

# Weight-bearing status may influence rates of radiographic healing following reamed, intramedullary fixation of diaphyseal femur fractures

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## Abstract

**Objective:** To investigate the effect of weight-bearing status on radiographic healing of diaphyseal femur fractures.

**Design:** Retrospective 1:1 matched cohort study.

**Setting:** Single-level 1 trauma center.

**Participants:** One-hundred forty-four (N=154) patients matched 1:1 in non-weight bearing (NWB) and weight-bearing as tolerated (WBAT) groups.

**Intervention:** Non-weight bearing following reamed, statically locked intramedullary fixation of diaphyseal femur fracture, generally due to concurrent lower extremity fracture.

**Main Outcome Measurement:** Postoperative radiographic healing using modified Radiographic Union Scale for Tibia fractures (mRUST) scores.

**Results:** Groups were well matched on age, sex, race, prevalence of tobacco and alcohol use, diabetes mellitus status, Injury Severity Score, fracture pattern and shaft location, vascular injury, open fracture prevalence, and operative characteristics. Radiographic follow-up was similar between groups (231 vs 228 days,  $P=.914$ ). At 6 to 8 weeks status post intramedullary fixation, the median mRUST score in the NWB group (9) was lower than that of the WBAT group (10) (mean: 8.4 vs 9.7,  $P=.004$ ). At 12 to 16 weeks, the median mRUST in the NWB group (10) was again lower than the WBAT group (12) (mean: 9.9 vs 11.7,  $P=.003$ ). The median number of days to 3 cortices of bridging callous was 85 in the WBAT group, compared with 122 in the NWB group ( $P=.029$ ). Median time to mRUST scores of 12 (111 vs 162 days,  $P=.008$ ), 13 (218 vs 278 days,  $P=.023$ ), and 14 (255 vs 320 days,  $P=.028$ ) were all longer in the NWB group compared with the WBAT group.

**Conclusions:** Non-weight bearing after intramedullary fixation of diaphyseal femur fractures delays radiographic healing, with median time to 3 cortices of bridging callous increased from 85 days in WBAT groups to 122 days in NWB groups. These results provide clinicians with an understanding of the expected postoperative course, as well as further support the need to expeditiously advance weight-bearing status.

Level of Evidence: IV

**Keywords:** femur fracture, mRUST, radiographic healing, weight-bearing status

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IRB approval was obtained for this study.

The authors have no conflicts of interest to disclose.

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## 1. Introduction

Femoral diaphyseal fractures managed with intramedullary fixation heal reliably; union rates approach 85% to 100%.<sup>[1-7]</sup> While uncommon, non-unions do occur, with prior work suggesting that open injury, increased preoperative morbidity, and tobacco use may increase this risk.<sup>[8-13]</sup> Interestingly, delayed weight bearing has also been cited as a potential risk factor for non-union.<sup>[14]</sup> While biomechanical and clinical studies have shown that early weight bearing is safe following appropriately sized, reamed, statically locked intramedullary nailing, early postoperative mobilization may be delayed in certain cases secondary to concomitant injury or surgeon preference.<sup>[15,16]</sup> Therefore, identifying differences in radiographic healing rates based on weight-bearing status would provide clinicians with an improved understanding of the expected postoperative course, as well as further support the need to expeditiously advance weight-bearing status.

Healing of diaphyseal femur fractures treated with intramedullary fixation has previously been analyzed as a dichoto-

mous variable (e.g., union/non-union), with limited consideration for graded approaches, and with qualitative measures used to define non-union.<sup>[12]</sup> Traditionally, this has been related to the lack of consensus regarding the assessment of union amongst orthopaedic surgeons.<sup>[17,18]</sup> Recently, the Radiographic Union Scale for Tibia, and its modified version (mRUST), have offered clinicians a reliable, validated tool to quantitatively assess radiographic healing of long bone fractures.<sup>[19-21]</sup> While initially intended for the tibia, this scale has also been used to assess healing in femur fractures. This allows for the evaluation of large numbers of femoral shaft fractures without limiting analysis to the uncommon event of non-union.<sup>[22,23]</sup> Therefore, the goal of this study was to use mRUST scores to investigate the effect of weight-bearing status on radiographic healing of diaphyseal femur fractures managed with intramedullary fixation.

