Original article

Predictors of mechanical complications after intramedullary nailing of tibial fractures

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ABSTRACT

Introduction: Intramedullary (IM) nailing is the gold standard treatment for tibial shaft fractures, but can be associated with various mechanical complications, including delayed union.
Hypothesis: We believe that complications do not occur randomly, but in certain conditions that contribute to their development. Risk factors likely to predict delayed union can be identified to support prevention.
Materials and methods: A cohort of 171 fractures treated by IM nailing between 2005 and 2015 was reviewed retrospectively. Independent variables included intrinsic, patient-related factors and extrinsic factors such as those related to the fracture or surgery. A multiple logistic regression model was used to determine which factors can predict each type of complication.
Results: Delayed union occurred in 22.8% of patients. Smoking and high-energy trauma were risk factors. Hardware breakage was significantly reduced ($p < 0.05$) when the nail diameter was greater than 10 mm. A nail diameter/reamer diameter ratio outside the recommended limits (0.80–0.99) was more likely to be associated with screw failure. Diabetes is a risk factor for hardware migration, which itself is associated with other complications.
Discussion: Nonunion is the most common complication after IM nailing of tibial shaft fractures. Smoking cessation after a fracture is necessary in our opinion, even if the literature is ambivalent on this aspect and stopping to smoke once the fracture occurs may not be sufficient to prevent a poor outcome. Use of a nail diameter/reamer diameter between 0.80 and 0.99 favors union and prevents hardware breakage. Hardware migration in a diabetic patient may be a warning sign of other types of complications.
Level of evidence: Retrospective cohort study. Level IV.

1. Introduction

Tibial shaft fractures are the most common type of long bone fractures and make up 37% of all lower limb fractures [1,2]. Intramedullary (IM) nailing has become the gold standard treatment [1,3]. Healing occurs quickly, the lower limb functions improves, and complications are reduced by one-third [4].

Despite this technical progress, mechanical complications, such as nonunion or delayed union, migration or breakage of the fixation hardware, can occur. This can cause residual pain, long-term functional disability [3] and often requires reoperation (12% to 60% of cases) [4–10].

Currently, the postoperative risks are hard to predict, and the disastrous consequences occur independently of the surgeon and his/her experience [5]. We hypothesized that if we are better able to identify the risk factors susceptible to generate these complications, we can better prevent them in the future and reduce the complications associated with tibial fractures.

2. Materials and methods

This retrospective study captures all the patients treated for a mid-shaft tibial fracture by IM nailing at the Saint-Luc University Hospitals between 2005 and 2015. The study protocol was approved by our university's research ethics board (B403201523492). The candidate patients were identified from our

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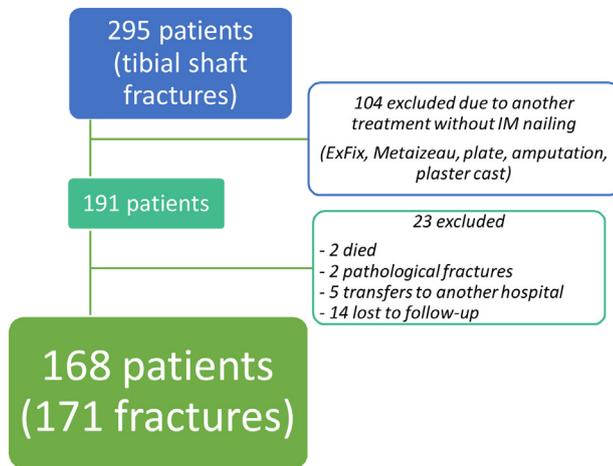*E-mail address:* olivier.cornu@uclouvain.be (O. Cornu).

Fig. 1. Flow chart for patient selection.

medical records database: 295 patients had been treated for a mid-shaft tibial fracture in this time period. Each patient's treatment followed good clinical practices guidelines. Patient selection and exclusion criteria are listed in Fig. 1. After applying these criteria, 168 patients were included in the study, including 3 with a bilateral fracture, thus a total of 171 fractures.

The risk factors explored were patient-related intrinsic factors and extrinsic factors such as those related to the fracture event or surgery (Fig. 2).

