

Long Bone Union Accurately Predicted by Cortical Bridging within 4 Months

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Background: Previous retrospective research found that the presence or absence of bridging callus within 4 months postoperatively discriminated accurately between eventual union and nonunion of fractures of the tibial shaft. However, there remains no consensus regarding early prognostication of long bone nonunion. We prospectively assessed the accuracy and reliability of the presence of any bridging callus within 4 months in a cohort that was expanded to include both tibial and femoral shaft fractures.

Methods: We identified 194 consecutive fractures of the shaft of the tibia (OTA/AO type 42-A, B, or C) and femur (OTA/AO type 32-A, B, or C) that were treated with intramedullary nailing. Exclusions for inadequate follow-up (55), extended delay prior to nailing (10), and skeletal immaturity (3) resulted in a study population of 126 fractures (56 tibiae and 70 femora) in 115 patients. Digital radiographs made between 3 and 4 months postoperatively were independently assessed by 3 orthopaedic traumatologists. The accuracy of assessment of the presence of any bridging callus, bicortical bridging, and tricortical bridging to predict union or nonunion was assessed with chi-square analysis and by interobserver reliability (kappa statistic).

Results: The nonunion rate was 4% (5 of 126 fractures). The presence of any bridging callus by 4 months accurately predicted union (121 of 122 fractures) and its absence predicted nonunion (4 of 4 fractures). There was 1 incorrect prediction of union for a fracture that failed to unite ($p < 0.001$). Bicortical or greater bridging predicted union when present (116 of 116 fractures) and nonunion when absent (5 of 10 fractures), incorrectly predicting that 5 healing fractures would go on to nonunion ($p < 0.001$). Tricortical or greater bridging predicted union when present (103 of 103 fractures) and nonunion when absent (5 of 23 fractures), incorrectly predicting that 18 healing fractures would go on to nonunion ($p < 0.001$). Interobserver reliability was calculated for any bridging (kappa value, 0.91), bicortical bridging (kappa value, 0.79), tricortical bridging (kappa value, 0.71), and the exact number of cortices bridged (kappa value, 0.67).

Conclusions: The presence of any bridging callus within 4 months accurately predicts the final healing outcome for tibial and femoral shaft fractures treated with intramedullary nailing. This criterion is simple and reliable, and only standard radiographs are needed to make the determination. Basing the prognosis on the bridging of additional cortices risks overestimation of the nonunion rate and is associated with relatively poor reliability.

Fracture nonunion is a condition in which further observation alone will fail to result in union. Nonunion has been described as failure to unite after 8 months of observation or after more than 6 months of observation with a lack of progressive healing over the last 3 months^{1,2}. Despite these more stringent guidelines, reports in the literature have defined the timing of nonunion over a broad range and as early as 2 months following injury³⁻⁸.

Despite the importance of fracture union as an outcome, there remains no consensus regarding early prognostication of union. The variability in definitions of radiographic evidence of union complicates interpretation of the literature^{3,9-11}. Early formation of callus seen with ultrasonography has been shown to predict union, but the lack of callus seen with such imaging has failed to accurately predict nonunion¹².

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Observations made in the SPRINT (Study to Prospectively Evaluate Reamed Intramedullary Nails in Patients with Tibial Fractures) trial have led to recommendations that further intervention for tibial shaft fractures should be withheld until at least 6 months after injury⁹. This has been extrapolated to other long bones including the femur. Such recommendations limit the number of unnecessary procedures performed for fractures that will heal with observation alone. However, these recommendations delay treatment for fractures that will go on to nonunion⁶. Timely and accurate treatment of fracture nonunion requires early and accurate assessment of fracture-healing.

Previously, a retrospective single-center study determined that the presence or absence of bridging callus at 4 months postoperatively accurately discriminated between tibial shaft fractures that would or would not eventually unite¹³. We hypothesized that prospective assessment for any cortical bridging by 4 months postoperatively would accurately and reliably predict the final healing outcome of tibial and femoral shaft fractures treated with intramedullary nailing.

