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ORIGINAL ARTICLE

The relevance of the number of distal locking planes and nail to canal ratio in bone healing after intramedullary nailing in tibial shaft fractures

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Abstract

Introduction The objective of this retrospective study was to assess the effect of the nail to canal ratio and the number and configuration of distal locking screws in bone healing in tibial shaft fractures.

Methods We analyzed 223 consecutive tibial shaft fractures treated with reamed intramedullary nailing between January 2014 and December 2020. We recorded and evaluated the nail to canal ratio (NCR) and the number and configuration of distal locking screws. Median NCR was 0.87 (IQR 0.82-0.94). Ten (4.48%) fractures were treated with one distal locking screw, 173 (77.57%) with two, and 40 (17.93%) with three. Uniplanar fixation was used in 63 (28.25%), biplanar in 150 (67.26%), and triplanar in 10 (4.48%) cases. Uni-, bi-, and multivariate analyses were performed to compare patients who achieved bone union with those who did not.

Results Bone union was achieved in 195 (87.44%) patients. Uni- and bivariate analyses showed that bone union increased significantly with larger NCR ($p = 0.0001$) and a greater number of locking planes ($p = 0.001$) and distal screws ($p = 0.046$). NCR > 0.78 (OR 48.77 CI 95% 15.39–154.56; $p = < 0.0001$) and distal locking screw configuration (OR 2.91 CI 95% 1.12–9.91; $p = 0.046$) were identified as independent variables for union.

Conclusion Our findings suggest that in tibial shaft fractures treated with intramedullary nailing, NCR should be equal to or greater than 0.79. Additionally, distal locking screws should be used with a biplanar or triplanar configuration.

Keywords Tibia · Tibial shaft fracture · Intramedullary nailing · Nail to canal diameter ratio · Distal locking screw · Distal locking planes

Introduction

Intramedullary nailing is the treatment of choice for most tibial shaft fractures [1, 2]. Despite the progress made in implant design and surgical techniques, bone healing remains a challenge [3]. Currently, the reported rate of nonunion in tibial shaft fractures ranges between 12 and 33% [3–5] and has been associated with patient-, fracture- and surgical technique-related factors [4, 6–9].

At the time of nailing, there are multiple surgical technique-related factors to consider, such as the diameter of the definitive nail and the number and configuration of distal locking screws [8, 10]. In this study, we will use the acronym NCR (nail to canal ratio) to refer to the ratio of intramedullary nail diameter to tibial canal diameter [3]. Agreement has established an NCR > 0.80 as desirable to promote bone healing [3, 8].

Distal locking screws are an essential part of nailing [10]. However, in shaft fractures, there is still no clear agreement as to the optimum number of screws and the best configuration to promote bone union. Several studies have attempted to clarify these concepts, although most have focused on distal tibial fractures [11–13]. As for the number of locks in

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tibial shaft fractures, some authors suggest that the use of a single distal locking screw is safe [14], while others prefer two or three [15–17]. This lack of consensus is also reflected in recommended configurations, while some advocate for uniplanar fixation [14, 15], others propose biplanar fixation [17].

To the best of our knowledge, few studies have assessed the effect of the number and configuration of distal bolts in bone healing in tibial shaft fractures or the relationship between these variables and NCR. Therefore, the objectives of this retrospective study were (i) to assess the effect of NCR on bone healing; (ii) to analyze the impact of the number and configuration of distal locking screws on bone healing; and (iii) to identify if there is an association between NCR and the number and configuration of distal locking screws. Our hypothesis was that a greater number of distal locking screws and fixation planes has a positive impact on bone union rates. Likewise, more bolts (in number and configuration) result in a larger NCR range to achieve bone union.

Materials and methods

After obtaining approval from each institution's ethics committees, we retrospectively reviewed our databases to gather information on all surgeries performed. We identified consecutive patients with a diagnosis of tibial shaft fracture (AO/OTA 42) treated between January 2014 and December 2020 with reamed interlocking nailing.

