.

Step 3: Definite fracture fixation with a hexapod capable circular frame

Definitive fracture fixation was performed by completing the ring external fixator, and six struts were added to allow for deformity correction and bone transport. If a circular fixator was used for temporary fixation earlier, an additional proximal and/or distal ring was added to the existing external fixator ring construct. At this stage the hexapod fixator was also readjusted as required to achieve a more anatomical reduction. Thereafter, patients were allowed to mobilize as tolerated. If infected, tailored antibiotic therapy was commenced according to culture sensitivities and typically continued for 6 weeks.

S*tep 4: Removal of PMMA spacer and corticotomy*

The cement spacer was removed at six weeks. This arbitrary cut-off period allowed the flap to mature and the soft tissue to settle so that the tibia was ready for bone transport when necessary. The spacer was removed using a mini-open approach, lifting the flap from the opposite side away from the vascular pedicle. The induced membrane was split longitudinally, and closed with resorbable sutures once the spacer was removed. At this stage a low energy percutaneous metaphyseal corticotomy was performed to prepare for distraction osteogenesis and bone transport [19,20].

Step 5: Latency period, gradual distraction

Distraction was commenced after a latency period of 7-10 days, and gradual controlled mechanical distraction performed resulting in osteogenesis in the gap created. Distraction at a rate and rhythm of 1 mm daily in four increments of 0.25 mm was typically used, modified as indicated based on the radiographic appearance.

Step 6: Docking site modification

Once the desired length was achieved, an open docking site modification procedure was completed. This involved debridement of the docking site, opening of the intramedullary canal, and autologous bone grafting obtained from the proximal tibia. The docking site was acutely compressed using the frame under image intensifier guidance. If the patient had developed an equinus deformity an Achilles tendon lengthening was performed by triple hemi-section [21].

Step 7: Functional rehabilitation

Rehabilitation included progression to full weight bearing and functional loading exercises as tolerated for active, active-assisted, and passive range of motion of all joints of the lower extremity. In particular, active and passive ankle dorsiflexion to avoid equinus deformities was encouraged. Physical therapists implemented both, isometric and isokinetic strength exercises, and patients were asked to complete the prescribed exercise regime at least once daily after discharged home.

Step 8: Frame removal, long-term surveillance

After completing the docking procedure, patients had monthly follow-up visits. Once union was observed at the docking site and the regenerate demonstrated cortication over its entire length, the circular fixator was destabilized but left in situ. Radiographic union was defined as evidence of bridging callus for at least three of four cortices, or obliteration of the fracture lines on plain radiographs [22]. Radiographic qualitative assessment of bone regenerate was assessed using the criteria of Fischgrund et al. [23], requiring three of four cortices to be continuous and at least 2 mm thick. In addition to the radiographic assessment, clinical criteria were also applied which required the patient to be pain free when weight bearing, and non-tender to palpation over the entire length of the tibia. Patients were re-evaluated 7-10 days later, and if there was no radiological evidence of deformity and patients remained painfree the fixator was removed. After fixator removal the leg was protected in a functional brace for 6 weeks.

Outcome measures

The time in the external fixator (EFT) was recorded and defined as the time from initial application of the fixator until removal. The external fixation index (EFI) was calculated by dividing the time (days) in the external fixator by the achieved lengthening (centimeters). The distraction-consolidation index (DCI) was calculated as described by Fischgrund, et al [23].

Statistical analysis

Descriptive statistics (means and standard deviation) was used to determine the demographic variables, as well as EFT, EFI and DCI. Pearson's product-moment correlation coefficients were used to establish the strength of the relationships between EFI and DCI. A Spearman Rank test was used to investigate the strength of the relationship between EFT and distraction gap/existing bone defect post debridement. An a-priori sample size analysis was conducted using G*Power 3.1.9.2 using the following variables: Cohen's effect size $q \geq 0.6$, $p=0.05$, power of 0.8, critical $z=-1.2$, ß error 0.2, two tailed. The sample size calculation based on these parameters indicated that a minimum of 30 patients were required to provide 80% statistical power. All analyses were conducted using STATA SE (Version 12.0; StataCorp, College Station, Texas, USA) for Windows.

