Two-stage combined ortho-plastic management of type IIIB open diaphyseal tibial fractures requiring flap coverage: Is the timing of debridement and coverage associated with outcomes?

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Conflicts of interest

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ABSTRACT

Objective: To delineate whether timing to initial debridement and definitive treatment had an effect on patient outcomes in those undergoing two-stage ortho-plastic management of Gustilo-Anderson type IIIB open tibial diaphyseal fractures.

Design: Retrospective comparative cohort study over a two year period.

Setting: Level 1 trauma centre

Patients/Participants: A total of 148 patients were identified. Following exclusion of ankle fractures, non-diaphyseal fractures and those who did not undergo two-stage ortho-plastic management, 45 patients were eligible for final analysis.

Intervention: Time to initial debridement and definitive management

Main Outcome Measurement: Deep infection. Secondary outcomes being nonunion and flap failure. Multiple linear regression was utilised for outcomes. We assumed *a priori* that p values of less than 0.05 were significant.

Results: Mean age was 54 years (SD 23.0), with 28 males and 17 females. Over a mean 2 year follow up, there were four (4/45) deep infections, two infection associated flap failures and one vascular flap failure. All patients progressed to union. The mean time to initial debridement for the whole cohort was 19 hours (SD 12.3), and the mean time to definitive reconstruction was 65 hours (SD 51.7). Longer time to both initial debridement and definitive reconstruction was not found to be significantly associated with deep infection, infected flap failure or nonunion.

Conclusion: Utilising a two-stage ortho-plastic operative algorithm, timing to initial debridement and definitive fixation with soft tissue coverage was not associated with negative outcomes.

STUDY TYPE: THERAPEUTIC. LEVEL OF EVIDENCE: III

Introduction

Type IIIB open tibial fractures are severe, high energy injuries that require soft tissue free flap as well as bone reconstruction. Combined orthopaedic and plastic specialist input is key in managing these injuries, and the subsequent emergence of this combined approach is now considered by some to be the gold standard.[1-3] This treatment approach is a core recommendation in the standards of care in the United Kingdom, with the prevention of unfavourable outcomes such as deep infection, nonunion and flap failure being key treatment aims.[4] However, Tte effect of time to debridement and definitive soft tissue coverage on these outcomes remains contentious. The traditional “six-hour” rule established on the back of evidence by Kindsfater et al.[5] has not stood the test of time and is now considered outdated.[6] Additonally, it is widely accepted that early intervention with combined orthopaedic and plastic surgical input for both the initial debridement and definitive treatment is desirable.[7]

Our unit has utilized a combined ortho-plastic (orthopaedic and plastic surgery) approach for all open fractures, defining a clear staged treatment algorithm for type IIIB open tibial shaft fractures. To validate the safety of the unique approach used in the study unit, timing at every stage is a key component that must be analyzed. We hypothesized that the timing of debridement and definitive coverage may be associated with better outcomes when utilizing a combined ortho-plastic approach consisting of a two-stage debridement and intramedullary nailing for type IIIB open diaphyseal tibial fractures.

Patients & Methods

Inclusions and exclusions

This was a retrospective comparative cohort study over a two year period from May 2014 to May 2016. A total of 148 consecutive patients were identified that met the BOAST 4 criteria – primarily an open tibial injury which requires transfer to a level 1 trauma centre for specialist care .[4] This comprised 145 type IIIB and 3 type IIIC open tibial fractures. The national Trauma Audit and Research Network (TARN) database was reviewed for these patients along with case notes, operation notes, clinic letters and radiographs. Sixty-one cases were categorized as ankle fractures and were excluded. A further 21 were excluded as they were metaphyseal tibial fractures (9 proximal (AO-41) and 12 distal (AO-43)). Seven patients were also excluded due to early mortality pre-operatively (n=1), peri-prosthetic fracture (n=2), primary bone transport procedure (n=2) or primary amputation (n=2). A further 14 patients were not fit for more than one anaesthetic and therefore had initial debridement, definitive fixation and local flap coverage as a single sitting. All type IIIC fractures were excluded as part of the above criteria. A total of 45 patients were therefore eligible for final analysis. This is shown in figure 1.

