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Augmented compression in exchange nailing for femoral and tibial non-unions accelerates time to radiographic union

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Keywords –Femoral non-union, Tibial non-union, Exchange nailing, Augmented compression, Reamed intramedullary nailing.

Introduction

Intramedullary nailing remains the gold standard method of fixation for diaphyseal fractures of the femur and tibia, having the benefit of preserving fracture site biology and allowing early mobilisation [1-3]. Non-union is a well-recognised complication in fracture management and significantly impacts on patient recovery and outcomes, as well as consuming healthcare resources. Non-union rates for femoral and tibial shaft fractures vary in the literature but are typically reported between 1-2% in closed fractures managed with reamed, locked intramedullary nails [1, 4].

Exchange nailing is widely used in the management of aseptic non-union with many series reported in the literature [5, 6]. This typically involves removal of the existing nail, and reaming to accommodate a larger size nail with the aim of increasing the rigidity of fixation. ‘Backstriking’ of a nail can also be employed, which serves to provide fracture apposition when undertaking exchange nailing. This fracture apposition does not allow for or maintain compressive forces at the fracture site. Active compression however can be applied either by use of the design features of a nail with a dedicated active compression bolt added to the construct, or by external compression applied with the use of a femoral distractor in reverse prior to locking the nail construct. This results in generating tension within the implant-bone construct which translates to a continual compressive force at the fracture site. This is inherently different to the apposition achieved with backstriking which does not generate a continual compressive force at the fracture site. Similarly, dynamic locking of the nail utilising the oval locking holes, serve only to allow for intermittent compression when weight-bearing, as opposed to a continual compression.

The purpose of this study is to assess whether the additional step, in the form of application of compression to the exchange nail construct, has the predicted benefits of increased stability and thus markedly reducing strain over standard exchange nailing, ultimately resulting in a faster time to radiographic union.

Patients and Methods

The design of this study was a retrospective analysis of a prospectively collected trauma database encompassing a single surgeon series undertaken at a level 1 major trauma centre and specialist tertiary referral unit for non-union, in the United Kingdom.

All patients with lower limb non-union surgery were identified from prospectively collected trauma database of the senior author and verified with the electronic hospital operating theatre record (TheatreMan, Trisoft Healthcare) from January 2014 to June 2018.

Non-union post intramedullary nailing was defined according American Food and Drug Association (FDA) as failing to form bony union on serial radiographs over a 3 month period at least 9 months post the initial surgery[7].

From the collated non-union data, all the patient’s images of tibia and femur non-unions were then reviewed to identify any AO/OTA 32 and 42 fractures and all their subtypes[8]. We then applied our exclusion criteria for cases:

- managed with external fixation (including circular frame) or open reduction internal fixation using plates / screws.
- that had undergone ‘additional fixation’ during the exchange nailing procedure e.g. adjuvant plating or percutaneous blocking screws around the nail construct.
- that had any form of axis realignment at the time of exchange nailing.
- identified as having a deep infection (with either positive deep surgical samples at the time of revision surgery or frank pus seen at time of exchange nailing)
- that had type AO/OTA Type C3 fractures (simple segmental and fragmented segmental fractures)

This left a final cohort of patients who were treated with pure exchange nailing without additional hardware or axis realignment, for aseptic femoral and tibial non unions with a minimum of 12 months follow up. These patients were then grouped according to the use of additional compression or not.

Data for the size of the intramedullary nail removed and the new nail was taken from the operation note. Baseline demographics along with the smoking status and ASA of the patients was retrieved from the preoperative assessment and interoperative anaesthetic chart.

Operative technique

The patient is positioned on a radiolucent flat top trauma table in the supine position. Femoral exchange nailing (antegrade or retrograde) was performed freehand. Tibial exchange nailing was performed with flexed knee to remove the prior implant, and either infrapatellar or suprapatellar approaches for insertion of the new nail. In this series, all fractures were well aligned and therefore the original entry point was used for exchange. The locking screws were removed through the original incisions where possible. The Stryker implant extraction set (Stryker Trauma GmbH Prof.- Küntscher -Str. 1-5 24232 Schönkirchen Germany) was used where necessary.

Once the original nail was removed the canal was sequentially reamed starting at the size of the original nail to allow at least a 1mm increase in the diameter of the exchange nail.