Results

Between 2007 and 2015 a total of 43 patients with a mean age of 34.7±14.2 years were treated for complex tibial trauma. Eleven of these patients were excluded from the study: six patients did not complete the standard protocol, three patients underwent amputation, and in two patients the external fixator was removed and replaced with internal fixation.

Of the remaining 32 patients, 12 patients were treated for acute complex tibial trauma. All these patients presented with Gustilo-Anderson Grade 3 open fractures and/bone defects. Thirteen patients were treated for infected non-unions; of these, six patients sustained open fractures that were initially treated elsewhere. Seven patients were treated for non-union, and four of these were initially treated at a different hospital. The demographic details are summarized in table 1.

All 32 patients underwent bone transport, with a mean bone defect of 66+/-32mm. Nine of the twelve patients (75%) with trauma, and eight of the thirteen patients with infected non-unions (61%) were treated using a cement spacer. None of the patients with malunion required PMMA spacer placement. All 12 patients with acute traumatic injuries had Grade IIIB open fractures and required soft tissue cover with a free flap. Flap coverage was achieved at a mean of 1.2 days. Fifty-four percent of patients in the infected malunion group also required flap coverage; all of these patients were previously treated for open fractures (Table 2).

The time in the external fixator (EFT), the external fixation index (EFI), and the distraction-consolidation index (DCI) was similar for all of the subgroups and the overall total. Total EFT was 42.5±14.8 weeks; the EFI measured 51.9±25.3 days/cm, and the DCI measured 48.3±21 days/cm (Table 3). Pearson's correlation moments revealed a strong and significant relationship (r=0.92, p=0.0001) between EFI and DCI. For defects less than 7 cm (n=23), Pearson's correlation moment was r=0.90 (p=0.0001). Spearman Rank test established a strong but non-significant relationship (r=0.75) between EFT and the distraction gap. Similar relationships were observed when subdividing groups into tibial fracture (r=0.80), infected non-unions (r=0.85) and non-union (r=0.89). Although the latter analysis was not sufficiently powered, the data served to establish whether there were substantial differences between the three groups, and in particular, to investigate whether use of a PMMA spacer increased the time in external fixation. Post hoc analysis using G*Power 3.1.9.2 revealed that the sub-analysis of the relationship between EFI and DCI was sufficiently powered (ß=1). However, it was demonstrated that the EFI was inaccurate when the distraction gap was less than 8 cm.

Complications were seen in 53% of all patients. Minor pin tract infections occurred in 11 cases and resolved with oral antibiotics and local pin site care. In the infected non-union cohort, one patient sustained a fracture through the regenerate that was later successfully treated with intramedullary nailing. Persistent infection and non-union in a 32 -year-old immunocompromised HIV positive male patient, required subsequent above knee amputation. One patient who sustained a stress fracture at the docking site was treated non-operatively. In the trauma cohort, another patient with a mangled extremity after attempted limb reconstruction had a persistent non-union, and elected to undergo below knee amputation. One patient required two adjustments of his circular fixator, and further leg lengthening for a four centimetre short tibia. In the aseptic nonunion cohort, one patient underwent below knee amputation for chronic unremitting pain and persistent non-union.

Discussion

The results of this study demonstrate that a standardized approach using circular fixation for the management of complex tibial trauma, both acute and chronic in nature, has a high probability of success in a specialized centre. Union was achieved in 91% of all cases, and this is comparable to other previously reported series [24-27]. However, all of these series were limited by their small size, and union rates might have been significantly higher with the inclusion of more patients. This is supported by the results of a systematic review by Dickson, et al. where a union rate of 98.6%

was achieved in 420 patients with grade III open fractures treated with a circular frame [3].

