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Plate assisted intramedullary nailing of Gustilo type IIIB open tibial diaphyseal fractures: Does adjunctive plate retention affect complication rate?

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Abstract

Objectives: To investigate the complication rates after use of retained adjunctive plate (RAP) fixation with intramedullary nailing of Gustilo-Anderson type IIIB open tibia fractures, as part of a two-stage orthoplastic approach.

Design: Consecutive cohort study.

Patients/Participants: One hundred and thirty seven consecutive patients with a Gustilo-Anderson type IIIB open diaphyseal tibia fracture (OTA/AO 42) treated between May 2014 and January 2018. Nighty eight patients (RAP = 67; non-RAP = 31) met the inclusion criteria and underwent 2-stage reconstruction. All patients were treated using a small fragment adjunctive plate to hold the fracture reduced prior to intramedullary nailing.

Intervention: At stage two, the temporary small fragment (in-fix) plate was removed and the site further thoroughly debrided. Following this the fracture is reduced and held with a new small fragment plate to facilitate the definitive intramedullary nailing. This new plate was either retained (RAP) as part of the definitive fixation at second stage or removed prior to wound coverage.

Main outcome measurement: The main outcome measures were re-operation rate, deep infection, nonunion and flap related complication.

Results: Six patients (6/98, 6.1%) proceeded to nonunion (RAP 5/67, non-RAP 1/31). This was not significant (p = 0.416). 212 operations were undertaken, the median was two. Sixteen (16/212, 7.5%) complication related re-operations were undertaken, affecting eight patients (8/67, 11.9%) in the RAP group. Eight patients (8/98, 8.2%) developed a deep infection (RAP 6/67, non-RAP 2/31). This was not significant (p = 0.674).

Conclusions: In the context of an orthoplastic approach, the use of a retained adjunctive plate with definitive intramedullary nailing does not appear to significantly increase the rate of deep infection or nonunion in patients with type IIIB open tibial shaft fractures.

Level of evidence: Therapeutic level III.

Key words: open fracture, type IIIB, tibia, plate assisted nailing, retained adjunctive plate, RAP, nonunion

Introduction

Open fractures represent approximately 20% of all tibial fractures(1). These are ideally managed by both experienced orthopaedic and plastic surgeons, particularly where the wounds cannot be primarily closed. This approach has been shown to lead to better outcomes(2,3) and entails an initial debridement of the wound, temporary stabilisation, and then a planned definitive soft tissue and bony reconstruction as a combined procedure in a single surgical sitting.

The choice of definitive osseous fixation is largely based on local practice but an intramedullary nail is commonly used. Particularly with complex fractures, plate assisted nailing is an established technique(4–9), allowing maintenance of difficult reductions during nail insertion but in the majority of cases the adjunctive plate is removed at the end of the procedure. In the study unit, the practice has been that following the 'plate-assisted' nailing, the adjunct plate fixation can be left in situ and covered as part of the definitive soft tissue coverage.

The aim of this study was to determine if the retained adjunctive plate (RAP) was associated with an increased rate of complications in patients with type IIIB open tibial shaft fractures.

The outcome measures were re-operation rate, deep infection, nonunion and flap related complication.

Patients and methods

Inclusions/exclusions

This was a consecutive cohort study using prospectively collected data between May 2014 and January 2018. The national Trauma Audit and Research Network (TARN) and our local trauma database were used to identify all patients with an open tibial fracture presenting to the study centre in this period. Patient notes, letters, medical photography and radiographs were also used.

A total of 287 consecutive patients were identified as meeting the "British Orthopaedic Association Standards for Trauma" (BOAST 4)(10) guidelines for open tibial fractures. This consisted of 279 type IIIB(11) injuries. One hundred and thirty-seven patients sustained open diaphyseal tibial fractures (AO 42). Twenty five patients were excluded due to: early peri-operative mortality (n=3), primary bone transport procedure (n=3), primary amputation (n=2), periprosthetic fracture (n=3), fracture through previously infected tibia (n=1), acute fusion with hindfoot nail (n=1) and less than one year follow up (n=12). A further fourteen patients underwent a single stage-procedure as definitive management, with an IM nail and local flap coverage. Following exclusions (Fig 1), 98 patients were included in the final analysis.

Local institutional review board approval was obtained for the collection, processing and publication of this data.