The Stryker T2 system was used for the exchange nail in all identified cases. This was either the T2 Antegrade/Retrograde femoral nail or the T2 tibial nail (Stryker Trauma GmbH Prof.- Küntscher -Str. 1-5 24232 Schönkirchen Germany).

The implant instrumentation allows for internal compression to their T2 devices via the advanced locking mode. Once the nail is inserted, it is first locked distally with at least 2 screws. This is followed by inserting a partially threated locking bolt through the dynamic position of the proximal oblong hole. In the group undergoing the additional step, compression is applied either with an internal compression screw, or an external compression driver is passed into the nail to abut the proximal locking screw. This allows for up to 10mm of additional apposition/compression in the femoral nail and 7mm of compression in the tibial nail. The amount of compression applied was not specifically quantified in the operative note – the compression applied was therefore at the operating surgeon’s discretion and was at least until the dynamic locking screw of the nail was seen to bend in all cases. Once achieved a static locking screw is used to maintain the compressive force and the deformed screw exchanged. Figure 1 shows a case example.

Outcome measures

Radiographic union was the primary outcome and the Radiographic Union Score for Tibia (RUST) was used to quantify the union pre and post exchange nailing. The RUST score is a validated scoring system used to assess the healing of long bone fractures following intramedullary nailing [9, 10]. Originally validated for tibial fractures, it has been routinely used to assess union in all long bone fractures. It is calculated by assessing callus formation and scoring the 4 cortices (2 each on AP and lateral radiographs) of the fracture site individually. The total score ranges from 4 – 12, with bony union defined when radiographs demonstrated bridging callus on at least three cortices i.e. RUST score of ≥ 10.

Two authors (SW, MG) were blinded to the operative technique by removing all details and time points. Each assessor calculated an initial RUST score from pre-operative radiographs, 6 - 8 week clinic review imaging and any subsequent follow up radiographs until final union was achieved.

The number of clinic visits and radiographs per patient was recorded, along with the additional hardware used so that a cost analysis could be undertaken to determine the financial impact of the technique.

Statistical analysis

Based on whether they followed a normal distribution, continuous variables were presented as mean ± standard deviation (SD) or median (interquartile range, IQR). Categorical variables were shown as percentages. Normality was assessed by performing the Shapiro-Wilk and Kolmogorov-Smirnov tests and evaluating the kyrtosis, skewness and boxplots. The Mann-Whitney U Test (non-parametric data) and the independent samples t-test (parametric data) were used to compare continuous variables. All analyses were performed using the IBM SPSS Statistics Software for Windows, Version 25. Values of $P<.05$ were considered statistically significant. An Intraclass correlation coefficient was calculated from the two scores to assess inter-rater reliability.

Results

The prospectively collected trauma database yielded a total of 119 patients with diaphyseal femoral or tibial non-unions over the 4-year period from 2014-2018. We then sequentially applied our exclusion criteria to the data as can be seen in figure 2. The majority of patients (80) in the database treated for non-union were excluded on the basis that their primary fixation was not intramedullary nailing. 3 AO/OTA type C fractures were excluded, 2 were segmental femoral fractures (32C2) with segmental non-union and one was a fragmented segmental tibial fracture (42C3).

This resulted in a total of 19 patients treated for aseptic non-union with exchange intramedullary nailing; of which 10 underwent exchange nailing with augmented compression and 9 underwent no additional compression (standard exchange). The mean age of the patients was 41 (Range 23-74). 16 of the patients were male and 3 female. 13 of the cases were femoral exchanges (7 compressed) and 6 tibial exchanges (3 compressed). 3 of the patients in the compressed group were recorded as smokers at the time of surgery vs 2 in the group with no additional compression. The average ASA was 1.5 in both groups with only 1 patient in each group having an ASA above 2 (which was ASA 3 in each case).

The nail diameter varied between 9mm – 13mm for the initial nail and 11 – 15mm for the exchange nail. The increase in diameter ranged from 1-3mm with no significant difference in the amount of upsizing between the two groups. When comparing the fracture patterns, 6/10 in the compressed group and 4/9 in the non-compressed group were AO/OTA type A with no significant difference between the two groups (table 1).