In this study, as expected there was a direct and strongly positive relationship between the size of the bone defect and time spent in external fixation. Sub-analysis was not sufficiently powered to draw meaningful conclusions, but there was a clear trend demonstrating that spacer placement does not increase EFT. In fact, patients who presented with infected non-unions spent an average of only 39.7 weeks in the circular fixator, compared to 43.4 weeks for patients with acute open fractures, and 46.1 weeks in patients with aseptic non-unions. One possible explanation for this discrepancy could be that the induced membrane facilitates osteogenesis by secreting growth factors (angiogenic, chondrogenic and osteogenic) that potentiate bone regeneration, especially when combined with distraction osteogenesis [28,29].

In addition, the PMMA spacer mechanically blocks soft tissue invagination, and provides a stable envelope through which bone transport can be performed [24]. In our cohort, the mean external fixation index (EFI) of 52 days per cm is very similar to that reported by Marais & Ferreira, who reported a mean of 53 days per cm in patients with tibial bone defects in chronic osteomyelitis [24]. This is also corresponds closely to the result reported by Sangkaew, a mean of 50 days per cm in 70 patients with nonunions, malunions, infected open fractures, and short limbs [30].

Similar to Fischgrund, et al. [23], we observed a direct and significant relationship (r=0.53, p=0.0001) between the magnitude of the distraction gap and EFI. However, we found no difference for EFI or DCI when comparing between defects either smaller or larger than 7 cm. In our study, as expected, very strong and significant relationships between EFI and DCI (r=0.98, p=0.0001) were observed. Furthermore, there were strong and significant relationships between EFI and DCI for all three subgroups, which were powered sufficiently according to the post hoc analysis. It is not clear why we could not confirm Fischgrund's findings. However, we would speculate that there might be a critical threshold between these two variables to reach a significant difference, but the mean difference between EFI and DCI in our study was only 5.1%.

The time interval from the application of the ring fixator and commencement of bone transport is the only variable that could possibly influence differences between these two parameters. The general recommendation is to allow a latency period of 7-10 days prior to distraction. In an earlier study, Yasui, et al. were able to demonstrate that immediate distraction after corticotomy resulted in delayed callus formation resulting in a premature bony fusion [31]. Fischgrund, et al. [23] began bone distraction 7 days after the corticotomy, whereas the mean time in our cohort was 14.1 days. However, this study had two outliers (44 and 121 day latency periods) and when removed, the latency period was only 9.3 days, which was still 30% longer than in Fischgrund et al's study [23]. It is certainly possible that the latency period is instead the critical factor, and a slightly longer latency period may have resulted in the regeneration of both the intramedullary blood supply and increased local microvascular supply.

Another potential factor to explain the differences between DFI and EFI could be that the consolidation of the regenerate is highly dependent upon the length of the regenerate bone. For instance, Sakurakichi, et al. [32] has previously suggested a direct relationship between regenerate maturation and length gained. This was observed as an exponential increase in time to consolidation with length gain, however, this improvement was only seen if the length gain was less than 3 cm, which is significantly shorter than the 7 cm reported by Fischgrund [23]. The findings of this study are supported by Kristiansen et al., who were also unable to demonstrate a relationship between EFI and length of the regenerate bone [33].

There were several complications associated with this procedure, as have been reported in prior studies. Minor pin tract infections occurred in 11 cases (34%), all of which successfully resolved with oral antibiotics and local wound care. These rates are similar to previously reported findings on pin tract complications in several studies [3,24,34,35]. In addition, three patients had persistent non-union, one patient fractured through his regenerate, and one patient sustained a stress fracture at the docking site. One patient required multiple adjustments of his fixator resulting in a shortened tibia requiring subsequent limb lengthening. The overall complication rate was 53%, but when subtracting the cases with pin tract infections the major complication rate was only 19%, which is again comparable to other studies [3,33,34]. It could be argued that the HIV positive male patient should have undergone amputation rather than limb reconstruction. Earlier studies certainly demonstrated that positive HIV status was associated with higher rates of infection and delayed union [36,37]. However recent evidence clearly suggests that there is no association between HIV status and surgical outcome in these patients unless the CD4 count is below 350 cells/μl [38-41]. It is therefore suggested that HIV status should not alter the management of open tibial fractures [39].