## 2. Methods

### 2.1. Design and setting

This retrospective case-control series was performed at a single-level 1 trauma center in the Midwest region of the United States. An institutional database was established to identify femoral shaft fractures (OTA/AO type 32 injuries) managed from January 1, 2010 to December 31, 2018.<sup>[24]</sup> Institutional review board approval was obtained for the study.

### 2.2. Patient selection

Six-hundred ninety-five (N=695) skeletally mature patients with OTA/AO type 32 injuries were identified. Demographic data, baseline health metrics, injury characteristics, and operative specifics were recorded (Table 1). Postoperatively, the variables of interest included weight-bearing status and radiographic follow-up. The number of days from surgery until a patient was advanced to weight-bearing as tolerated (WBAT) was also noted,

as were the number of days from surgery to each postoperative femur radiograph. For each radiograph, the mRUST score was calculated. Briefly, the mRUST score measures the radiographic healing of a femur fracture on a scale of 4 to 16. Each cortex is graded: 1=no callus, 2=callus present, 3=bridging callus present, 4=remodeled; the sum of these values gives the mRUST score.<sup>[20,21,22,25,26]</sup> An mRUST score of 11 generally corresponds to 3 cortices of bridging callous. Three reviewers (CDF, JC, NMJ) performed mRUST ratings; ICC values have previously been reported (ICC=.74) and were not recalculated for this investigation.<sup>[27]</sup>

Patients were eligible for study inclusion if: the injury was managed with intramedullary fixation (retrograde or antegrade); postoperative weight-bearing status was non-weight bearing (NWB) or WBAT; patients in the NWB group were assigned this status for at least 6 weeks; a postoperative radiograph from 6 to 8 weeks after injury was available for review. To isolate the effect of weight-bearing, patients were excluded for the following indications: severe traumatic brain injury; high-spinal cord injury; initial external fixator temporization; dual construct fixation (e.g., plate and nail fixation); initial presentation was of peri-implant fractures; bone loss requiring advanced reconstruction (e.g., bone transport). For implant selection, all surgeons performed reamed, statically locked fixation utilizing the Synthes Retrograde/Antegrade Femoral Nail (Depuy Synthes Companies, Warsaw, Indiana).

Eligible patients in NWB and WBAT groups were then matched 1:1 to control for baseline demographic, health, injury, and operative differences. Patients were matched on the following variables: age, sex, race, tobacco use prevalence, alcohol use prevalence, body mass index, diabetes mellitus status, ASA score, mechanism of injury, AO fracture classification, vascular injury presence, Injury Severity Score (ISS) score, location of fracture in the femoral shaft (proximal, middle, distal), presence of open fracture, time to OR, and retrograde or antegrade start point. The number of patients in each group was N=77.

**Table 1**  
Patient demographic and injury characteristics

	Non-weight bearing (NWB) N=77	Weight-bearing as tolerated (WBAT) N=77	P value
Age (years) (SD)	33.0 (13.4)	32.4 (15.3)	.796
Sex			1.00
Male	52 (67.5%)	53 (68.8%)	
Female	25 (32.5%)	24 (31.2%)	
Race			.945
Caucasian	47 (61.0%)	49 (63.6%)	
African American	29 (37.7%)	27 (35.1%)	
Other	1 (1.3%)	1 (1.3%)	
Tobacco use	40 (52.0%)	39 (49.4%)	1.00
Alcohol	35 (45.5%)	31 (40.3%)	.625
BMI	28.6 (7.1)	27.5 (5.5)	.284
Diabetes mellitus	4 (5.2%)	3 (3.9%)	1.00
ASA Score	2.3 (0.7)	2.2 (0.7)	.100
Mechanism of injury			.425
MVC	46 (59.7%)	37 (48.1%)	
MCC	14 (18.2%)	12 (15.6%)	
Fall	3 (3.9%)	9 (11.7%)	
Pedestrian struck	4 (5.2%)	6 (7.8%)	
Ballistic	6 (7.8%)	8 (10.4%)	
Other	4 (5.2%)	6 (7.8%)	
Length of radiographic follow-up (d)	231 (214)	228 (222)	.914

## 3. Analysis

Statistical analysis was completed with Prism 7.0a software (GraphPad Software Inc, La Jolla, California) and MatLab R2016b software (Mathworks, Natick, Massachusetts).