There was no significant difference in the pre-operative RUST score between groups. 9 of the 10 compression exchange nails achieved radiographic union (RUST ≥10) within 6 to 8 weeks, whereas only 3 of the 9 exchange nails in the non-compressed group had achieved a RUST of ≥10 in that time. The median RUST score at 6 to 8 weeks post-operatively in patients undergoing the additional step of compression through the exchange nail construct was 11 compared to 8.39 in the non-compressed cohort (p = 0.001) – as shown in table 1.

Intraclass correlation coefficient for the pre-op RUST score was 0.982 (95% CI, 0.954, 0.993) showing excellent inter-rater reliability . The Intraclass correlation coefficient for post-op RUST score was 0.968 (95% CI, 0.956, 0.994) also showing excellent inter-rater reliability

The compressed group had a total of 34 (Mean 3.4) radiographs and 34 (Mean 3.4) clinic follow ups. The non-compressed group had total of 45 (Mean 5) radiographs and 45 (Mean 5) clinic visits.

All patients in both groups went on to successful union within 12 months post exchange nailing. Two cases had post-operative complications and both were from the additional compression group: one required a proximal locking screw to be removed from a tibial exchange due to discomfort around the screw head and the second required the 2 distal locking screws of a femoral nail to be removed due to infection at a year post exchange. Both cases had united at the fracture site prior to the additional procedures being undertaken.

Cost Analysis

Table 2 shows the cost analysis of follow up in the two different groups. The cost of an Anterior-Posterior and Lateral femur or tibia radiograph at our institution was £98 and a single clinic follow up was £59.

For both groups the implant and distal locking screws would be equivalent. In the non-compressed nail, additionally there are two fully threaded locking screws at a cost of £92 each. In the compression augmented exchange nail procedure, additionally there is a single fully threaded locking screw (£92),a compression screw (£87) and a partially threaded screw (£87). Therefore the total implant cost difference is an additional £82 when the compression is applied.

The faster union time has a socioeconomic benefit by reducing the number of outpatient clinics required in the compression group to a mean of 3.4 vs 5. There were also fewer radiographs required in the compressed group with a mean of 2.4 vs 3.5. Overall this results in a follow up cost saving of cost saving of £252 per patient and a net saving of £170 after taking the cost of additional metalwork into account.

Discussion

Studies have found exchange nailing for non-union achieves high union rates. Tsang et al in their study of 102 diaphyseal non-unions found 92 patients (95.4%) united after exchange nailing for aseptic non-union[11]. Hierholzer et al described osseous union in 71 patients (98%) that underwent exchange nailing for non-union[6]. In the Hierholzer study they found that after exchange nailing, in the majority of patients (61%) bone healing occurred within the first 2 to 5 months but that in 21% patients it was between 5 to 8 months, and in 18% of patients, duration of bone healing exceeded 8 months. They also had 18 patients requiring further therapy (including further exchange nailing, nail dynamization, or shock wave therapy). Tsang et al had a mean union time of 7.6 months (IQR 5.7 to 10.8 months) for aseptic tibial diaphyseal non-unions. Both studies defined union as bridging callus on 3 cortices, the same criteria we applied. Both studies also reported the AO/OTA classification in their papers but they did not state its effect on the results of exchange nailing and time to union. In our study, 9 of the 10 patients that underwent additional compression at the exchange had achieved bridging callus on 3 cortices by the 6-8 week review. Only 3 of the 9 patients with no additional compression had achieved this. We found no difference between the two groups when compressing type A and B fractures suggesting that both there fracture patterns are appropriate for augmented compression.

Elliott et al postulate that most non-unions occur due to mechanical factors and that the correct strain environment will aid union[12]. In hypertrophic non-union this almost always means reducing the strain environment. With exchange nailing to a larger diameter nail it is suggest that the strain environment for bone formation is optimised. To further improve the strain environment “local strain can be reliably reduced by a device that spans the non-union and is then preloaded itself." This is normally achieved using plates and screws or external fixation, however we applied this same concept of pre-loaded compression to the nail construct by using the advanced locking/additional compression device.

A biomechanical study looking at the effect of nail diameter and compression on the stability of fixation after intramedullary nailing on human tibias found that using larger diameter intramedullary nails allowed interfragmentary movements to be reduced by about 40%, in both torsional and shear loading tests. Compression of the fixation construct, applied in the same way that was used for our investigation, further reduced torsional loading by 55%; interfragmentary movement and shear loading were also reduced. The study concluded that with appropriate cases, compression of the fracture is probably the most important stabilisation principal[13]. Data from our patients, where the increase nail diameter was equivalent in the two groups, supports the idea that additional compression further optimises the strain environment for fracture healing.