Materials and Methods

At a level-I trauma center, between September 1, 2013, and December 2, 2015, we identified 194 consecutive tibial shaft fractures (OTA/AO types 42-A, B, and C) and femoral shaft fractures (OTA/AO types 32-A, B, and C)¹⁴ in adult patients treated with reamed, locked intramedullary nailing. After exclusion of those with inadequate follow-up (55), delay of >14 days prior to nailing (10), or skeletal immaturity (3), 126 fractures (56 tibiae and 70 femora) were available for study in 105 patients with a single fracture and 10 patients with multiple fractures. Four patients had a fracture of the femur and tibia; 4, fractures of both femora; 1, fractures of both tibiae; and 1, fractures of both femora and 1 tibia. Follow-up was considered adequate if the treating surgeon documented clinical and radiographic union or diagnosed nonunion. Clinical healing was defined as full weight-bearing by the patient through a stable limb, without an assistive device and without pain at the fracture site. Radiographic evidence of healing was defined as at least tricortical bridging of the fracture without fracture lucency. Patients were treated with a watchful waiting approach, and interventions for delayed healing or nonunion were not per-

formed <6 months after injury unless construct failure occurred prior to that time. Nail dynamization and bone simulators were not used. This prospective study was approved by the institutional review board.

Radiographic assessment consisted of digital radiographs at 6 to 8 weeks and 3 to 4 months postoperatively, followed by radiographs at 3-month intervals until final healing was achieved (average follow-up, 12 months). Three of us who are fellowship-trained orthopaedic trauma surgeons (W.D.L., H.S., and M.B.) prospectively and independently assessed the number of cortices bridged on radiographs made between 3 and 4 months postoperatively. The observers were blinded to the healing outcome because the radiographs were reviewed prior to further evaluation of the patients. Interobserver reliability was calculated with the kappa statistic for these assessments (using SPSS version 13.0). The declaration of union or nonunion by the treating surgeon was recorded for each fracture. We also noted if late complications of healing occurred in any patients whose fracture had previously been declared healed.

We defined 3 distinct criteria for bridging that were assessed at 4 months. (After 4 months, fractures were further observed to determine if healing progressed to full union). Unicortical bridging was defined as the presence of bridging callus at 1 or more cortices (inclusive of bicortical or tricortical bridging). Bicortical bridging was defined as bridging at 2 or more cortices (inclusive of tricortical bridging). Tricortical bridging required bridging of at least 3 cortices. The predictive accuracy was defined as the percentage of fracture-healing outcomes that were accurately predicted based on a given criterion of bridging. Chi-square analysis was used to compare the accuracy of assessment of the bridging. For all analyses, 2-tailed p values were used and were deemed significant if $p < 0.05$. A power analysis was performed, based on a previous retrospective study, and we determined that a study population of 100 fractures (femur and tibia combined) was needed to determine the accuracy of prospective assessment¹³.

Results

The nonunion rate was 4% (5 of 126 fractures). Of 56 tibial shaft fractures, 4 (7%) went on to nonunion and of 70 femoral shaft fractures, 1 (1%) went on to nonunion. Of the

TABLE I Characteristics by Healing Outcome

	Tibia		Femur	
	Union (N = 52)	Nonunion (N = 4)	Union (N = 69)	Nonunion (N = 1)
Sex, M/F	31/21	3/1	45/24	0/1
Median age (IQR)* (yr)	38 (IQR, 23-51)	46 (IQR, NA)	34 (IQR, 23-54)	46 (IQR, NA)
Open fracture†	37% (19)	100% (4)	19% (13)	100% (1)
Smoking	42% (22)	50% (2)	23% (16)	0%
Diabetes	6% (3)	0%	10% (7)	0%

*IQR = interquartile range, and NA = not applicable. †The only characteristic significantly associated with nonunion was open fracture, $p < 0.01$.

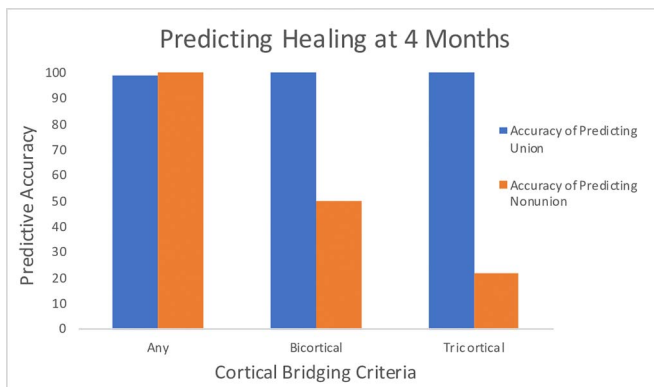


Fig. 1
Cortical bridging criteria vary in their ability to predict union and nonunion. Requiring a greater number of cortices to be bridged at 4 months leads to overestimation of the nonunion rate, predicting nonunion for fractures that healed with further observation alone.