### 3.1. Power analysis

While the utility of a power analysis in a retrospective study is open to debate, we had an interest in powering the study to ensure the effect of weight bearing was captured. An a priori power analysis was performed to calculate sample size. For mRUST scores at 6 to 8 week follow-up, setting  $\beta=0.80$ ,  $\alpha=0.05$ , and assuming a 1-point difference in mRUST scores between groups with a standard-deviation of 2 units, sample size was determined to be 63 patients per group. As this was a novel investigation, a 25% increase to this number was applied to account for possible errors in the power analysis estimation.

### 3.2. Cohort matching and outcomes of interest

Outcomes of interest included: differences in mRUST scores between NWB and WBAT groups at 6 to 8 weeks and 12 to 16 weeks following injury; time to mRUST scores of 11, 12, 13, and 14. To evaluate the quality of the matching process, as well as to analyze these outcomes, Student *t* test with Welch correction,

Chi-squared, Fischer exact, Kolmogorov–Smirnov normality test, and Mann–Whitney test were utilized, in the appropriate setting. Controversy exists regarding what mRUST score corresponds to fracture union; therefore, results are reported as time to individual mRUST scores of 11 through 14.<sup>[20,21,22,25,26]</sup> An mRUST score of 11 generally corresponds to 3 cortices of bridging callous. Time-to-event analysis was performed using the Kaplan–Meier estimator. Log-rank (Mantel-Cox) test was used to identify differences between time-to-event curves.

**4. Results**

**4.1. Patient characteristics and case-control matching**

The number of patients in each group was N=77. Overall, patients in this series were majority male (68.2%) and Caucasian (62.3%) with mean age 32.7 years. Tobacco and alcohol use were prevalent (51.3%, 42.9%, respectively). Mean body mass index was in the overweight category (28.0), with a low rate of diabetes mellitus (4.5%).<sup>[28]</sup> Patients most commonly sustained injury in a motor vehicle or motor cycle collision (70.8%), resulting in ISS of 16.4.

Right and left-sided injuries were equally represented. A majority of fractures were middle 1/3 diaphyseal injuries (51.3%), with the majority being simple patterns (50.0%). Open fractures, including ballistic injuries, occurred in 24.0% of cases; vascular injury was rare (2.6%). Most patients underwent operative fixation within 24 hours of injury (94.8%), with a mean ASA score of 2.2. Intramedullary fixation most commonly was performed through an antegrade start point (83.8%), with an 11 mm diameter nail and 3 or 4 total interlocking screws (Tables 1–3). In the NWB group, the most common reason for this weight-bearing status was an ipsilateral lower extremity or acetabular/pelvic ring injury (77.9%); however, in 22.1% of cases, the indication for NWB was not attributable to a concomitant injury. Patients in the NWB group had this weight-bearing status for mean 75 days (standard deviation 25 days).

Patients in the NWB and WBAT groups were well matched. Specifically, there were no differences in patient age, prevalence of tobacco or alcohol use, prevalence of diabetes mellitus, fracture pattern or shaft location, vascular injury, open fracture, or delay

**Table 2**  
**Femoral shaft fracture characteristics**

	Non-weight bearing (NWB) N = 77	Weight-bearing as tolerated (WBAT) N = 77	P value
Side			.747
Right	42 (54.6%)	39 (50.7%)	
Left	35 (45.4%)	38 (49.3%)	
OTA/AO frx type			.980
A—Simple	44 (57.1%)	43 (55.8%)	
B—Wedge	17 (22.1%)	17 (22.1%)	
C—Multifragmentary	16 (20.8%)	17 (22.1%)	
Vascular injury	2 (2.6%)	2 (2.6%)	1.00
Injury severity score (ISS)	17.3 (9.7)	15.6 (9.8)	.274
Shaft location			.755
Proximal 1/3	14 (18.2%)	19 (24.7%)	
Middle 1/3	40 (51.9%)	39 (50.6%)	
Distal 1/3	21 (27.3%)	17 (22.1%)	
Segmental	2 (2.6%)	2 (2.6%)	
Open fracture	21 (27.3%)	16 (20.8%)	.451