Surgical interventions

The majority of patients presenting to our (level 1) major trauma centre with an open type IIIB diaphyseal tibial fracture undergo a two-stage ortho-plastic approach.[8] Stage one consists of initial wound excision and thorough debridement, whilst the bone is temporarily stabilized using a 3.5mm LCDCP plate as temporary internal fixation (TIF). External fixation as a temporizing measure has ceased to exist as part of the novel ortho-plastic protocol in the study unit.[9] This has been the case since May 2015, one year prior to the end period of the study. Patients prior to this novel protocol received external fixation. The switch in protocol primarily owed to the unnecessary added risk of pin site infection, which has been shown to be as high as 28%.[10, 11] The use of a temporary internal fixator negates this risk, and can be used (as a bridging device) even in fractures with large zones of comminution, provided there is intact shaft integrity proximal and distal to the plate. This is fixed bicortically following fracture reduction. Use of the plate is a very simple technique that encourages adequate exposure of the zone of injury.[9, 12] All wounds, regardless of type of temporary fixation, were dressed with negative pressure wound therapy (NPWT) and this is not removed until the second stage. Following stage one, the patient is physiologically stabilised until definitive fixation and soft tissue coverage, This is then undertaken on a dedicated ortho-plastics operating list.

At the second stage, the TIF is removed and the site re-debrided before a fresh transcortical 3.5mm DCP is applied to the anterior tibial cortex. This plate-assisted technique facilitates the intramedullary nailing procedure in all cases as part of the unit's ortho-plastic protocol. Definitive soft tissue free flap coverage and bony stabilisation is then undertaken during this single theatre episode. This second stage has previously been referred to as "fix and flap".[13] Intravenous antibiotics are continued until definitive management has been completed.

The above treatment algorithm forms the basis for almost all of open tibial fractures treated in our major trauma unit. As per the British Orthopaedic Association Standards for Trauma (BOAST4) [4], we aimed to achieve all initial debridements within 24 hours regardless of whether this was a primary or secondary transfer from another trauma unit. We aimed to achieve the 72 hour target for definitive soft tissue reconstruction.

Outcomes

The primary outcome measure was deep infection rate with secondary outcomes being nonunion and flap failure.

The diagnosis of deep infection was based on the criteria for 'deep incision surgical site infection', as outlined by the Centers for Disease Control and Prevention (CDC).[14] The primary outcome measure of deep infection was defined as infection requiring surgical debridement and/or prolonged antibiotic therapy following definitive soft tissue reconstruction. The definition was not reliant on positive cultures.

Diagnosis of nonunion was based on clinical and radiological findings over a minimum clinic follow-up period of >1.2 years, according to the principle outlined by Frölke et al, which reaffirms the contribution of the Weber and Cech model of nonunion, specifying that in long bones, a minimum of 6 months should pass before nonunion is considered.[15, 16] Finally, flap failure was defined as total or partial necrosis of the transferred tissue. Flap failure occurring 1 month or more after definitive coverage was assumed to be secondary to deep infection.

Statistical analysis

Analyses were undertaken with IBM "SPSS" Statistics version 23 (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Descriptive statistics were used for categorical data and Shapiro-Wilkes testing for normality for any continuous data. Parametric data was expressed as mean and standard deviation, with non-parametric data as median and interquartile range (IQR). Collinearity testing via data tolerance and variance inflation factors (VIF) for independent variables was carried out. A data tolerance output of < 0.5 and VIF of > 4 for age and ASA indicated that these two factors were highly correlated. Therefore, ASA was removed from the model. Multiple logistic regression analysis was utilized for the outcomes of deep infection, nonunion and flap failure. The predictor variables analyzed were time to initial debridement, time to definitive fix and flap, whether the patient was a primary referral or secondary transfer, type of temporary fixation (external fixation vs. TIF), flap type, age at the time of injury, gender, laterality, comorbidities (smoking and diabetes), severity of shaft fracture (AO classification) and whether the new plate used to facilitate tibial nailing was retained or removed. Significance for mean time to initial and definitive management was ascertained via an independent samples t-test with the grouping variables being the outcomes described above. Receiver operating characteristic (ROC) curves were used to ascertain timing cut-offs for when a negative outcome would be more likely. We assumed *a priori* that p values of less than 0.05 were significant. The observed power for this study was 0.173 with regards to the primary outcome of deep infection.