patient and injury characteristics that we identified (Table I), only open fracture was significantly associated with a diagnosis of nonunion ($p < 0.01$). The presence of any bridging callus by 4 months accurately predicted union (121 of 122 fractures) and its absence predicted nonunion (4 of 4 fractures) ($p < 0.001$). The single fracture for which the assessment of any bridging callus was inaccurate was an infected, hypertrophic tibial nonunion. Bicortical bridging predicted union when present (116 of 116 fractures) and nonunion when absent (5 of 10 fractures), incorrectly predicting 5 healing fractures as nonunions ($p < 0.001$). Tricortical bridging predicted union when present (103 of 103 fractures) and nonunion when absent (5 of 23 fractures), incorrectly predicting 18 healing fractures as nonunions ($p < 0.001$). These results are presented in Figure 1. If only 1 cortex was bridged at 4 months, 5 of 6 fractures went on to eventually achieve radiographic and clinical union without intervention, and this was true for 13 of 13 fractures with exactly 2 cortices bridged at 4 months. Interobserver reliability was calculated for any bridging (kappa value, 0.91), bicortical bridging (kappa value, 0.79), tricortical bridging (kappa value, 0.71), and the exact number of cortices bridged (kappa value, 0.67). No patient whose fracture was deemed to have united was later diagnosed with implant failure or required any additional treatment for healing-related complications.

Discussion

In this study of 126 tibial and femoral shaft fractures treated with intramedullary nailing, the overall rate of nonunion was 4%, which is consistent with reports in the literature¹⁵⁻¹⁹. Many fractures that united needed >6 months to achieve tricortical bridging, but these slowly healing fractures had all achieved either unicortical or bicortical bridging within 4 months. All but 1 of the 5 fractures that did not unite had failed to achieve cortical bridging within 4 months. The 1 exception was an infected, hypertrophic nonunion of the tibia.

Our results indicate that prospective assessment of cortical bridging within 4 months postoperatively can be assessed reliably

and is accurate in predicting the final outcome of healing for both femoral shaft and tibial shaft fractures treated with intramedullary nailing. Cortical bridging implies a sufficient early healing response and is highly predictive of union (Fig. 2-A). Conversely, failure to achieve cortical bridging within 4 months postoperatively accurately predicts eventual nonunion (Fig. 2-B).

The accuracy of radiographic assessment in predicting the healing of tibial shaft fractures has been reported to be as low as 50%²⁰. Our prospective results confirm previous findings¹³ that radiographic criteria applied at the appropriate time interval can be more accurate than has been reported previously. Some degree of cortical bridging occurred within 4 months for all fractures that later achieved union, and no bridging occurred for 4 of the 5 fractures that did not unite. In other words, a lack of cortical bridging within 4 months was 80% sensitive and 100% specific for nonunion. Employing more stringent criteria of bicortical or tricortical bridging within 4 months reduces the predictive accuracy of radiographic assessment. Notably, the single fracture for which the assessment was inaccurate was an infected, hypertrophic nonunion. This type of nonunion is particularly difficult to assess radiographically because of the periosteal changes that can be associated with infection. History and examination findings, although always necessary, are particularly important to aid in the diagnosis in such cases.

Both basic-science research and clinical studies have found bridging callus to be a relatively reliable predictor of the mechanical strength of healing fractures²⁰⁻²⁵. However, evidence is sparse regarding the minimum number of bridging cortices required to consider a fracture healed. Tricortical bridging has previously been employed as a radiographic criterion required to document a healed fracture^{19,26,27}, and bicortical bridging also has been suggested as sufficient¹². However, neither bicortical nor tricortical bridging has been shown to be accurate in early assessments of healing. In our patients, employing the threshold of any cortical bridging at 4 months to guide clinical decision-making would have resulted in earlier treatment of 4 of 5 fractures that went on to nonunion and would not have led to overtreatment of any fracture. Requiring bicortical bridging at 4 months for a diagnosis of eventual union would have resulted in an overdiagnosis of nonunion for 5 fractures; requiring tricortical bridging would have led to an incorrect diagnosis of impending nonunion for 18 fractures.

Assessment of bridging of any cortex was the most reliable criterion studied, with excellent interobserver agreement (kappa value, 0.91)²⁸. This reliability is greater than that generally reported for radiographic assessments of fracture-healing and surgeons' general impression of healing (kappa values of 0.6 and 0.67, respectively) and is similar to that found for the RUST score (Radiographic Union Score for Tibial fractures)²³⁻²⁶. It is also very similar to the interobserver reliability found in a retrospective study of cortical bridging²⁹. As in that study, we found greater interobserver agreement for the formation of any cortical bridging than for the more stringent criteria requiring bicortical bridging (kappa value, 0.79) and tricortical bridging (kappa value, 0.71). The reliability for assessment