Out of a total of 298 patients identified, two were excluded for being under 18 years of age, one for presenting a history of rheumatic disease, one for having a pathological fracture, and five for having less than 12 months of medical/radiological follow-up. To avoid potential confounders, we also excluded 16 patients with polytrauma, 15 with Gustilo-Anderson (GA) type III fractures, 18 fractures extending into a distal joint, seven with a postoperative gap at the fracture site > 5 mm, and ten for fracture-related infection.

Open fractures received urgent care with surgical debridement and bone stabilization. On admission, 1 g of I.V. cefazolin was administered every 8 h for 48 h. Nailing was performed after completing antibiotic prophylaxis. The size of the last reamer and the number and configuration of distal locking screws were decided by the surgeons based on their own criteria.

According to medical records, two proximal locking screws were inserted from medial to lateral in all cases. As for distal blocks, their orientation was defined as uniplanar (medial to lateral angulation), biplanar (medial to lateral and anteroposterior), or triplanar (medial to lateral, AP, and oblique angulation).

The demographic characteristics and the details of the number and configuration of distal locking screws for all 223 patients included in this study are summarized in Table 1.

Variables, measurements, and definitions

We analyzed demographic data such as age and gender, medical comorbidities (body mass index, diabetes mellitus, smoking), mechanism of injury (high- or low-energy), type of fracture (AO/OTA 42-A, B, or C), open or closed (Gustilo-Anderson-GA), and time to bone healing.

We measured the diameter of the medullary canal at the level of the isthmus in the anteroposterior (AP) and lateral (L) radiographic views of the fracture, and the average of both measurements was considered the final diameter (Fig. 1). The nail diameter was determined on the basis of operative notes. Then, we calculated the nail to canal ratio (NCR) = nail diameter/medullary canal diameter [3].

We recorded the total number of distal locking screws and their configuration (1, 2, or 3 planes) according to immediate postoperative radiographs.

The preoperative AP and L radiographs, immediate postoperative radiographs, and those taken 3, 6, 9 and 12 months after the procedure were assessed independently by two observers. Discrepancies were settled by consensus or by the most experienced surgeon. The digital software at each

Table 1 Summary of the characteristics of the patients analyzed

	Overall $n = 223$
Male gender$_{n\text{-}\%}$	164-73.5
Age$_{\text{median (IQR)}}$	34 (26–40)
DBT$_{n\text{-}\%}$	10-4.48
BMI > 30$_{n\text{-}\%}$	49-21.97
Smoking	23-10.31
Trauma$_{\text{n-}\%}$	
High	206-92.37
Low	17-7.39
Open	84-37.66
Close	139-62.33
AO/OTA 42$_{\text{n-}\%}$	
A	170-76.23
B	47-21.07
C	6-2.69
DLS number$_{\text{n-}\%}$	
1	10-4.48
2	173-77.57
3	40-17.93
DLS configuration$_{\text{n-}\%}$	
Uniplanar	63-28.25
Biplanar	150-67.26
Triplanar	10-4.48

DBT diabetes, *BMI* body mass index, *DLS* distal locking screws

Fig. 1 Measurement of the diameter of the medullary canal on AP and lateral radiographs. The average of both measurements was considered the definitive diameter of the canal

Table 2 Uni- and bivariate analysis of patients who did or did not progress to bone healing

	Union $n=195$	Nonunion $n=28$	*p* value
Male gender$_{n\text{-}\%}$	145-74.35	19-67.85	0.53
Age$_{\text{median (IQR)}}$	34 (26–47)	32.5 (25.5–38.5)	0.22
DBT$_{n\text{-}\%}$	10-0.51	0	0.61
BMI > 30$_{n\text{-}\%}$	44-22.56	5-17.85	0.57
Smoking	19-9.74	4-14.28	0.50
Trauma$_{\text{n-}\%}$			
High	179-91.79	27-96.42	0.70
Low	16-8.20	1- 3.57	
Fracture			
Open	69-35.38	15-53.57	0.63
Close	126-64.61	13-46.42	
AO/OTA 42$_{\text{n-}\%}$			
A	153-78.46	17-60.71	0.05
B	38-19.48	9-32.14	0.13
C	4-4.21	2-7.14	0.16
NCR$_{\text{median (IQR)}}$	0.88 (0.83–0.90)	0.66 (0.60–0.77)	0.0001
DLS number$_{\text{n-}\%}$			
One	6-3.07	4-14.28	0.046
Two	151-77.43	22-78.57	
Three	38-19.48	2-7.14	
DLS configuration$_{\text{n-}\%}$			
Uniplanar	46-23.58	17-60.71	0.001
Biplanar	139-71.28	11-39.28	
Triplanar	10-5.12	0	