Patient-perceived outcomes can be poor following limb salvage, despite good functional outcomes and a high incidence of return to work. Pain often persists in more than 50% of patients [7,42.43]. Many potential confounders influence successful union outcomes [6,44.45], and Metsemakers, et al. demonstrated that smoking, diabetes, obesity, and open fractures are all at increased risk for deep infection [44]. Nevertheless, the severity of the injury, including open fractures and polytrauma, remains the most common risk factor for non-union. A study by O'Halloran et al. found that open fractures, compartment syndrome, Gustilo type IIIB, and chronic disease (HIV, hepatitis) were major risk factors for non-union [45]. Therefore, to minimize the risk of these complications, the principles of treatment include meticulous debridement and excision of all devitalized tissue, early soft-tissue coverage, appropriate antibiotic cover, and stable skeletal fixation [11-13,46]. These principles have not changed in over 20 years [47], yet unfortunately over 50% of all patients still receive substandard care [13].

The findings of this study demonstrate that a formal structured approach to management of these severe injuries results in reproducible and reliable outcomes with a high rate of union. The application of a circular fixator facilitates early soft tissue management, correction of deformity, restoration of limb length, and allows early weight bearing to promote rapid functional recovery [2,3,11].

This study has some inherent limitations. The sample size is relatively small, although this is typical of studies dedicated to similar patient cohorts. The retrospective nature of the study might have introduced some selection bias. Because the study cohort reflects the outcomes from a single centre specialized in limb reconstruction, the results demonstrated here may be difficult to replicate in less experienced units.

Conclusion

The findings of this study demonstrate that a standardized staged treatment protocol of debridement, circular external fixation, soft-tissue management, distraction osteogenesis, and functional rehabilitation can result in a high rate of union, in cases of complex tibial trauma, both acute and chronic in nature. The correlation between EFI and DCI was strong and significant, and did not suggest that there were meaningful differences between smaller and larger bone defects.

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Table 1: Demographic details of all patients included and the subdivided groups

	Number of included patients	age	gender	Grade III open #	Mechanism of Injury
Total	32	34.7±14.2	M=21 F=11	N=25	MVA=8 MBA=5 Fall=3 Direct Trauma=6 Sports Injury n=1 PVA=1 Other trauma n=6 Gunshot injury n=2
Sepsis	13	33.6±4.4	M=6 F=7	N=9	MVA=5 MBA=0 Fall=2 Direct Trauma=0 Sports Injury n=1 PVA=0 Other trauma n=5 Gunshot injury n=0
Trauma	12	32±14	M=10 F=2	N=12	MVA=1 MBA=3 Fall=1 Direct Trauma=5 Sports Injury n=0 PVA=1 Other trauma n=1 Gunshot injury n=0
Non-Union	7	41.2±14	M=5 F=2	N=4	MVA=2 MBA=2 Fall=0 Direct Trauma=1 Sports Injury n=0 PVA=0 Other trauma n=0 Gunshot injury n=2

Table 2: Treatment details for all patients

	Flap Cover	Type of reconstruction	Mean time to reconstruction post trauma (in days)	Defect Size (in mm)	Mean spacer time (in weeks)
Total N=32	20 Open # n=20	M=17 B=32 L=2	N/A	66±32	8.7±3.2
Sepsis N=13	7 Open # n=7	M=8 B=13 L=2	N/A	52±26	9.9±3.6
Trauma N=12	12 Open n=12	M=9 B=12 L=0	1.2±1.2	82±36	7.7±2.2
Non-Union N=7	1 Open # n=1	M=0 B=7 L=0	N/A	62±24	N/A

Table 3: Treatment Results

	EFT (weeks)	EFI (days/cm)	DFI (days/cm)
Total N=32	42.5+14.8	51.9+25.3	48.3+21.4
Sepsis N=13	39.7±13.5	64.6+33.6	57.7+28.4
Trauma N=12	43.4±14.7	38.2+10.5	36.4+9.9
Non-Union N=7	46.1±18.2	51.6+11.5	51.4+10.2