Surgical interventions

The study centre treats approximately 240 open fractures per year, with the majority of patients presenting with a type IIIB open diaphyseal tibial fracture undergoing a two-stage approach. The study unit receives open fractures directly as well as from the surrounding hospitals as part of the wider trauma network(12). This is a civilian population and all injuries were as a result of blunt trauma, predominantly road traffic accidents. Prophylactic antibiotics are given either prehospital or immediately on arrival to the emergency department where the trauma protocol is followed, and the wound is then photographed and dressed. The antibiotic choice is according to local antimicrobial policy and consists of intravenous flucloxacillin and gentamicin for a maximum of 72 hours (unless contraindicated), or until soft tissue closure. The limb is placed in a long leg splint (backslab). Initial debridement occurs on the next available operating list, with both consultant orthopaedic and plastic surgeons present. An extensile incision is made, allowing debridement of devitalized soft tissue within the zone of injury. Bone ends are delivered, debrided and irrigated with a minimum of 5 litres of normal saline. The fracture is provisionally stabilised using a 3.5mm dynamic compression plate (DCP) as temporary internal fixation (TIF)(13). This is applied with transcoritcal screw fixation most commonly to the anteriomedial tibia. A negative pressure wound dressing is applied and the leg splinted in a backslab.

At stage two, the TIF is removed and discarded. The site is further thoroughly debrided and lavaged. A new transcortical 3.5mm DCP is applied to the anterior tibial cortex, bridging any communition or butterfly fragments. This bridging plate allows the 'plate-assisted' technique that facilitates the intramedullary nailing and is part of the unit's orthoplastic protocol(14). If it was felt the new plate was essential for stability of a mechanically relevant fragment following nail insertion it would be retained at the fracture site (Fig 2). This occurs in all fracture patterns and locations, including simple transverse isthmal fractures. Retention of the plate is left to the operating surgeon's discretion and if the bone construct was felt to be mechanically stable the plate could be removed. Definitive soft tissue flap coverage is undertaken during this same theatre episode. Post-operative care involves a strict flap protocol, including documented flap observations, warming blanket use, careful fluid balance and bed rest before being allowed to weight bear as tolerated on day 5 post op.

The unit aims for the first debridement to be performed within 24 hours, regardless of whether this was a primary or secondary transfer. There is also a 72-hour target for definitive soft tissue reconstruction. In the study cohort, this was achieved in 83 (83/98, 85%) and 66 patients (66/98, 67%) respectively.

All patients were followed up in a dedicated plastics dressing clinic to monitor the soft tissue coverage, as well as a joint ortho-plastics clinic which provides both consultant orthopaedic and plastic surgeon decision making. Patients were discharged once there was no pain on weight bearing, no movement at the fracture site and callus evident on radiographs(15), and the flap healed. All patients were followed up for a minimum of one year.

Outcomes

The primary outcome measure was number of operations, deep infection and nonunion. The secondary outcomes were infection-associated flap failure, isolated flap failure and overall complication rate.

Diagnosis of deep infection was based on criteria described by the Centers for Disease Control and Prevention (CDC) for 'deep incision surgical site infection', see Figure, Supplemental Digital Content 1, http://links.lww.com/JOT/A985(16). The definition was not reliant on positive cultures, and assumed that any surgical debridement, revision or antibiotic use within this cohort was indicative of deep infection(3,13).

For nonunion, the US Food and Drug Administration (FDA) definition was used; a fracture that is over 9 months old with no radiographic signs of progression towards healing for 3 months(17). Flap failure was defined as total or partial necrosis of the transferred tissue. Flap failure occurring 1 month or more after coverage was considered secondary to deep infection.

Statistical analysis

Analysis was undertaken with IBM "SPSS" Statistics version 25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Descriptive statistics were used for categorical data and Shapiro-Wilkes testing of normality for 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/variance inflation factors (VIF) for independent variables was undertaken. No collinearity was found between the independent variables.

Binary logistic regression models were utilised for primary and secondary outcomes. The independent variables considered were RAP, age, laterality, gender, time to initial and definitive management, use of mechanically relevant devitalized bone, flap type, follow up, smoking status, diabetic status, American Society of Anesthesiology (ASA) grade and injury severity score (ISS).

The odds ratios (OR) and 95% confidence intervals (95% CI) were calculated for both RAP and non-RAP groups.