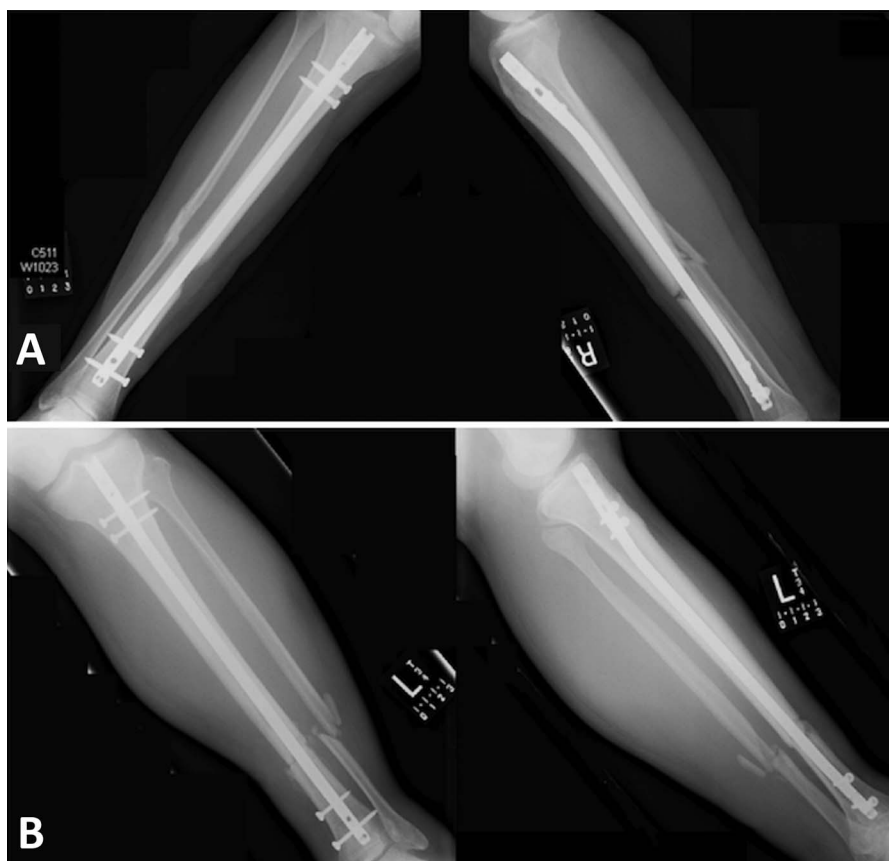


Fig. 2

Figs. 2-A and 2-B Radiographs showing fractures without and with cortical bridging at 4 months. **Fig. 2-A** This type-IIIa open fracture had unicortical bridging of the lateral cortex. This fracture eventually achieved tricortical bridging without fracture lucency, and union was later confirmed clinically. **Fig. 2-B** This high-energy closed fracture lacked cortical bridging. The fracture did not unite.

of the exact number of cortices bridged demonstrated an even lower kappa value (0.67), similar to that found in previous research²⁹. That assessment did not require observers to agree on the exact number of cortices bridged, fracture line lucency, or quality of the callus present, but simply that bridging callus existed.

One limitation of this study is that it was based on patients from a single institution. Additionally, a large number of patients were excluded due to lack of adequate follow-up; however, this is not unexpected because of the inclusion criterion of the final outcome of healing. The findings are most clear regarding tibial shaft fractures; because there was only 1 femoral nonunion, further research may be necessary to confirm the optimal criteria for a prognosis of union or nonunion of the femoral shaft. Despite its limitations, the study has several strengths. It was powered based on previous retrospective research, and observations were made prospectively. Additionally, the study design attempted to avoid previously reported limitations of research on this topic by defining and requiring both clinical and radiographic union and by assessing reliability³⁰.

This prospective study adds further evidence to previous retrospective findings regarding tibial shaft fractures treated with intramedullary nailing as well as fractures of the distal part

of the femur treated with locked plating^{29,31}. The prognostic accuracy in our prospective study was much greater than has been reported for other methods³². These findings have implications for surgical indications, optimal timing of radiographic follow-up, and future studies of fracture-healing.

In conclusion, prospective assessment for any bridging callus within 4 months postoperatively accurately predicted union and nonunion in tibial and femoral shaft fractures in this study. The criterion is simple, is highly reliable, and requires only standard radiographic views. The presence of bridging callus is a relatively early radiographic finding that consistently discriminated between fractures that achieved late union with observation alone and fractures that went on to nonunion. Requiring additional cortices to be bridged risks overestimation of the nonunion rate and is associated with relatively poor reliability. ■

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