It is important to distinguish between augmented compression of the nail construct from loading of the non-union using the dynamic locking holes. The theory behind dynamic locking of the nail is that the fracture/non-union is compressed on cyclical loading. However that means when sedentary, the patient is not applying loading forces through the non-union site – this drawback is likely even more pronounced in the first few weeks post-operatively where pain can inhibit weightbearing. This is not the case with the internal compression as the preload is applied to the nail at the time of the operation therefore keeping the tension across the non-union postoperatively at all times, regardless of patient loading.

A systematic review on dynamic locking for non-union found that exchanging nailing for non-union had an 85% union rate compared with only 66% union rate when dynamisation alone was used. They also found that when dynamisation was applied to an exchange nail for non-union there was no significant difference in the success rates or time to union between static and dynamic locking [14]. Dynamically locking a nail construct may serve to increase the strain at the fracture site by producing a less stable implant-bone composite construct.

In our study, this additional step of compression whilst incurring a small in increase in additional metalwork cost, ultimately resulted in an average cost saving of £170 per patient owing to a reduction in the number of follow-up appointments and radiographs.

There are limitations to our study. The number of patients in the study is relatively small. This is reflective of the low incidence of non-union (1-2%) of closed femoral and tibial fractures managed initially with intramedullary nailing. When comparing demographics, both groups were well matched with the exception of age where the additionally compressed group has a younger mean age. This may be a confounding factor. Owing to the retrospective nature of the study, follow up times were not standardised after the initial routine follow-up at the 6-8 week mark. There were also no functional or patient reported outcomes undertaken/available.

To our knowledge, our study is the first to assess outcomes of the use of augmented compression in exchange nailing.

Conclusion

Our study shows that the time to union is greatly accelerated when the additional compression is applied intra-operatively to the exchange nail construct. It is a quick and simple technique adding minimal intra-operative time with an overall cost saving, therefore this technique could be considered routinely when exchange nailing for tibial and femoral non-unions.

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Figure 1

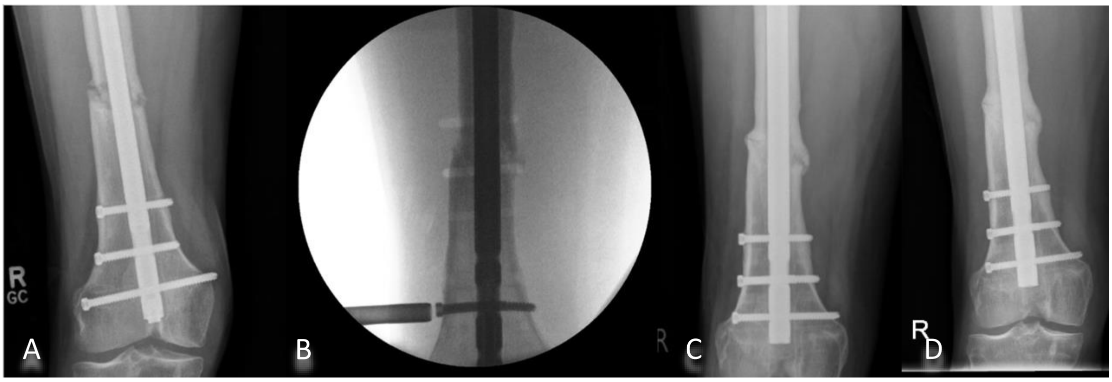

Figure 1

Figure 1. A case of a retrograde femoral nail for a distal third femoral fracture. A. preoperative radiograph showing a distal third non-union with a nail in situ. B. An intraoperative imaging showing the application of the additional compression with the advancement and bending of the shaft screw. C. Post operative image taken at 7 weeks post operatively showing bridging of the bridging callus of on both cortices. D shows a radiograph taken at 3 months showing further progression.

