

# **Optimizing Tibial Fracture Healing with Prescribed Early Weight Bearing and Real-Time Feedback: A Case Report**

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## **ABSTRACT**

**Case:** A 24-year-old female and a 38-year-old male sustained closed diaphyseal tibial fractures and underwent intramedullary nailing of the tibia with fibular plating. Both patients used Smart Crutch Tips™ attached to standard forearm crutches. Patient A was managed according to standard of care and used the device in blinded mode without feedback. Patient B received real time biofeedback and followed a personalized weight bearing prescription based on finite element analysis of the postoperative CT scan, combined with a structured walking protocol of five daily 500 step sessions. Radiographic and CT scan outcomes differed markedly. Patient A demonstrated no callus formation at 8 weeks and minimal progression at 12 weeks. In contrast, Patient B showed early bone formation at 4 weeks, cortical bridging at 8 weeks, and complete radiographic union by 12 weeks. Patient B achieved 86% adherence to the prescribed loading range, whereas Patient A demonstrated variable ambulation with consistently subtherapeutic loading, plateauing at approximately 33% of body weight.

**Conclusion:** Personalized, FEA based weight bearing prescriptions combined with real time biofeedback may optimize mechanical stimulation at the fracture site, enhance adherence, and

accelerate radiographic bone union compared with standard weight bearing as tolerated protocol. Larger controlled studies are warranted to validate these findings and to define the role of individualized, data driven rehabilitation in fracture care.

## **INTRODUCTION**

Early weight-bearing (WB) is a key factor influencing bone healing outcomes, as the WB strategy implemented during rehabilitation plays a critical role in recovery. Recent studies indicate that early controlled WB enhances osteogenesis, vascularization, and mechanical stability without increasing hardware-related complications<sup>(1,2)</sup>. Preclinical models<sup>(3)</sup> and clinical data<sup>(1,2,4)</sup> strongly suggest that earlier and individualized WB protocols could reduce nonunion rates, shorten recovery times, and improve overall outcomes<sup>(5,6)</sup>. Despite this evidence, many surgeons remain cautious and restrict WB to avoid implant failure. In addition, rehabilitation protocols, particularly WB progression, remain generalized and imprecise<sup>(7)</sup>. Current guidelines, such as “partial weight-bearing” or “weight-bearing as tolerated,” do not account for patient specific factors, including fracture stability, fixation mechanics, and individual loading capacity.

One of the major barriers to implementing evidence-based, patient-specific WB protocols is the absence of reliable technology to monitor and guide patients in real time<sup>(8)</sup>. Traditional methods such as verbal instructions, bathroom scales, or force plate assessments, are limited and often lead to poor patient compliance<sup>(9)</sup>. Some patients unintentionally overload the injured limb, increasing the risk of fixation failure, while others underload it, leading to muscle atrophy, delayed healing, and prolonged recovery, ultimately resulting in inconsistent compliance and higher rates of complications, including nonunion and implant failure.

To address these challenges, recent advances in wearable technology <sup>(10)</sup>, and the implementation of computational modeling enable individualized, precise, and optimized weight-bearing. Real time biofeedback systems have been shown to significantly improve patient adherence to prescribed weight bearing restrictions compared with conventional training methods <sup>(8,11)</sup>. When combined with finite element analysis (FEA), which enables calculation of patient specific safe loading thresholds based on implant and bone geometry <sup>(11,12)</sup>, rehabilitation can be precisely adjusted to optimize the mechanobiological environment surrounding the fracture site.

However, many existing devices are expensive, difficult to use for extended periods, or lack sufficient precision, limiting their practicality for widespread clinical adoption. Therefore, the Smart Crutch Tips™ device (ComeBack Mobility, San Antonio, TX) was developed and received FDA clearance to provide real time weight bearing monitoring and feedback. The intervention integrates this technology with patient specific weight bearing prescriptions calculated through FEA based on postoperative CT scans. This approach allows rehabilitation strategies to be tailored to each patient's fracture mechanics while providing immediate feedback to improve compliance.

A study by Brueilly et al. <sup>(13)</sup> demonstrated that patients using Smart Crutch Tips™ achieved a 73% compliance rate with prescribed weight bearing regimens, compared with 18% in those following a standard rehabilitation protocol. These findings were associated with faster functional recovery and improved adherence. In addition, a pilot randomized controlled clinical trial conducted at NYU Langone in 20 patients demonstrated improved rehabilitation outcomes and higher patient satisfaction with use of Smart Crutch Tips™ (submitted manuscript).

This report describes the first use of integrated finite element analysis, FEA, modeling and Smart Crutch Tips™ within a personalized rehabilitation protocol to evaluate whether FEA

based, biofeedback supported weight bearing guidance improves compliance, enhances healing rates, reduces implant failure, and shortens the time to full weight bearing compared with standard rehabilitation protocols.