Results

Demographics

A total of 45 patients were included in final analysis, all of whom underwent two-stage definitive bony stablization and soft tissue coverage as defined in the methods. The mean age of the patients was 54 years (SD 23.0), with 28 males and 17 females. There were 23 left sided injuries with 22 right sided. Eleven patients were smokers at time of injury and 3 were diabetic. The median American Society of Anesthesiologists (ASA) grade was 2 (IQR 1). There was a mean follow up of 2.0 years (SD 0.42). Thirty patients underwent free flap soft tissue reconstruction with 15 undergoing a local flap. Of the free flap group, the majority (25) were anterolateral thigh (ALT) flaps. An external fixator was used in 11 (11/45) patients, with TIF in the remaining 34 (34/45). With regards to fracture severity, 22 (48.9%) shaft fractures were AO type A, 17 (37.8%) type B and 6 (13.3%) type C. The plate was retained in the final construct in 29 patients (64%).

Outcomes

A total of 5 (5/45) patients developed complications, with 1 (1/45) metalwork associated infection, 3 (3/45) infection associated flap failures and 1 (1/45) vascular associated flap failure.

For the primary outcome, there were a total of four (4/45) deep infections in this study. This is presented in table 1. Of those who developed deep infection, two were smokers (2/4 in the deep infection group compared to 9/41 in the group that did not develop deep infection; p=0.499) and one was diabetic (1/4 in the deep infection group compared to 2/41 in the group that did not develop deep infection; p=0.077). There was no association between bone injury severity and the outcomes of deep infection (p=0.754), infection or vascular associated flap failures (p=0.378, p=0.997) and non-union (0.997).

For secondary outcomes, there were four (4/45) flap failures, three of which (3/4) were associated with infection with one (1/4) a vascular associated flap failure. This vascular associated flap failure was not considered as part of the primary outcome. There were no cases of nonunion.

Timing

A total of 17 patients were secondary transfers from a trauma unit within our network, the remainder were direct admissions to our major trauma center. The mean time to initial debridement for the whole cohort was 19 hours (SD 12.3), and the mean time to definitive reconstruction was 65 hours (SD 51.7). Fourteen patients (14/45) were debrided within 12 hours, seven of which (7/14) debrided within 6 hours. Thirty-nine (39/45) patients underwent initial debridement within 24 hours, with 32 patients (32/45) undergoing definitive soft tissue reconstruction with fix and flap within 72 hours.

There was no significant association between secondary transfer from another center and outcomes such as infection (p=0.61, flap failure (p=0.20), and overall complication rate (p=0.29).

Timing and outcomes

Of those patients who developed deep infection, the time to initial debridement and definitive reconstruction was comparable to those who did not develop infection. Mean difference in time to initial debridement was under 1 hour when comparing infected and non-infected groups (p=0.990). This was also under 1 hour for time to definitive management (p=0.952). Patients who were transferred had a longer mean time to initial debridement, with a mean difference of 10 hours (p=0.01) (Table 2).

For those who developed infection associated flap failure, time to initial debridement was lower (mean difference 3 hours), compared to those who did not develop this. However mean time to definitive treatment was longer (mean difference 9 hours) than those who did not develop this complication. The differences were not significant (p=0.724, p=0.873 respectively)).

There was one case of ALT flap failure alone, which was as a result of a microvascular event and happened at less than 24 hours after the second stage reconstruction. This was associated with a significant increase in time to initial debridement (p = 0.007). These figures are represented in Table 3.

For the significant results above, no time-point seemed to offer a definitive cut-off to determine optimal timing for initial and definitive debridement that would lead to a reduced odds of associated negative outcomes.

Independent variables including age, gender, laterality, type of flap, type of temporary fixation and whether the fresh plate was retained as part of final fixation construct (following nailing) were not found to be predictive of the primary or secondary outcomes.

Discussion

This study analyzes both time to initial and definitive bone and soft tissue management in the context of a two-stage ortho-plastic technique for open type IIIB tibial shaft fractures. We report low infection (8.9%), flap failure (8.9%) and no nonunions with use of a coordinated ortho-plastic treatment protocol for type IIIB open tibial fractures. Whilst underpowered, the data demonstrates no association between an increased time to management and the primary outcome of deep infection. Furthermore, there was no significant association between secondary transfer from another center and the development of a deep infection.