DBT diabetes, *BMI* body mass index, *NCR* nail–canal ratio, *DLS* distal locking screws

institution (Synapse PACS; Fujifilm Corporation) was used to obtain and analyze images and to take measurements.

Fracture healing was defined as the absence of pain on weight bearing together with the presence of at least three bone bridges between the main fracture fragments on AP and L radiographs. Nonunion was defined as the absence of bone healing 9 months after surgery or lack of union at two successive control visits 6 months after the surgery [18].

Statistical analysis

Variables were expressed either as median and interquartile range (IQR) or as frequency and percentage according to their nature. Differences between variables obtained from the groups that achieved bone union and those who did not were analyzed using *t test* and Chi-square (χ^2) (or Fischer's exact test when necessary). As for NCR, a ROC curve was used to determine the point of greatest sensitivity and specificity for union and nonunion. Once this value was established, we performed a multivariate analysis to determine the impact of these variables on bone union. A *p* value less than 0.05 was considered statistically significant. All data were entered into an Excel spreadsheet (Microsoft 2010), and statistical calculations were performed using MedCalc (MedCalc Software Ltd, Osted, Belgium) and GraphPad Prism 8.0 (LA Joya, CA, USA).

Results

Out of the 223 patients with 223 tibial shaft fractures included in our study, 195 (87.44%) achieved bone healing; 185 (94.87%) within a term of 3–6 months; and the remaining ten (5.23%) within 9 months. Nonunion was observed in 28 (12.55%) fractures.

A comparative analysis of these groups showed no significant differences in demographics or preoperative comorbidities.

The most frequent type of fracture was AO/OTA 42-A (76.23%), and there were no significant differences in fracture morphology between those patients who achieved bone union and those who did not (Table 2).

Nail to canal ratio

The median NCR was 0.87 (RIQ 0.82-0.94). There was a significant difference in the values of patients who achieved bone union versus those who did not (0.88 vs. 0.66; $p = 0.0001$). (Table 2).

Sensitivity and specificity of NCR for union and nonunion

Based on the significant difference observed in the NCRs of the bone union group and the nonunion group, we performed ROC curves to identify the point of highest sensitivity and specificity. We found a value of ≥ 0.79 for union and a value of ≤ 0.78 for nonunion. (Fig. 2a, b).

Number of distal locking screws

The use of two locking screws was the most frequent scenario in both groups (77.43% vs 78.57%, respectively). A comparative analysis of the number of locking screws used in patients with and without bone union showed a significant increase in bone union percentages with more locking screws ($p = 0.046$). (Fig. 3).

Configuration of distal locking screws

The biplanar configuration was the most frequently used in the entire series (150 cases; 67.26%), as well as the most frequent among the patients who achieved bone union (71.28%). On the other hand, for those who did not achieve union, the most frequently used system was uniplanar distal interlocking (60.71%). When comparing the group that achieved bone union with those who did not, we found that the greater the number of planes, the greater the consolidation rate (Fig. 4).

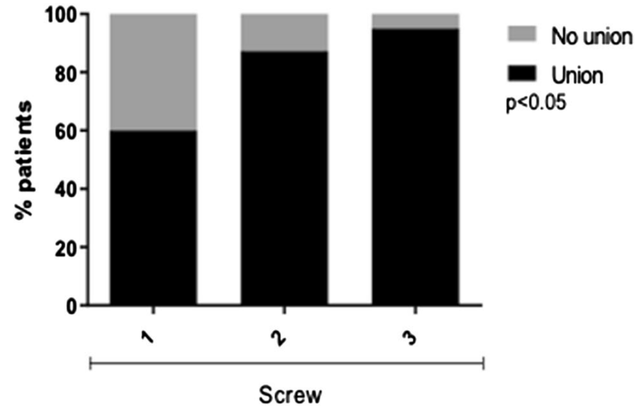

Fig. 3 Relationship between bone union and number of distal locking screws. The greater the number of screws used, the higher the percentage of bone union ($p = 0.046$ increase). Consolidation rates were as follows: 60% with one screw, 87.28% with two screws, and 95% with three screws