The study assumed that p values of less than 0.05 were significant. All data was stored on a secure database for patient confidentiality.

Results

Demographics

Nighty eight patients were included. Median age was 44.1 years (interquartile range (IQR) 37) with a median follow up of 1.9 years (IQR 0.7). There were 63 males to 35 females, with 42 left sided injuries and the remaining 56 right sided. Twenty-three patients were smokers and five patients were diabetic at time of injury. A total of 33 patients were secondary transfers from other hospitals. Median time to initial debridement was 18.3 hours (IQR 8.0), with median time to definitive management 59.2 hours (IQR 47.1). Median ASA grade was 2 (IQR 1) and ISS score 9 (IQR 1). Twenty-four patients (24.5%) did not require a free flap but had local rotational flaps performed by a consultant plastic surgeon.

There were 42 (42.9%) type A, 44 (44.9%) type B and 12 (12.2%) type C fracture patterns using the AO Classification system. More plates were removed in simpler fracture patterns (58.1% vs 41.9%, p = 0.039). There were a higher proportion of multifragmentary fractures in the RAP group (14.9% vs 6.5%), however this was not statistically significant (p = 0.234). Despite this, plates were retained in all fracture patterns and locations including simple transverse isthmal fractures according to surgeon discretion.

Of the 98 patients, the small fragment plate was retained as part of the definitive fixation in 67 patients. The RAP and non-RAP groups had comparable patient demographics as shown in table 1.

Primary outcome

Six patients (6/98, 6.1%) proceeded to nonunion. This consisted of five patients (5/67, 7.5%) in the RAP group, with the remaining one (1/31, 3.2%) in the non-RAP group. This was not significant (p = 0.416).

Of those six patients proceeding to nonunion, four (4/6) had an infected nonunion diagnosed clinically and on cultures, with two patients (2/6) remained culture negative and the non-union thought to be a result of patient physiology and inadequate construct stiffness (Table 2). These two patients had physiological risk factors for nonunion (smoking and diabetes) and were subsequently revised to a stiffer nail, resulting in a healed outcome.

The binary logistic model was not predictive of any variable being associated with this outcome.

Overall, eight patients (8/98, 8.2%) developed a deep infection in this study. In the RAP group, six patients (6/67, 9.0%) had an infection at follow up compared to two (2/31, 6.5%) in the non-RAP group. This was not significant ($p = 0.674$). Of the total eight infected patients, four had an associated flap failure.

The binary logistic model was predictive of diabetes being associated with developing an infection ($p = 0.005$), OR 26.4 (95% CI 3.561 to 195.7).

The median number of operations in this cohort was 2.0 (IQR 0). Of the 212 operations performed in this cohort, 16 (7.5%) were reoperations due to complications (Table 3). Eight (8/67, 11.9%) patients in the RAP group underwent eleven additional operations due to complications.

Secondary outcomes

Infection-associated flap failure

Four patients (4/98, 4.1%) developed infection-associated flap failure requiring revision surgery. Three patients developed infection-associated flap failure in the RAP group (3/67, 4.5%) compared to one (1/31, 3.2%) in the non-RAP group. This was not significant ($p = 0.771$).

Isolated flap failure

One patient (1/98, 1.0%) developed isolated flap failure, this was a patient who had RAP. This was a result of a microvascular event and happened at less than 24 hours after the second stage reconstruction.

Overall complications

Eleven patients (11/98, 11.2%) developed complications. Eight of these (8/67, 11.9%) in the RAP group compared to three (3/31, 9.7%) in the non-RAP. This was not significant (p = 0.741).

All five patients with diabetes developed a complication.

Discussion

This consecutive cohort study demonstrates that retaining an adjunct fixation plate in the GA type IIIB open tibial fractures treated with an intramedullary nail does not appear to be associated with a significantly increased deep tissue infection or nonunion rate. Furthermore, there does not appear to be an association shown between RAP and other negative secondary outcomes.

The use of intramedullary nail in these fractures has the advantage of being minimally invasive, stabilises the long bone and allows immediate unrestricted weight bearing, with current evidence suggesting this is the superior treatment in open tibial fracture(18). Multiple methods have been proposed to facilitate and maintain fracture reduction during insertion of the nail, including use of percutaneous or open clamping, blocking screws or external fixator(19,20).