To the authors' best knowledge, there is limited evidence on the use of a two-stage ortho-plastic approach in the management of type IIIB open tibial fractures, particularly with regards to timing. Traditional management of this type of injury involves skeletal stabilization using an external fixator following first debridement. This is usually followed by definitive stabilization and soft tissue coverage, often performed at two separate surgical sittings.[10, 17] This study follows a novel protocol and treatment algorithm that consists of initial aggressive debridement and temporary internal fixation in the majority (34/45, 75.6%) of cases. This is followed by definitive management at a later date with definitive bony stabilization and soft tissue coverage performed as a single procedure. The benefits of a definitive ortho-plastic reconstruction as a combined procedure on deep infection has previously been reported by Mathews et al.[8] In their study, the deep infection rate was found to be significantly reduced under this protocol (4.2%) compared to those who had fixation and soft tissue coverage over two separate theatre visits (34.6%). Since the publication of this paper, our unit has adopted this protocol as standard.

The deep infection rate in this study is 8.9% and this compares favorably to other studies.[8, 12, 18-22] Certain factors are known to reduce complication rates in these injuries including antibiotic prophylaxis [23] and early transfer to a major trauma center with combined orthopaedic and plastic surgical input.[24] More recently, the LEAP group looked at timing in the management of 315 patients with varying degrees of open lower limb and ankle fractures. Time from injury to initial debridement was not found to be a predictor of deep infection, however timely transfer to an appropriate treating center was.[25] An even larger multi-center prospective study by Weber et al has also analyzed timing of surgery in relation to outcomes. In 736 patients looking at all open injuries, factors associated with an increased risk of infection were increasing Gustilo type or tibial injuries. Time to surgery did not seem to be associated with the risk of infection, although in their study the deep infection rate of type IIIB tibial fractures was 18%, with the overall complication rate of type IIIB injuries including upper limb being 16%.[24] Other significant studies have also failed to establish an association between timing of debridement and negative outcomes, particularly infection. Patzakis et al. showed there was a marginally increased infection rate in open fracture in those with a time to debridement over 12 hours, but this finding was not statistically significant.[26] This is supported by others in the literature.[27, 28] Perhaps the most robust study to contradict a negative correlation with timing was that by Hull et al, which consecutively analyzed 364 patients with 459 open injuries. In this series of all upper and lower limb open fractures presenting to their unit, every one hour delay to debridement was associated with a 3.3% increase in deep infection rate, with a greater absolute effect on type IIIB/C tibial injuries. It was also suggested that timing of definitive procedure, type of anesthetic used and tibial site were all additive factors in determining infection rate.[29] The authors also postulate that since 2010, and with the emergence of LEAP data, the creation of the major trauma network in the UK has been successful in reducing delay in patient transfer and time from injury to debridement. This has contributed to the similar timings seen in our study for both initial and definitive debridement regardless of whether the patient was a primary referral or secondary transfer.

In this study, there was no association between bony severity and nonunion, with no patients developing this complication. This may be attributed to a lower proportion (13.3%) of patients sustaining an AO type C bony injury, in comparison to literature where nonunion rates vary from 41-60% in those with severe injury and bone loss.[17, 30, 31]

In our study one patient experienced non-infective ALT flap failure attributed to a microvascular event. This 82 year old diabetic patient underwent a significantly longer time to initial debridement (initial debridement 86 hours, final reconstruction 217 hours). The failed flap was revised to a local flap and split skin grafting with no further complications. In addition to risk factors such as age [32-35] and diabetes [36-38], delayed flap reconstruction is a recognized risk factor for flap failure. The mechanism by which early flap coverage is thought to be important revolves around the obliteration of dead space by a healthy conforming muscle flap.[13] This is designed to reduce bacterial contamination and subsequent local inflammatory response, with avoidance of pro-thrombotic and fibrotic effects that lead to flap failure.[39] In addition, it is believed that bringing healthy muscle into clean fracture site introduces vital humoral and cellular elements which are critical to the fracture healing process.[40] Infection rates seem to be lower as there are studies that indicate delay of flap coverage converts any contaminated wounds into colonized wounds.[41, 42]