The patients were informed that data related to their cases would be submitted for publication, and they provided informed consent.

### Case Report

A 24-year-old female (Patient A) and a 38-year-old male (Patient B) presented after a fall with closed diaphyseal tibial fractures. The only comorbidity was Class I obesity in the female patient. Both patients underwent surgical stabilization of intramedullary nailing (IMN) of the tibia and plating of the fibula. Postoperative imaging confirmed satisfactory reduction of the fracture gap in both cases. At the initiation of the rehabilitation program, physical examination demonstrated soft tissue edema involving the entire lower leg and foot in both patients. Although baseline functional disability levels were comparable, their symptomatic and psychological profiles differed markedly, as summarized in Table 1.

**Table 1 Patients Demographics and Physical Information Pre-op.**

Parameters at baseline	Demographics	BMI (kg/m <sup>2</sup> )	Fracture Type (AO/OTA)	LEFS Score (0–80)	VAS Pain (0–10)	Edema (0–10)	TSK-17 Score	Residual Fracture gap, (mm)
<b>Patient A (SOC)</b>	24-year-old female	34.5	Tibia: 42B1; Fibula: 4F3B	48	0–1	10	43	5
<b>Patient B (Intervention)</b>	38-year-old male	23.0	Tibia: 42A3; Fibula: 4F3B	47	4–5	5	29	5

Both patients were provided with Smart Crutch Tips™ (ComeBack Mobility Inc, San Antonio, TX, USA), attached to standard forearm crutches. These Class II electronic medical devices incorporate embedded pressure sensors that measure axial load and transmit data via Bluetooth to a centralized monitoring platform. The Smart Crutch Tips™ interface with the CBM Patient application.

Patient A was managed according to the standard of care protocol and used the device in blinded mode for data logging only, with feedback disabled. Ambulation was guided by weight bearing as tolerated, WBAT, instructions and relied solely on subjective pain thresholds rather than prescribed quantitative load percentages or step count targets. The transition to full weight bearing, FWB, was defined as the achievement of independent, pain free ambulation indoors without the use of crutches or canes.

For the intervention Patient B, the application delivered real time biofeedback through a visual smartphone gauge, device light indicators, and audio alerts. The CBM Doctor application was used to remotely prescribe and adjust weight bearing parameters and to generate Rehabilitation Reports. These reports compiled longitudinal data, including compliance metrics, steps within and outside the prescribed loading range, activity volume, and daily patient reported outcomes of edema, and pain measured using a visual analog scale (VAS). Moreover, Patient B followed a personalized weight bearing prescription based on FEA, of his postoperative CT scan. The target load was calculated at 40 to 60% of BW in accordance with established mechanobiological principles<sup>(14)</sup>, ensuring that interfragmentary micromotion remained within the therapeutic window of 0.41 to 0.58 mm, corresponding to approximately 8 to 12% strain across the 5 mm residual fracture gap, while maintaining a high implant safety factor of 4.4 to ensure mechanical stability. He adhered to a structured walking protocol consisting of five daily sessions of 500 steps each, separated by rest intervals of at least two hours. The weight bearing prescription was titrated according to healing progression confirmed by follow up CT

scans and radiographs. The initial loading range was set at 30 to 50% BW to allow physiologic adaptation and was increased to the target range of 40 to 60% BW on postoperative day 10 (Table 2).

In addition to gait training, both patients followed an identical, video guided home exercise program designed to prevent muscle atrophy and preserve joint range of motion. The regimen included isometric strengthening exercises, such as quadriceps and gluteal sets, performed as six 25s holds, active mobilization exercises including ankle pumps and circumduction, targeted muscle strengthening exercises, such as straight leg raises and hamstring curls, performed for 12 repetitions per set, and functional range of motion exercises including heel slides and towel assisted foot stretches.

Progression of fracture healing was monitored with serial radiographs obtained postoperatively and at 4, 8, and 12 weeks. Follow up visits also included physical examination, CT imaging at 8 and 12 weeks, and patient reported outcome measures, including the Lower Extremity Functional Scale (LEFS) and the Tampa Scale for Kinesiophobia (TSK 17). Device usability was assessed at the interim visit.