Provisional plating of tibial fractures is an accepted technique that allows maintenance of the reduction while definitive intramedullary fixation is achieved. This technique has been described with both one-third tubular plates(5), reconstruction plates(6), and compression plates(21). Despite both using the technique in open tibial fractures, Dunbar et al(5) describe removing the plates following insertion of the nail, whereas Archdeacon et al(4) would retain the plate as an adjunct to avoid deformity. This technique has been extrapolated to complex closed tibial fractures, with no increase in complications(6,7,22–24).

Dunbar et al(5) were the first to describe the technique in open fractures, and reported an infection rate of 13.3% and nonunion of 16.7%. They however, removed all plates following intramedullary nailing. Nork et al (21) also describe the technique in both open and closed proximal tibial fractures, they concluded that both temporary and retained adjunctive plates were not associated with complications. Ludwig et al(22) looked specifically at complication in retained plates as a subgroup in their 2016 paper. Their cohort, which included both open and closed injuries, had infection rates of 20% and nonunion rates of 5.7%. They found no statistical significance in the complication rates with retained plates.

There is a theoretical risk of infection and non-union when retaining the adjunctive plate due to additional periosteal stripping during application(25) or due to biofilm formation(26,27) around the implant. The study cohort of open tibial fractures had a deep infection rate of 8.2% which is in keeping with best reported infection rates(9,28–31). It is lower than those reported in open tibial fractures managed with plate assisted intramedullary nailing(5,22). We think this is due to our two stage, orthoplastic approach to debridement and soft tissue coverage, which has been shown to reduce the rates of deep infection(3,13). The infection rate was similar in both groups in the current study. Our working hypothesis with regard to the retention of the plate in this setting is that it provides a much more stable structure at the site of the free flap therefore a more optimised environment for the soft tissue as well as the bone construct. This is particularly the case where there is comminution.

Our overall nonunion rate was 6.1% which is lower than the best reported union rates(24,28,32–34), we believe this is due our low reported infection rates(3,13,35) reducing septic nonunions. The retention of the small fragment plate has the potential of modifying the overall bony construct, aiding fracture stability at the site of the previous maximal tissue damage. As above, our hypothesis is that this helps support the soft tissue reconstruction and therefore healing. Our experience is that there is early callus that remodels quickly suggesting that concerns about over-stiffening are not an issue. In this study, both groups had similar nonunion rates, with a larger proportion of communited/segmental fractures being treated with a retained plate.

The current paper has various strengths. It represents the largest consecutive cohort study reported. Our unit is a high volume, level 1 trauma centre with a robust and standardised orthoplastic set up. Therefore, unlike much of the literature on open diaphyseal tibial fractures, the availability of good soft tissue cover was not a limitation in any of these patients. While the injury severities and the resulting reconstructive requirements will vary, as far as possible, the soft tissue element has been controlled for. The approach and management were standard across the groups, with procedures performed by a number of orthopaedic and plastic surgeons within the unit. The method described of retained plates differs from other groups using adjunctive plates to assist the nailing. The underlying hypothesis is that the low rate of deep infection is likely to be related to the orthoplastic approach of which the retention of the plate forms a part.

This study has several limitations. The unit described has an established and integrated orthoplastic approach to managing these injuries, and although it represents the new standard of care in the United Kingdom, it lacks generalisability beyond specialised centres. Its retrospective design means that only routinely recorded data was available, and so lacks functional outcomes and patient reported outcome measures. Longer term follow up is ongoing in all patients to monitor for late complications such as chronic infection. The decision to retain the adjunct plate fixation was based on the intraoperative findings and assessment of fracture stability and so could introduce a selection bias. This would need to be considered in future prospective studies.

In conclusion, this is the largest consecutive cohort study looking at adjunct plate fixation of open IIIB tibial fractures. When undertaken as part of an orthoplastic approach, plate retention as part of the bony management of these injuries appears to be safe.