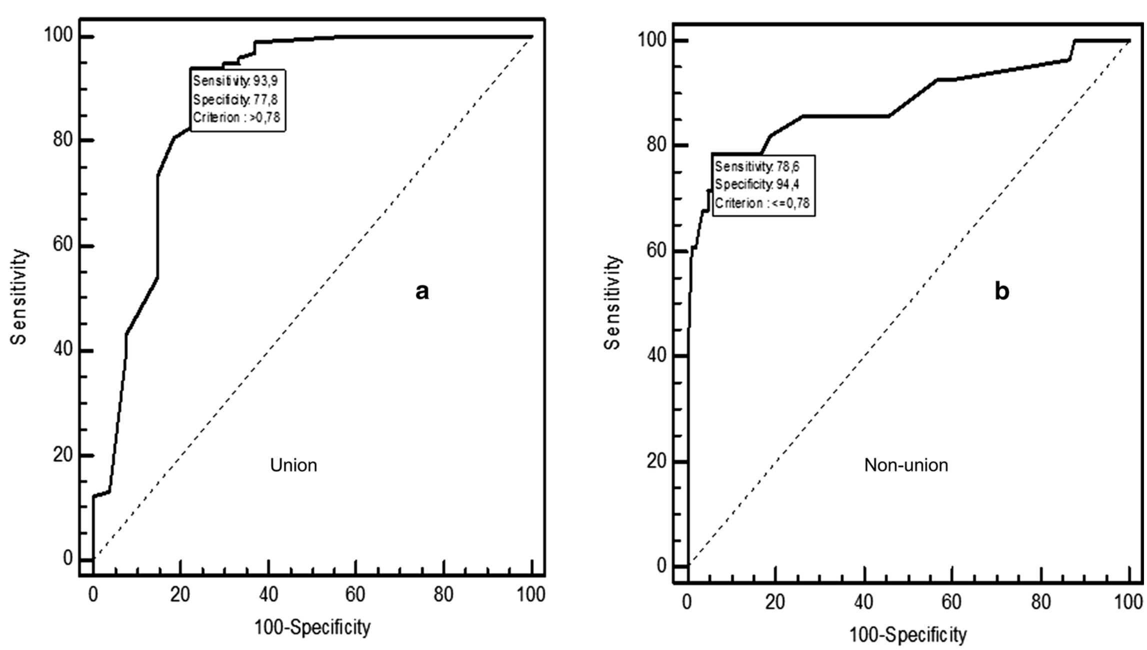

Fig. 2 ROC curves. **a**: for union. NCR > 0.78, AUC 0.88; $p = < 0.0001$; **b**: for nonunion NCR ≤ 0.78; AUC 0.88; $p = < 0.0001$

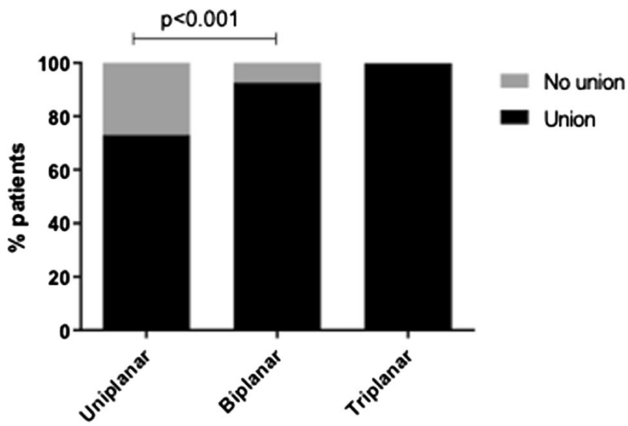

Fig. 4 There is a significant association between the number of fixation planes and bone union. Bone union percentages: 73.01% with one plane, 92.66% with two planes, and 100% with three planes