**Table 3**  
**Specifics of operative fixation**

	Non-weight bearing (NWB) N = 77	Weight-bearing as tolerated (WBAT) N = 77	P value
Time to OR			.719
0–24 h	72 (93.5%)	74 (96.1%)	
25–48 h	5 (6.5%)	3 (3.9%)	
Start point			.189
Antegrade	61 (79.2%)	68 (88.3%)	
Retrograde	16 (20.8%)	9 (11.7%)	
Nail length (mm) (median)	380	380	.586
Nail diameter (mm) (median)	11.0	11.0	.529
Number interlocks			.144
2	10 (13.0%)	11 (14.3%)	
3	35 (45.5%)	23 (29.9%)	
4	32 (41.6%)	42 (54.5%)	

to surgery. There was also no difference in overall injury severity as measured by ISS or ASA score. Operative fixation characteristics were also similar between groups (Tables 1–3).

**4.2. Radiographic healing by weight-bearing group**

Mean radiographic follow-up was approximately 7.7 months (231 vs 228 days,  $P=.914$ ). Radiographs 6 to 8 weeks status postintramedullary fixation were available to review for all patients. The mean number of days from surgery to radiograph was similar between groups (52.7 vs 50.9,  $P=.27$ ). The median mRUST score in the NWB group (9) was lower than that of the WBAT group (10) (mean: 8.4 vs 9.7,  $P=.004$ ).

While most patients had multiple additional radiographs after the 6 to 8 week window, the time points for these radiographs were less standardized. For example, a 12 to 16 week postoperative radiograph was available for review in 51.3% of patients (NWB: 50.6%, WBAT: 51.9%). As before, the mean number of days from surgery to radiograph was similar between groups (93.5 vs 88.0 days,  $P=.202$ ). The median mRUST in the NWB group (10) was again lower than that of the WBAT group (12) (mean: 9.9 vs 11.7,  $P=.003$ ).

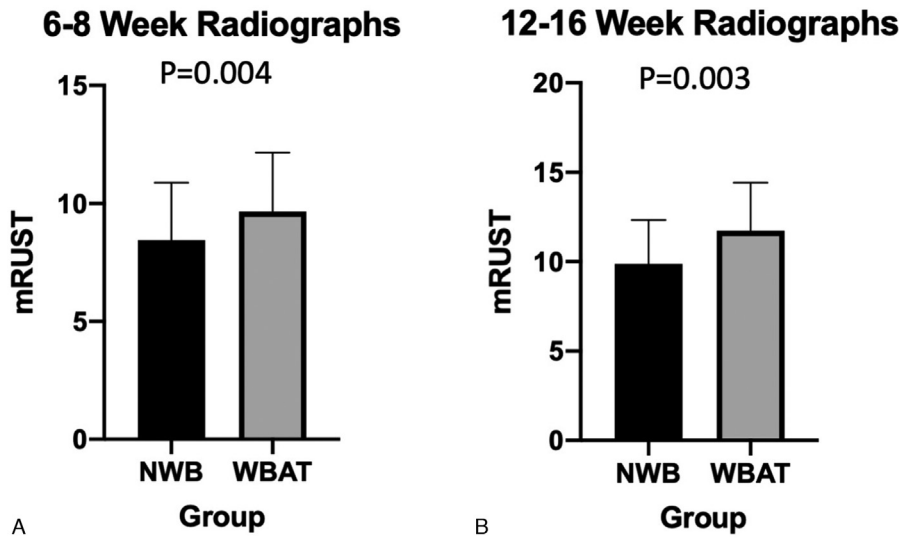
Two patients in the WBAT group and 3 patients in the NWB group went on to have revision operations for fracture non-union. Mean time to revision in the WBAT group was 385 days, compared with 372 days in the NWB group (Fig. 1).

**4.3. Time to mRUST scores 11 through 14**

The number of patients who achieved radiographic follow-up to an mRUST score of 11 was N=60 in the NWB group (77.9%) and N=63 in the WBAT group (81.8%). In the WBAT group, median time to mRUST of 11 was 85 days, compared with 122 days in the NWB group ( $P=.029$ ) (Fig. 2A).

The number of patients who achieved radiographic follow-up to an mRUST score of 12 was N=50 in the NWB group (64.9%) and N=53 in the WBAT group (68.9%). In the WBAT group, median time to mRUST of 12 was 111 days, compared with 162 days in the NWB group ( $P=.008$ ) (Fig. 2B).