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Table 1 – Patient demographics by Retained adjunct plate fixation (RAP) use

Characteristic	Total	RAP	Non-RAP	*p*
Age, median (IQR), y	44.1 (36.3)	45.7 (36.0)	41.0 (25.0)	0.954
Gender, No. (%)				
Female	35 (35.7)	22 (32.8)	13 (41.9)	0.382
Male	63 (64.3)	45 (67.2)	18 (58.0)	
Smoking Status, No. (%)				
Yes	23 (23.5)	17 (25.4)	6 (19.4)	0.513
No	75 (76.5)	50 (74.6)	25 (80.6)	
Diabetes mellitus, No. (%)				
Yes	5 (5.1)	5 (7.5)	0 (0.0)	0.118
No	93 (94.9)	62 (92.5)	31 (100.0)	
Side of injury, No. (%)				
Left	42 (42.9)	26 (38.8)	16 (51.6)	0.233
Right	56 (57.1)	41 (61.2)	15 (48.4)	
Free flap, No. (%)				
Yes	74 (75.5)	55 (82.1)	19 (61.3)	0.026
No	24 (24.5)	12 (17.9)	12 (38.7)	
AO Classification, No. (%)				
42-A	42 (42.9)	24 (35.8)	18 (58.0)	0.039
42-B	44 (44.9)	33 (49.3.2)	11 (35.5)	0.202
42-C	12 (12.2)	10 (14.9)	2 (6.5)	0.234
Median ASA, (IQR)	2 (1)	2 (2)	2 (3)	0.549
Median ISS, (IQR)	9 (1)	9 (4)	9 (0)	0.254
Hours to initial debridement, Median (IQR), h	18.3 (8.0)	18.3 (8.0)	17.1 (11.4)	0.827
Hours to definite coverage, Median (IQR), h	59.2 (47.1)	60.5 (46.7)	57.9 (63.8)	0.811
Follow up, Median (IQR), y	1.9 (0.7)	1.7 (0.8)	2.1 (0.8)	0.173

Table 2 – Retained adjunct plate fixation vs removed and complications

Complication	Total n (%)	RAP n (%)	Non-RAP n (%)	*P*	Adjusted Odds Ratio (95% CI)
Deep Infection	8 (8.2)	6 (9.0)	2 (6.5)	0.177	1.426 (0.271 to 7.503)
Nonunion	6 (6.1)	5 (7.5)	1 (3.2)	0.416	2.419 (0.271 to 21.636)
Infected Flap Failure	4 (4.1)	3 (3.9)	1 (3.2)	0.085	1.406 (0.140 to 14.087)
Isolated Flap Failure	1 (1.0)	1 (4.5)	0 (0)	0.467	n/a
All Complications	11 (11.2)	8 (11.9)	3 (9.7)	0.109	1.266 (0.312 to 5.137)

Table 3 – Patient Complications

Patient	Age	Gender	AO Classification	Risk Factors	RAP	Complication	Diagnosis	Duration post op	Cultures	Treatment	No. extra operations
1	48	Male	C3	Smoker Diabetes	Yes	Infected metalwork	Clinical	4 months	Negative	Exchange nail	1
2	81	Male	B1	Diabetes	Yes	Isolated flap failure	Clinical	1 week	Negative	Revision free flap	1
3	61	Female	C3	Diabetes	Yes	Aseptic nonunion	Clinical/ Radiographs	12 months	Negative	Exchange nail	1
4	68	Male	B1	Nil	Yes	Infected metalwork	Clinical/ Radiographs	12 months	B-haem. Strep	Exchange nail	1
5	22	Male	A3	Smoker	No	Aseptic nonunion	Clinical/ Radiographs	9 months	Negative	Exchange nail	2
6	31	Male	B1	Nil	No	Infected free flap	Clinical	1 month	Staph. Aureus	Revision nail and revision free flap	2
7	56	Female	B1	Nil	Yes	Infected metalwork/nonunion	Clinical/ Radiographs	2 months	Enterobacter Cloacae	Staged exchange nail and revision free flap	2
8	44	Female	A1	Diabetes	Yes	Infected metalwork/nonunion	Clinical	2 months	Staph. Aureus/ Enterobacter Cloacae	Exchange nail	1
9	21	Male	A2	Nil	Yes	Infected metalwork/nonunion	Clinical	1 month	Staph. Epidermidis	Exchange nail and revision free flap	1
10	38	Female	A3	Smoker Diabetes	Yes	Infected metalwork/nonunion	Clinical	3 months	Morganelli Morganii	Staged exchange nail and revision free flap	3
11	38	Male	C3	Nil	No	Infected metalwork	Clinical	2 months	Staph. Aureus	Exchange nail	1