Locking planes and number of screws

Uniplanar

Out of the 63 fractures fixed distally in a single plane, 46 (73.01%) showed bone union and 17 (26.98%) did not. In 53 cases, two locking screws were used and 24 (79.24%) of them achieved bone union. In the remaining ten, one screw was used and four (40%) patients achieved union. We observed a significant difference in the percentages of union achieved with two-screw fixation (79.24% vs. 40% $p = 0.0018$).

Biplanar

Out of the 150 fractures fixed in two planes, union was observed in 139 (92.66%), while 11 (7.33%) patients did not achieve bone union. In 120 fractures, two locking screws were used, out of which 111 (92.5%) healed (Fig. 5). In the remaining 30, three locking screws were used, and 28 (93.33%) achieved union. We found no significant differences in bone union percentages between patients with two and three screws, (92.5% vs 93.33% $p = 0.99$).

Triplanar

In ten patients, fixation was performed in three planes. Three screws were used in all of them, and the union rate was 100%.

Fig. 5 **a, b**: AP and lateral radiograph showing one of the diaphyseal tibia fractures (42A) of the series. **b, c**: AP and lateral radiograph showing bone union at 4 months postoperative, where two distal locking screws are observed, with a biplanar configuration, representing the most used quantity and configuration of the series

Relationship between number/configuration of screws and NCR

When analyzing the number and configuration of distal locking screws and the relationship between NCR and union, we found that for uniplanar fixation, the use of two distal screws results in a larger NCR range (0.74–0.94). (Fig. 6a). If fixation is performed in two planes, the use of a third locking screw does not affect the NCR (range 0.70–0.90), as shown in graph 4b. (Fig. 6b). On the other hand, the three-plane fixation allows the NCR range to extend (0.63–0.92) (Fig. 6c).

Multivariate analysis

A multivariate analysis adjusted for sex and age showed that the variables that significantly increased bone union were NCR > 0.78 and the configuration of distal screw fixation. (Table 3).

Table 3 Multivariate analysis

	Odds ratio	95% Confidence interval	*p value*
NCR > 0.78	48.77	15.39–154.56	< 0.0001
DLS configuration	2.91	1.12–9.91	0.046
DLS number	1.79	0.41–7.76	0.43
Open/close	0.4	0.17–1.03	0.23
DM	1.05	0.56–1.30	0.99
Smoking	0.98	0.89–2.34	0.56
BMI > 30	1.23	0.37–4.09	0.76

DBT diabetes, *BMI* body mass index, *NCR* nail–canal ratio, *DLS* distal locking screws

Discussion

The most important findings of this study were that the NCR and distal locking planes of an intramedullary nail independently affect bone healing in tibial shaft fractures.

Previously, some authors demonstrated the relevance of nail diameter in tibial fractures. In a biomechanical study, Penzkofer et al. [19] demonstrated that an 11-mm nail increased bone-implant stiffness and decreased fracture site mobility by up to 50%, as compared to a 9-mm nail. In 2016, Donegan et al. [3] established the importance of the nail diameter and width of the isthmus of the medullary canal. They found that an NCR below 0.80 or above 0.99 increased the chances of nonhealing by 4.4, as compared to patients with NCRs ranging from 0.80 to 0.99. Recently, Manon et al. [8] restated the importance of NCR as a predictor of implant failure for values below 0.80.

Although our NCR values are similar to Donegan et al. and Manon et al.'s, it is worth mentioning that ours are associated with a clinical–radiological outcome, while Donegan et al.‘s are only related with radiological findings, and Manon's with implant failure.