The number of patients who achieved radiographic follow-up to an mRUST score of 13 was N=30 in the NWB group (39.0%) and N=40 in the WBAT group (51.9%). In the WBAT group, median time to mRUST of 13 was 218 days, compared with 278 days in the NWB group ( $P=.023$ ) (Fig. 2C).

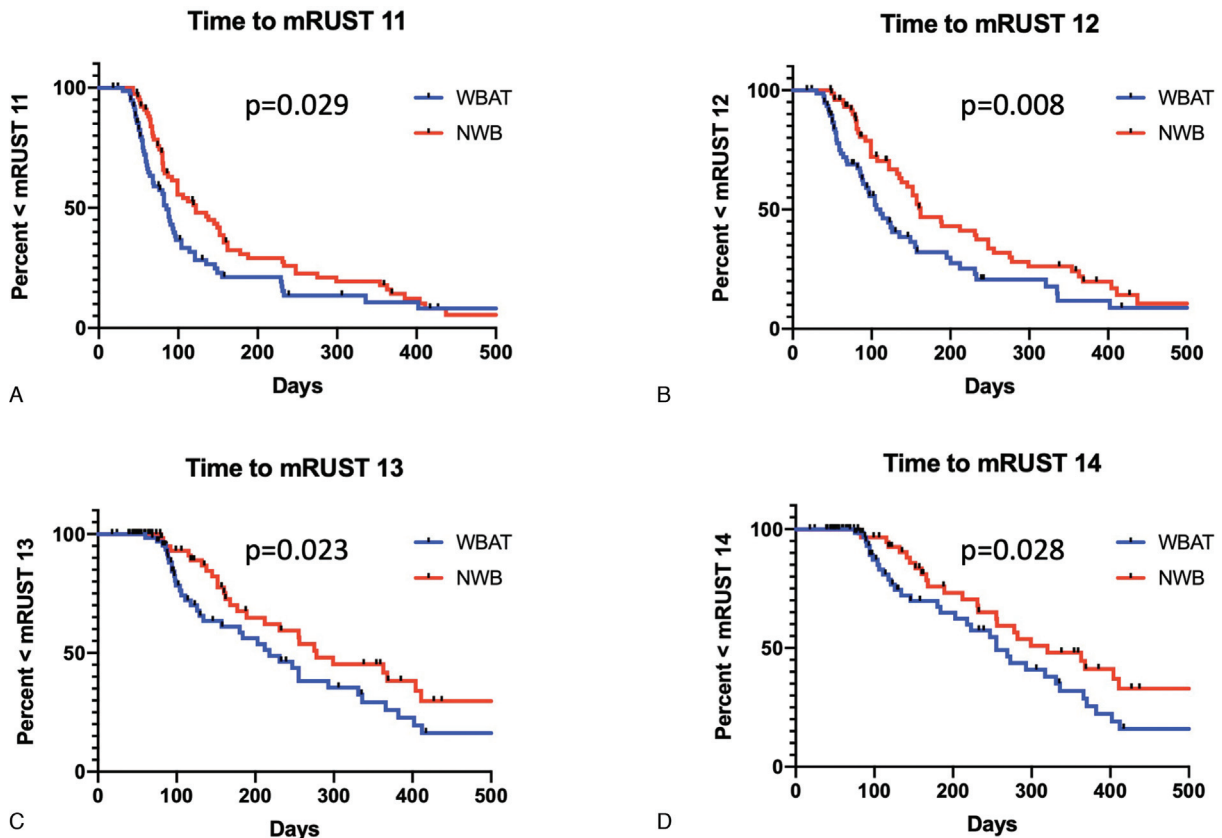


**Figure 1.** mRUST scores at (A) 6 to 8 weeks and (B) 12 to 16 weeks status post intramedullary fixation of diaphyseal femur fractures are lower in the NWB group compared with the WBAT group.

The number of patients who achieved radiographic follow-up to an mRUST score of 14 was N=29 in the NWB group (37.7%) and N=38 in the WBAT group (49.4%). In the WBAT group, median time to mRUST of 14 was 255 days, compared with 320 days in the NWB group ( $P = .028$ ) (Fig. 2D).