In this respect, Godina was a strong proponent of microvascular reconstruction within 72 hours of open injury. Along with faster bony union, flap failure and infection rates were lower in the early compared to delayed flap coverage group.[43] This is further supported by Hertel et al [44] and Gopal et al [13, 40] both of whom conducted studies showing similar outcomes of lower infection rate and faster bony union in those undergoing flap coverage within 72 hours. Furthermore, Wood et al conducted a systematic review of literature in 2012, comparing early, intermediate and late flap coverage in open fractures. He concluded that whilst the optimal timing of flap coverage remains controversial, a delay in flap coverage in open fractures leads to an increased likelihood of negative bony and soft tissue outcomes.

There are key strengths to this study, namely that this is a study looking at timing in this novel approach to the management of type IIIB open tibial fractures. Furthermore, in our department, we are afforded the opportunity to assess both orthopaedic and plastic surgical outcomes in tandem, allowing a more complete analysis of these patients. This study represents a consecutive cohort of patients with similar injuries and management strategy. There are limitations to our study design, this was a retrospective study offering an inferior level of evidence compared to a prospective study. The retrieval of past data allows for recall bias. Furthermore, any significant data in this study will show an association but not necessarily causation. This is particularly in view of the low post-hoc power of this study meaning that whilst the authors are confident of their findings based on accurate data and analysis, conclusions should be made with relative caution. This is particularly relevant as one case of vascular associated flap failure led to a skewe of results, highlighting the need for greater patient numbers to make a firm conclusion. None of our patients proceeded to nonunion however a future study could include further information such as delayed union or functional scores.

Conclusion

Utilizing a two-stage approach with combined ortho-plastic reconstruction is associated with favorable outcomes in comparison to the published literature. The timing of intervention does not appear critical in determining the risk of adverse outcomes. However, early operative management of open tibial fractures is advocated in a safe and timely manner within a definitive ortho-plastic center.

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TABLE AND FIGURE LEGENDS

Table 1. Details of deep infection management per patient.

Table 2. Time to initial management based on transfer or direct admission.

Table 3. Timing and associated complications

Figure 1. Flowchart of inclusions and exclusions.

Table 1

Table 1. Details of deep infection management per patient.

	Type	Diagnosis	Time point	Cultures	Operation
Patient 1	Infected metalwork	Deep tissue samples	12 months post-operatively	B-haemolytic streptococcus	Removal of metalwork
Patient 2	Infection associated flap failure	Deep tissue samples	10 weeks post operatively	Staphylococcus Aureus	Staged revision fixation and flap using circular frame
Patient 3	Infection associated flap failure	Deep tissue samples	2 weeks post-operatively	Enterobacter Cloacae	Exchange tibial nailing
Patient 4	Infection associated flap failure	1. Clinical assessment (rising CRP and new pain) 2. Deep tissue samples	16 weeks post-operatively	Culture negative (commenced on empirical antibiotics)	Exchange tibial nailing

Table 2

Table 2. Time to initial management based on transfer or direct admission.