Our analysis showed that the point of greatest sensitivity and specificity for union was ≥ 0.79, with a specificity of 77.8%. From a different perspective, the ROC curve calculated for nonunion showed a value of ≤ 0.78 and had a specificity of 93.4%. Additionally, when performing multivariate analyses, we observed that NCR was the independent variable with the greatest power to predict union, which confirms the importance of implanting the nail with the largest possible diameter. To our knowledge, this is the first analysis to describe a ROC curve for union and nonunion and to set an NCR value for reamed nails in tibial shaft fractures. Our study also found that the probability of bone union increases 48 times when the value is equal to or greater than 0.79 in the treatment of closed fractures up to GA type II.

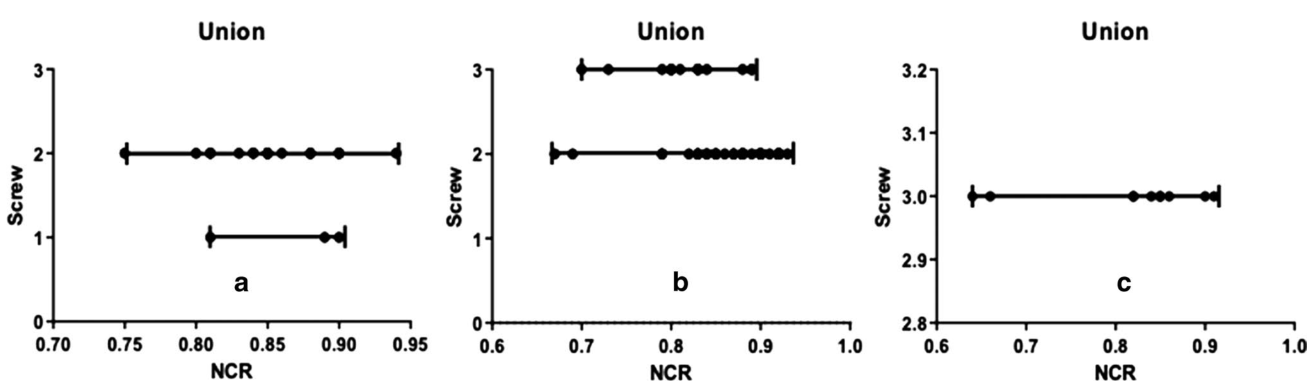

Fig. 6 **a**: Relationship between uniplanar fixation and NCR. The use of two distal locking screws resulted in a larger NCR. **b**: Relationship between biplanar fixation and NCR. The use of a third screw does not result in a larger NCR range (0.70–0.90). **c**: Triplanar fixation with 3 screws results in a broader NCR range for bone union (0.63–0.92)

At present, consensus is weak regarding the number and configuration of distal locking screws in tibial shaft fractures. The available literature is based on biomechanical studies and a limited number of clinical reports, generally including very few cases [14–17]. Ramos et al. [15] reported on 86 shaft fractures treated with unreamed nails. They emphasized that the use of two screws inserted in one plane resulted in shorter times to union than the use of three screws in two planes. They did not find significant differences in nonunion rates between groups. This contrasts our results where fixation in one plane, even with two screws, was associated with a union rate < 80%, i.e., under the percentages obtained with bi- or triplanar fixation.

In a comparative study of 44 patients, Kadir et al. [17] showed shorter union times with biplanar fixation (with three screws) over uniplanar fixation (with two screws), although they did not report nonunion rates. Although our analysis does not focus on time to union, we found some consistencies with these authors, as fixation in two planes increases the probability of bone union. However, in our series, adding a third screw in biplanar fixation did not result in better union rates.

In a comparative study of 57 patients, Happa et al. [14] reported that the use of a single locking screw was safe for closed fractures up to GA type I, with no significant differences in nonunion rates. Although these authors did not specify insertion planes for the group treated with two screws, their findings are not consistent with ours on single-plane fixations with one screw. On the other hand, the results reported by Happa et al. [14] contradict those reported by Kneifel et al. [16] who stated that the use of a single distal screw was associated with a higher rate of mechanical failure due to screw breakage—though without significant differences in union rates.

In our series, we observed that the greater the number of distal locking bolts, the higher the percentages of bone union, though we were unable to demonstrate this as an independent variable in multivariate analysis, probably due to the number of patients included in our study.