## **RESULTS**

Daily monitoring demonstrated a marked difference between physical activity and pain, and loading behavior between the two patients (Table 2). Patient A, managed according to the standard of care, exhibited minimal ambulation despite reporting low pain levels. This avoidance behavior was most pronounced during the first postoperative week, during which the patient mobilized exclusively using a wheelchair for several consecutive days, resulting in zero recorded steps. The patient transitioned to full weight bearing at 10 weeks, consistent with typical standard care timelines. Beyond this time point, crutches were used only intermittently

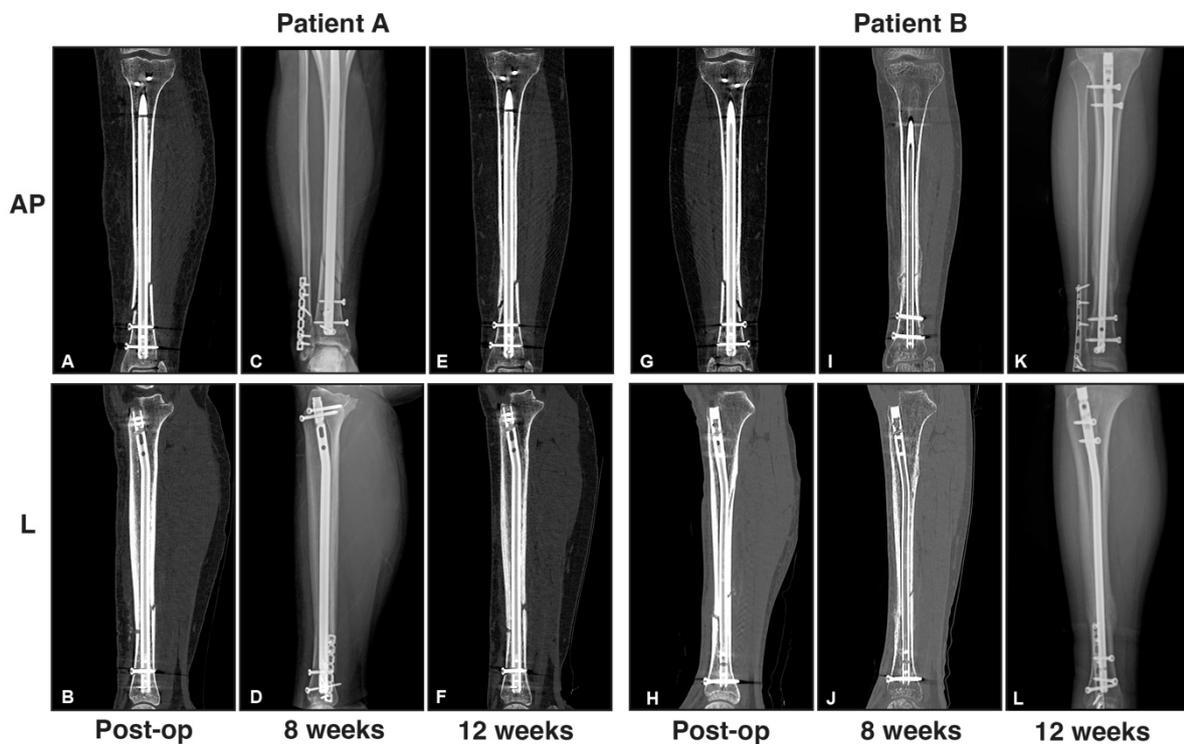
for longer distance ambulation. In contrast, Patient B, who followed the intervention protocol guided by real time biofeedback, recorded a total of 94,784 steps, approximately 4.8 times more than Patient A, who recorded 19,594 steps during the same period. Patient B demonstrated high protocol adherence, completing 161 iterative walking sessions, representing 64% of the prescribed plan, and performing 86% of steps within the therapeutic target range. By comparison, although permitted to weight bear as tolerated without formal restrictions, the control patient exhibited highly variable ambulatory behavior and consistently subtherapeutic loading, plateauing at approximately 33% of body weight. Furthermore, Patient B transitioned to FWB at 6 weeks, achieving this milestone 40% earlier than Patient A, who was managed according to the standard of care.

**Table 2 Weight bearing loading protocols**

<b>Patient Group</b>	<b>Period (Post-Op)</b>	<b>Prescribed Load (% BW)</b>	<b>Actual Mean Load (% BW)</b>
<b>Patient A (SOC)</b>	Weeks 1–8	0–100% (WBAT)	33%
	Week 9	0–100% (WBAT)	64%
	Weeks 10–11 (FWB)	0–100% (WBAT)	85%
<b>Patient B (Intervention)</b>	Week 1 (Adaptation)	30–50%	17%
	Weeks 2–5	40–60%	45%
	Weeks 6–9 (FWB)	50–80%	67%

It is important to note that the step counts after the transition to full weight bearing reflect only steps recorded while using crutches or a cane. Because the device is attached to the crutch tip, steps taken during independent ambulation were not captured and were assumed to represent 100% WB. Therefore, the observed decrease in recorded steps after full weight bearing reflects successful discontinuation of assistive devices rather than reduced mobility.