The patients were followed until signs of union were apparent and the fracture had healed completely. The latter was defined clinically as the absence of pain and stable walking, and radiologically

as the presence of three solid bone bridges connecting the fracture fragments on anteroposterior and lateral views [5].

Any complications and their time frame were recorded. Delayed union was defined as a fracture lacking signs of a fracture callus on two consecutive radiographs at least 2 months apart during the first 6 months postoperative and/or that required a second procedure (bone graft, IM nail replacement, dynamization, secondary immobilization, Sarmiento functional bracing). Nonunion was defined as a lack of bone union at 9 months postoperative or by the lack of progression of the fracture callus on two consecutive radiographs at least 2 months apart starting at 6 months postoperative and/or that required a surgical revision.

Malunion was defined as union in a non-physiological position: varus/valgus > 5°, rotational defect > 10° and/or lower limb shortening > 1 cm [4]. Failure of the surgical hardware included instances of screw or nail breakage observed on plain radiographs during the follow-up period. Migration was detected by comparing sequential radiographs.

The data were subject to a descriptive and univariate analysis (Chi^2 and odds ratio). Secondarily, a multiple logistic regression was used to determine the risk factors for each type of complication using SPSS Sigmaplot 13. The continuous variables were coded as dichotomic variables (0 or 1) using their median value. Some variables had to be excluded due to irregular standard errors or a variance inflation factor (VIF) > 5 to avoid multicollinearity. The odds ratios and 95% confidence intervals were calculated. Results were considered significant when $p < 0.05$.

3. Results

The mean age of the study population was 45.6 years (14–95 years). Men suffered 61.4% (105/171) of the fractures and 67.3% (115/171) were closed fractures. The fibula was also fractured

Fig. 2. Criteria selected for our study's analysis divided into three categories.

Table 1
Prevalence of comorbidities in the study population.

Comorbidities	Prevalence (%)
Smoker	23.4
Daily alcohol consumption	12.3
Diabetes	5.3
Recreational drug use	5.3
Long-term corticosteroid therapy	2.9

Table 2
Significant results after multiple logistic regression for each type of complication.

Variables	Odds ratio (95% confidence interval)	p-value
Hardware failure		
Nail diameter (≥ 10 mm)	0.08 (0.006–0.92)	0.043
Nail diameter/reamer diameter ratio (≤ 0.80 and ≥ 0.99)	29.05 (1.04–808.93)	0.047
Hardware migration		
Diabetes	46.82 (1.28–1710.28)	0.036
Delayed union		
Smoker	6.06 (1.02–36.16)	0.048
High-energy trauma	10.08 (1.18–85.97)	0.035
Malunion		
BMI > 25	14.22 (0.95–213.23)	0.055

in 89.5% of cases. The comorbidities are summarized in Table 1. Initial fracture stabilization was carried out with IM nailing (80.7%; 138/171), an external fixator (13.5%; 23/171) or a cast (5.8%; 10/171). Final fixation by IM nailing was carried out during the first day post-fracture in 78% of cases. The other 22% underwent IM nailing as a second-line procedure within 98 days (mean 16.5 days, median 11 days, SD 18.2 days). The large majority were reamed first (93.6%) with a reamer diameter between 9.5 and 14 mm for a nail diameter between 7 and 12 mm. The nailing technique involved intraoperative compression followed by static locking for all cases. Dynamization was not part of the standard treatment protocol and was only applied in our cohort in cases of delayed union. This was performed in an isolated manner in 14 cases after a mean of 4.8 months (± 2.2, median 4). Two cases were done within 4 months and two cases were done later (9 or 10 month).

The incidence of each complication is shown in Fig. 3. In the univariate analysis, the number of complications for a given patient is directly associated with the number of comorbidities ($p < 0.001$) and more specifically with smoking ($p < 0.001$). The risk of delayed union is the most frequent complication and increases with the complexity of the fracture in the AO classification ($p < 0.05$) based on the univariate analysis. The number of comorbidities that a patient has increases the risk of malunion ($p < 0.001$). Diabetes also impacted the presence of malunion ($p < 0.05$ and increased relative risk of 6.4) in the univariate analysis. However, the multivariate analysis found no significant risk factors for the prediction of a

malunion, although there was a non-significant trend towards a 14 times higher risk in overweight patients (BMI > 25).