Regarding the configuration of distal locking screws, we were able to demonstrate its relevance as an independent variable in the multivariate analysis. We observed that for each plane of distal blocking added, the probability of bone union increases significantly by 2.91. This shows that although there is a logical relationship between the number of screws and locking planes, this is not linear as the configuration is more determinant for bone union.

To our knowledge, this is the first study to assess the impact on bone union of the three possible locking planes in tibial shaft fractures. A comprehensive analysis of the number of distal locking screws and their configuration showed that with one-plane fixation—even if two screws are used—the percentage of bone union does not exceed 80%. As for biplanar fixation, the use of two or three screws does not significantly alter union rates (92.5 vs 93.3%, respectively).

Finally, when we assessed the number and configuration of distal locking screws and the NCR of the patients who achieved bone union, we observed that in uniplanar fixation, the use of two screws resulted in larger NCRs, as compared to the use of a single distal bolt, possibly reflecting that the addition of one screw improves construct stability. On the other hand, when fixation was performed using a biplanar configuration, the use of a third screw did not affect the NCR of the cases that achieved bone union. Going back to what was previously stated regarding union percentages for biplanar fixation with two or three screws, we believe that the use of a third screw in biplanar fixation may have minimal mechanical effect. These observations contradict the results reported by Kadir et al. [17]. Finally, when locking is performed triplanarly, NCR presents a wider range, possibly reflecting a stronger construct. Although there are some reports, like that of Sayana et al.'s [20], that show the addition of locking screws can modify the strain and stability of the fracture, we believe that our findings should be followed by deeper analyses and properly designed studies.

On the other hand, our analysis has also assessed other variables previously associated with healing issues in tibial shaft fractures. Bauwens et al. [6] showed an association between open fractures and reoperation due to nonunion. The exclusion of GA III fractures may account for the lack of significance of our analysis. Contrary to Sprague et al. [7], we did not find significant differences in the healing rates of fractures with different morphologies.

Obesity, diabetes mellitus, and smoking have also been associated with impaired healing in tibial fractures [6–9], though we did not find such association in our series, probably due to the fact that there was a small number of patients with these conditions in our study.

The clinical implications of our findings suggest that when treating tibial shaft fractures, nailing should be performed as tightly as possible at the level of the isthmus because this increases the probability of bone healing. On the other hand, uniplanar fixation should be avoided in favor of biplanar (possibly with only two locks) or triplanar fixation.

Our study has the limitations inherent to retrospective studies, and therefore, our conclusions are weaker than those drawn from prospective and randomized trials. However, if we consider the variables analyzed in this study, it is difficult to conceive prospective protocols capable of complying with current ethical standards while allowing for the correlation of all variables.

The number of patients included in this study may also have affected the statistical power of our analysis. However, we doubled and even tripled the number of patients included in similar series referenced herein.

We also excluded patients with possible confounding factors, which limits the ability of this study to extend our results to all tibial diaphyseal fractures.

On the other hand, the multivariate analysis performed included a considerable number of variables capable of affecting bone union, decreasing the confounding effect of covariates. Finally, although it was not the objective of this manuscript, it lacks functional analysis.

Conclusion

Our findings suggest that when treating tibial shaft fracture with nailing, surgeons should try to fill the medullary canal with an NCR equal to or greater than 0.79. Additionally, distal locking screws should be inserted in a biplanar or triplanar configuration.

Authors' contribution All authors contributed to the study's conception and design. Material preparation, data collection, and analysis were performed by GG, SP, GE, and LPA. The first draft of the manuscript was written by GG, CAP, SP, and FB. All authors read and approved the final manuscript.

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Data and material availability All data generated and analyzed during this study are included in this published article and are available from the corresponding author on reasonable request.

Declarations

Conflicts of interest The authors have no relevant financial or non-financial interests to disclose. The authors have no conflicts of interest to declare that are relevant to the content of this article. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. The authors have no financial or proprietary interests in any material discussed in this article.

Ethical approval All procedures followed were in accordance with ethical standards of the British Hospital of Buenos Aires and Sirio Libanes Hospital committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008 (Project number 6687).

Informed consent Informed consent was obtained from all patients for being included in the study.

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