Radiographic evaluation demonstrated distinct differences in fracture healing patterns between the two patients (Fig. 1A-L). Patient A showed no evidence of bone formation at 8 weeks (Fig. 1C, D), and only minimal callus formation at 12 weeks (Fig. 1E, F). In contrast, Patient B demonstrated early evidence of bone healing at 4 weeks. By 8 weeks, the fracture gap was bridged with osseous tissue and callus formation was evident (Fig 1I, J). At 12 weeks, radiographs demonstrated robust callus formation and complete radiographic union (Fig. 1K, L).



**Fig. 1** Management of closed diaphyseal tibial fractures in a 24-year-old female, Patient A (standard of care), and a 38-year-old male, Patient B (intervention). **1A and 1B)** AP and lateral CT images of the involved right tibia obtained immediately postoperatively following IM nail fixation for Patient A. **1C and 1D)** AP and lateral radiographs of the involved right tibia obtained at 8 weeks following IM nail fixation for Patient A. **1E and 1F)** AP and lateral CT images of the involved right tibia obtained at 12 weeks following IM nail fixation for Patient A. **1G and 1H)** AP and lateral CT images of the involved right tibia obtained immediately postoperatively following IM nail fixation for Patient B. **1I and 1J)** AP and lateral CT images of the involved right tibia obtained at 8 weeks following IM nail fixation for Patient B. **1K and 1L)** AP and lateral radiographs of the involved right tibia obtained at 12 weeks following IM nail fixation for Patient B.

Subjective outcomes indicated that optimal healing was associated with higher initial discomfort (Table 1). Patient A, managed according to the standard of care, reported minimal

pain and less edema using a low step count and higher kinesiophobia. In contrast, Patient B, who followed the intervention protocol, reported moderate pain and edema during activity, both of which resolved by 12 weeks, which was accompanied by a reduction in kinesiophobia. Although Patient B demonstrated superior early functional recovery at 12 weeks, Patient A reported better subjective function despite inferior radiographic healing, highlighting a discrepancy between patient perception and biological progression.

Device usability was assessed using the System Usability Scale (SUS). Both patients reported high usability, assigning the maximum score of 5 out of 5 for ease of use and confidence, and the minimum score of 1 out of 5 for perceived system complexity.

## **DISCUSSION**

This comparative case report represents the first reported clinical application of a personalized, biofeedback guided, prescribed weight bearing protocol and highlights the key limitations of standard weight bearing as tolerated approaches in the healing of closed diaphyseal tibial fractures. The protocol was designed to precisely calculate weight bearing prescriptions using FEA, of the postoperative CT scan. This approach ensured that interfragmentary micromotion remained within the therapeutic window of 0.41 to 0.58 mm, corresponding to approximately 8 to 12 % strain across the fracture gap. In addition, the structured walking regimen, consisting of five daily sessions of 500 steps separated by rest intervals of at least two hours, was implemented to optimize the mechanical environment and accelerate fracture healing. Patient A's reliance on traditional methods, such as verbal instructions and bathroom scales, combined with extensive wheelchair use during the first postoperative week, resulted in underloading of the fracture site and insufficient mechanical strain to adequately stimulate fracture healing. Radiographs at 8 weeks demonstrated persistent fracture lines without evidence of callus

formation, with only limited progression of healing at 12 weeks. In contrast, Patient B demonstrated cortical bridging and callus formation by 8 weeks and robust callus formation with complete radiographic union by 12 weeks.

These findings are consistent with foundational mechanobiological principles. Experimental and clinical studies by Perren, Carter, Claes, Kenwright, and Goodship have established that the mechanical environment at the fracture site is a critical determinant of both the pathway and rate of bone repair<sup>(14-19)</sup>. Controlled interfragmentary motion has been shown to promote callus formation and endochondral ossification, whereas insufficient or excessive strain may delay healing<sup>(16,20,21)</sup>. A study by Glatt et al.<sup>(22,23)</sup> demonstrated that controlled axial interfragmentary movement during early healing can enhance callus formation and accelerate bone remodeling. Collectively, these data support the concept that precise control of the mechanical environment throughout the healing period is essential<sup>(24-26)</sup>.

This case comparison suggests that biofeedback guided weight bearing can shift rehabilitation from a passive, symptom driven process to an active, data informed strategy. By delivering objective, real-time feedback, the device provided an external safety signal that may reduce fear avoidance and excessive protective behaviors. The intervention patient was able to distinguish expected activity related discomfort from injury related pain<sup>(27,28)</sup>, facilitating appropriate mechanical loading without compromising fixation stability during the early phase of healing.

In conclusion, personalized, FEA based weight bearing prescriptions combined with real time biofeedback may optimize mechanical stimulation at the fracture site, enhance adherence, and accelerate radiographic bone union compared with standard weight bearing as tolerated protocol. Larger controlled studies are warranted to validate these findings and to define the role of individualized, data driven rehabilitation in fracture care.

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