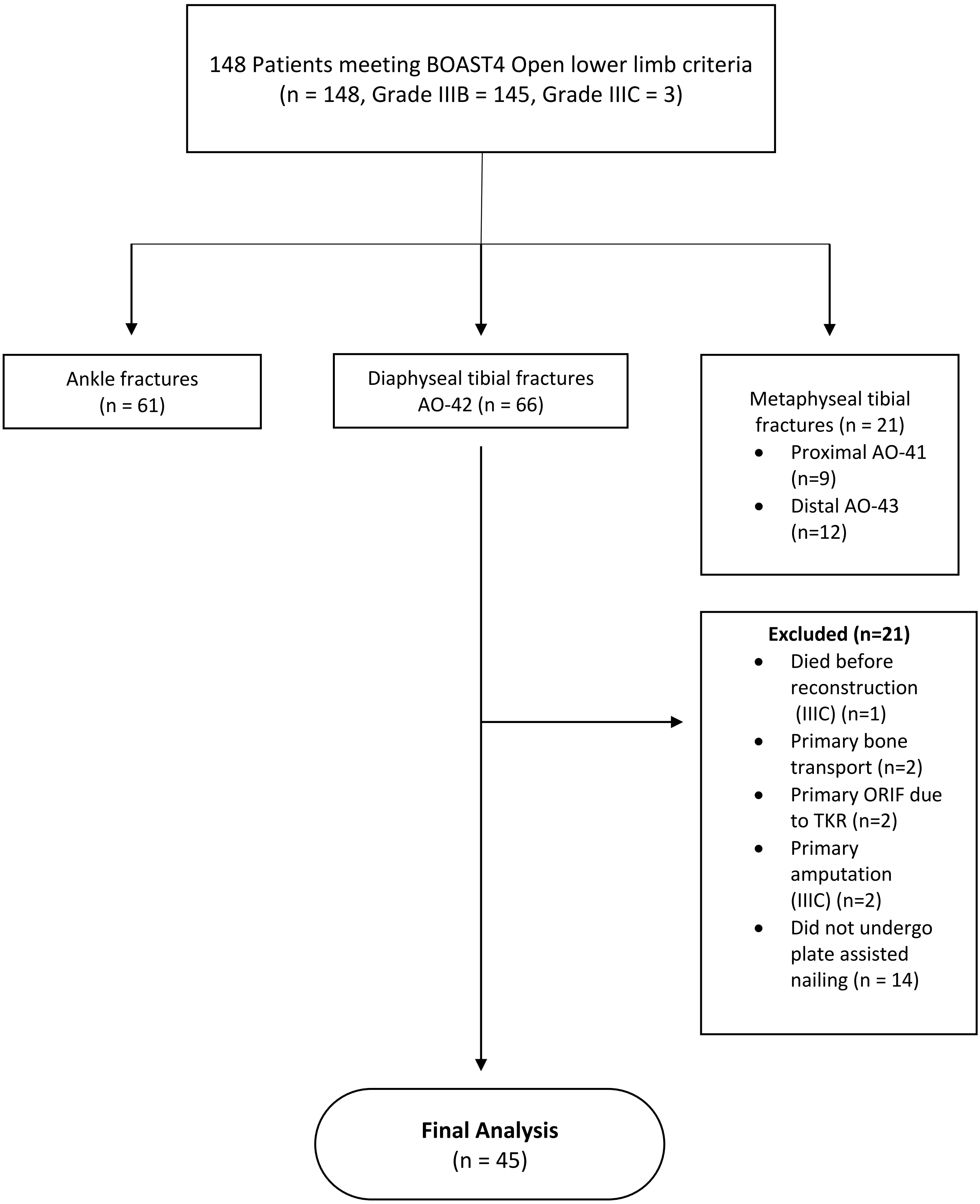
Transfer	Number	Mean hours to initial debridement	Standard Deviation	Significance ($p<0.05$)
Yes	17	25.2	16.9	Yes
No	28	15.10	6.4	

Table

Table 3. Timing and associated complications

		Number	Mean hours to initial debridement	Mean hours to definitive treatment
Infection	Yes	4	18.9 (SD 7.68)	66.0 (SD 20.4)
	No	41	18.9 (SD 12.8)	67.9 (SD 62.7)
Infection associated flap failure	Yes	3	15.8 (SD 8.01)	74.5 (SD 26.6)
	No	42	19.0 (SD 12.6)	67.4 (SD 61.3)
Flap failure	Yes	1	86.15 ($p<0.001$)	217.7 ($p=0.01$)
	No	44	17.4 (SD 6.97)	64.4 (SD 56.2)

Figure


148 Patients meeting BOAST4 Open lower limb criteria
(n = 148, Grade IIIB = 145, Grade IIIC = 3)
Ankle fractures
(n = 61)
Diaphyseal tibial fractures
AO-42 (n = 66)
Metaphyseal tibial fractures (n = 21)
Proximal AO-41 (n=9)
Distal AO-43 (n=12)
Excluded (n=21)
Died before reconstruction (IIIC) (n=1)
Primary bone transport (n=2)
Primary ORIF due to TKR (n=2)
Primary amputation (IIIC) (n=2)
Did not undergo plate assisted nailing (n = 14)
Final Analysis
(n = 45)