**5. Discussion**

Femoral shaft fractures managed with reamed, statically locked fixation heal reliably; however, the rates of healing depend on patient, injury, and operative factors.<sup>[29,30]</sup> Recently, the mRUST tool has allowed for the incremental assessment of radiographic



**Figure 2.** Median time to each mRUST score is longer in the NWB group (red) compared with the WBAT group (blue).

healing. Utilizing this tool, the results of this study suggest that non-weight-bearing status following intramedullary fixation of diaphyseal femur fractures slows the rate of radiographic healing compared with weight-bearing as tolerated counterparts.

Appropriate cohort matching was imperative to investigate this research question. Patients in the NWB and WBAT groups were well matched on demographic, health, injury, and operative characteristics. However, several potential confounders require discussion. First, no objective assessment of adherence to weight-bearing restrictions occurred in this study. However, prior research suggests a patient compliance rate to NWB restrictions of approximately 72.5%.<sup>[31]</sup> Therefore, while not specifically assessed, an assumption that a majority of patients adhered to their WB status appears valid. Additionally, the question of fracture energy, and the corresponding degree of periosteal stripping, requires evaluation, as this variable can influence healing rates. While NWB patients generally sustained concomitant fractures, this alone does not indicate a higher degree of energy for the femur fracture itself. Rather, the mechanism of injury, the degree of comminution, the presence of an open injury, and a segmental pattern may represent better indications of fracture energy. The degree of comminution was higher in the WBAT compared with the NWB group, whereas open fractures were more common in the NWB group, though neither difference was significant. Rates of segmental fractures were equal, and mechanisms of injury were similar. Therefore, an assumption that the NWB groups represent higher-energy fractures, and therefore slower healing rates are expected, is not well founded.

Radiographic healing in the WBAT group was improved by a mean clinical corollary of 1 cortex of novel callous formation or completed callous bridging at the 6 to 8 week and 12 to 16 week postoperative time points. The differences in mRUST scores were 1.3 and 1.8, respectively. While these numbers appear small, given the 4 to 16 point non-normal mRUST scale, these represent an approximately 10% to 15% difference between groups. Additionally, the clinical difference of 1 to 2 mRUST scores is the difference between callous formation versus bridging callous at 1 to 2 cortices. An additional cortex of healing often is the key for a provider to define a fracture as having achieved union. As such, these differences denote both significant statistical and clinical distinctions.

The reason for this improved radiographic healing rate may be related to the mechanism of healing in intramedullary fixation. Intramedullary fixation of femoral diaphyseal fractures typically produces a construct of relative stability. Fractures fixed with relative stability heal by secondary bone healing; to achieve this, strain rates should be between 2% and 10%.<sup>[32]</sup> Therefore, it is possible that NWB does not produce these levels of strain as effectively as WBAT, which results in slower rates of healing. More biomechanical and clinical studies are necessary to explore this hypothesis.

The value of this research is at least 3-fold. First, this research adds to the body of literature supporting the benefits of early weight-bearing following intramedullary fixation of femoral diaphyseal fractures. Non-weight bearing has been shown to be detrimental to return to work, patient income, and return to activities of daily living; this may be especially relevant in geriatric populations.<sup>[33–38]</sup> In the absence of discrete indications, patients should be advanced to WBAT as quickly as possible to minimize negative social, functional, and radiographic outcomes. Second, this data provides clinicians with an expected time course for radiographic healing based on weight-bearing status. Third, this provides surgeons with an additional variable to optimize to

achieve union in slow-to-heal fractures, along with such factors as nutrition optimization, smoking cessation, and endocrine normalization.

This study has several limitations not previously addressed. First, as a retrospective study, these results are subject to selection and information bias; however, the WBAT and NWB groups were well matched on many salient variables that have been shown to affect fracture healing. However, it remains possible that potential confounding variables, such as socioeconomic and insurance status, could influence our results. Second, it is important to note the study demographics; with mean age of 32.7 the generalizability of these findings must be considered. Finally, unlike other endpoints with discrete event markers (e.g., death), radiographs likely never capture the exact point of fracture progression from 1 mRUST score to another. In the absence of daily radiographs, this limitation must be accepted. However, the congruent follow-up between WBAT and NWB groups limits the concern of this limitation.

In conclusion, this study presents the novel finding that weight-bearing status following intramedullary fixation of femoral diaphyseal fractures may contribute to the radiographic rate of fracture healing. This adds support to the larger body of literature calling for the expeditious advancement of weight-bearing status. Prospective series are necessary to confirm the results of this retrospective evaluation.

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