Figure 2

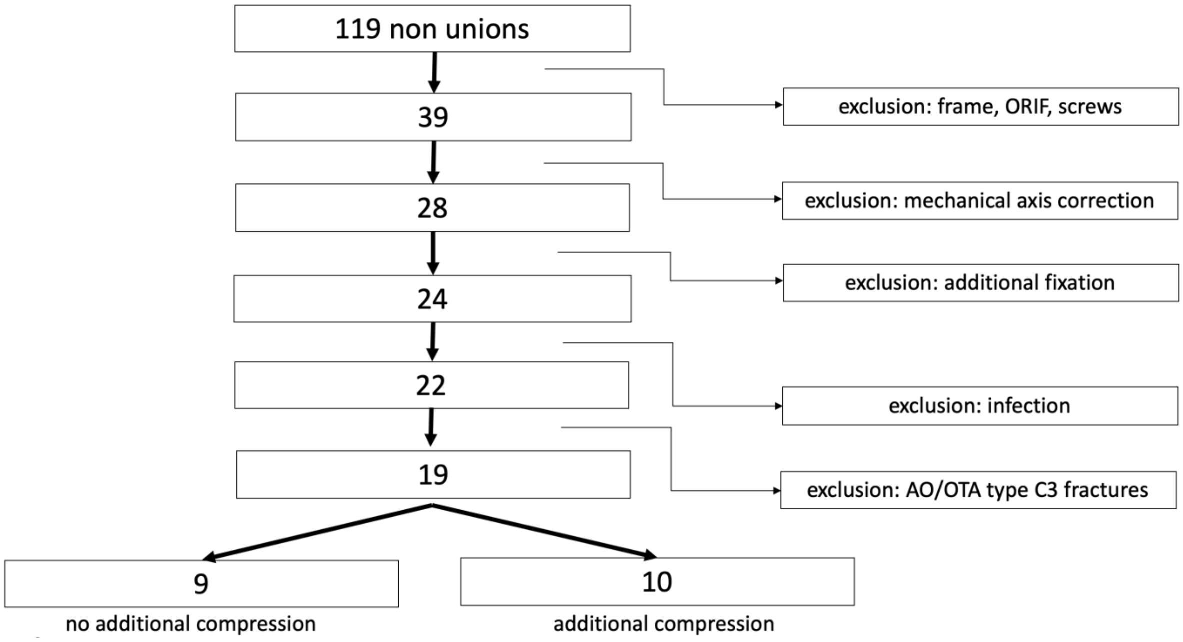

Figure 2

Figure 2. A diagram showing the sequential application of exclusion criteria to the data to leave two groups containing the final numbers in the compression and non-compression groups.

Table 2

Groups	Mean cost of Radiographs	Mean cost of Clinic follow up	Total mean cost of Follow up	Implant cost difference	Total mean cost per case
Compressed group	£333	£200	£533	£82	£615
Non-compressed group	£490	£295	£785	£0	£785

Table 2

Table 2. Cost analysis of follow up per patient in Pounds sterling (GBP).

Table 1

Groups	No Additional compression (N = 9)	Additional compression (N = 10)	P-value
Age	55.5 ± 21.55	31 (20.75)	0.043*
Sex (males)	N=7 (77.8%)	N=9 (90%)	0.582[$]
Pre-op RUST	7.11 ± 0.96	7.5 ± 2.23	0.636[+]
6-8 Weeks Post-op RUST	8.39 ± 1.6	11 (0.5)	< 0.001*
Delta-RUST	2 (2.5)	4 (2.50)	0.019*
AO/OTA Type (A)	4 (44.4%)	6 (60%)	0.656[$]
AO/OTA Type (B)	5 (55.6%)	4 (40%)	
Exchange nail diameter increase (mm)	2 (0.5)	2 (2)	0.721*

[+]Independent samples t-test, *Mann-Whitney U test, [$]Fisher's Exact Test

Data presented as mean ± SD, Median (interquartile range) or Absolute number (percentage)

Letter to Editor

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Title page

'Augmented compression in exchange nailing for femoral and tibial non-unions accelerates time to radiographic union'

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Declarations

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Conflicts of interest/Competing interests

The senior author on this paper (Mr Alex Trompeter) has to declare Paid services for Stryker (education and R+D) and Smith and Nephew and Orthofix (Education). No COI relating to this work. No payments for this work.

All other Authors have no conflicts of interest to declare.

Ethics approval (include appropriate approvals or waivers)

Not applicatable

Consent to participate

Not applicable.

Consent for publication (include appropriate statements)

Not applicable.

Availability of data and material (data transparency)

Not applicable

Code availability (software application or custom code)

Not applicable