The significant results in the multiple logistic regression analysis for each type of complication and the relative risk are shown in Table 2. Delayed union occurs in smokers and those who suffered high-energy trauma. The incidence of hardware breakage is affected by the nail diameter/reamer diameter ration and lastly, the fixation hardware is more likely to migrate in diabetic patients.

4. Discussion

Delayed union is the most common complication found in our study, like in the literature which reports a 4% to 48% rate in tibial shaft fractures [6,11]. Santolini et al. has ranked the risk factors for delayed union including smoking [9]. In our study, the latter
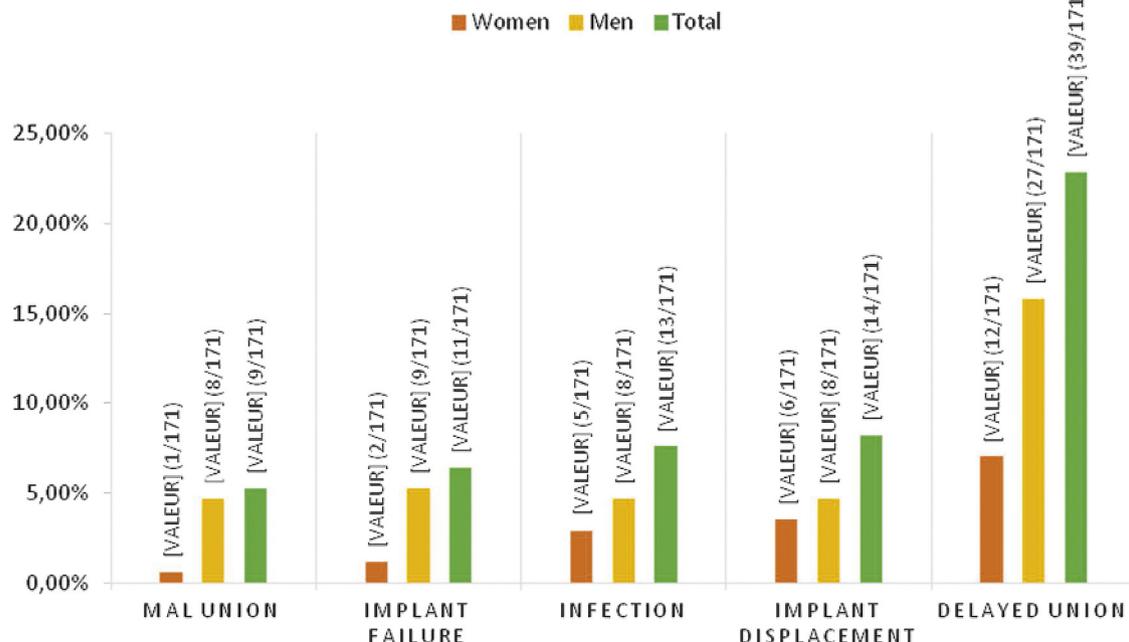

Fig. 3. Incidence of various complications.

Table 3
Incidence of other complications related to hardware migration.

Complication related to hardware migration	Incidence (%)
Infection	7 (1/14)
Malunion	7 (1/14)
Hardware failure	14 (2/14)
Delayed union	14 (2/14)
Total	43 (6/14)

and high-energy trauma were found to be risk factors based on the multivariate analysis.

Smoking is associated with a 3–18 times higher risk of delayed union in younger patients who smoke [12]. The rate for other types of complications, such as delayed wound healing or infection, is also 3 times higher [13–15]. These are additional factors negatively affecting the time to union [14,15] with a higher surgical revision rate [10,16]. Smokers have significantly lower TGF-β1 levels than non-smokers during the first 4 weeks after surgery [17]; this polypeptide increases in patients after surgery and serves as a healing marker. A reduction in this biomarker may explain the delayed union in these patients. However, a meta-analysis separating high-quality and low-quality articles found a significant relationship between smoking and nonunion in low-quality studies, but non-significant in high-quality studies [18]. Nevertheless, perioperative suspension and complete stoppage of smoking must be advised to improve the general prognosis of these patients [13,15].

Delayed union often occurs in the context of high-energy trauma such as motor vehicle accidents [19] and in patients who suffer polytrauma [5]. The chances of fracture healing in the first 6 months are significantly higher in grade I than grade III-B fractures (Gustillo classification) [2,20]; a type 42-B or C fracture (AO classification) is highly predictive of reoperation for nonunion [21], which confirms our findings. Factors related to the fracture are also predictive of surgical revision [22]. In fact, open fractures, the presence of a residual post-fixation gap and transverse fractures are predictors of revision in the year post-fracture. Patients who have two of three criteria are at much higher risk of nonunion, especially if the "residual gap" and "open fracture" criteria occur in combination [22]. If a patient has predispositions and is potentially at risk of developing delayed union, the surgeon must be more vigilant in avoiding any distraction of the fracture site during fixation [11].

Hardware breakage most often occurs in cases of nonunion because of the lack of progressive load transfer from the nail to the bone during healing [23]. Ruiz et al. [24] noted an increase in the incidence of this complication in patients with an open fracture and with more comminution, two features found in delayed union. In their study, like in ours, the incidence of hardware breakage can be reduced by using a nail diameter ≥ 10 mm. Donegan et al. [25] integrate the concept of nail diameter/reamer diameter ratio. The optimal ratio for healing is between 0.80 and 0.99 (healing 4.4 times better) [25]. In our cohort, 9% underwent IM nailing at higher or lower ratios and these patients had statistically more hardware breakage, thus are more likely to experience delayed union.

To our knowledge, no other study has evaluated the risk factors for hardware migration. However, this regularly occurs with delayed union and residual pain [26]. In our study, it was related to diabetes. The higher average age of diabetics (65 vs. 45.6 years, respectively) and the link with osteoporosis might explain this finding. However, age and BMI were re-evaluated in the multiple logistic regression for this complication and were not significant. Diabetes can affect bone metabolism and therefore increase the fracture risk but is also associated with more complications during the bone healing phase [19]. This can be explained by oral antidiabetic drugs that have anti-osteogenic effects [27], except for biguanides, which are pro-osteogenic [28]. We found that 43% of

patients with hardware migration had a concomitant complication. Knowing that diabetics are predisposed to infections [29], seeing a migrated screw on radiographs of a diabetic patient could raise the suspicion of an infection to explain this phenomenon. However, the distribution of complications present simultaneously is more homogeneous and not specifically in favor of infections (Table 3).

A recent study has linked fractures treated by IM nailing and plate in overweight patients and the rate of infection, delayed union, secondary implant removal [30] and longer rehabilitation time [31]. Our study also suggests that surgeons must be vigilant with overweight patients.

Our study has certain limitations. The complications can overlap each other, i.e. one could impact the appearance of another. For example, delayed union can occur following an infection and the predictors of infection can thus affect or distort those of delayed union. Some variables had to be excluded from the multivariate analysis, but it is impossible to say they had no effect. Also, we are conscious that all variables taken into account are not an exhaustive list of all the factors that can impact complications. Some of the subgroups had small sample sizes and it would be interesting to conduct a prospective analysis in a larger population.

While our study could not demonstrate that smoking cessation at the time of the fracture is likely to prevent the progression toward delayed union, we must recommend that it be stopped to reduce the risk of nonunion. Our study also shows the benefit of using the correct nail diameter/reamer diameter ratio; otherwise the risk of hardware breakage is increased, and the risk of healing is reduced. Lastly, if screw migration is observed on follow-up radiographs in a diabetic patient, surgeons should systematically look for other associated complications, to rule out reversible causes that negatively affect healing.

Disclosure of interest

The authors declare that they have no competing interest.

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Authors' contribution

Clinical study: Julie Manon, Olivier Cornu, Dan Putineanu, Karim Tribak, Simon van den Veyver.

Statistical study: Christine Detrembleur, Julie Manon, Olivier Cornu.

Writing: Julie Manon, Olivier Cornu, Christine Detrembleur, Dan Putineanu.

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