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Original Research Article

Functional and Radiological Outcomes of Early Versus Delayed Weight-Bearing after Intramedullary Nailing of Tibial Shaft Fractures: A Prospective Comparative Study

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Abstract

Background: There is considerable variation in the approach to rehabilitation following intramedullary nailing of tibial shaft fractures, and delayed loading is frequently recommended due to fear of loss of reduction, implant failure, delayed union and pain. Design: This study aimed to compare functional recovery and radiological union between early and delayed weight-bearing protocol in adults with tibial shaft fractures after locked IMN.

Methods: This study compared functional outcome and radiological healing between early and delayed weight bearing after locked IMN of tibial shaft fractures in adult population. The study was a prospective comparative study of 70 adults who had closed or Gustilo-Anderson type 1 tibial shaft fractures treated with reamed, statically locked intramedullary nails. Thirty-five patients were started on supervised weight-bearing as tolerated within 72 hours, while 35 patients were started on delayed weight-bearing at six weeks. Lower Extremity Functional Scale (LEFS), visual analogue scale (VAS), knee and ankle range of motion, and time to full weight-bearing were used to measure functional outcomes. Bridging callus and Radiographic Union Scale for Tibial fractures (RUST) were used for the radiological assessment of union.

Results: Baseline age, fracture pattern, injury mechanism and operative variables were similar. Early weight-bearing significantly reduced time to full unsupported weight-bearing (4.1 +/- 1.3 vs 9.6 +/- 2.1 weeks; $p<0.001$), improved six-month LEFS (73.4 +/- 7.5 vs 69.1 +/- 8.2; $p=0.026$), and shortened mean union time (17.2 +/- 3.8 vs 19.4 +/- 4.2 weeks; $p=0.024$). No significant difference was seen in delayed union, malalignment, infection or implant-related complications.

Conclusion: Early protected weight-bearing following stable intramedullary nailing of selected tibial shaft fractures led to an improvement in early rehabilitation and radiological outcomes without increasing the complication rate.

Keywords: Tibial Shaft Fracture; Intramedullary Nailing; Early Weight-Bearing; Delayed Weight-Bearing; RUST Score; Functional Outcome.

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Introduction

Tibial shaft fractures are one of the most common long bone fractures seen in orthopaedic trauma practice and are frequently seen in young working adults following road-traffic accidents, falls and occupations. Epidemiologic studies have demonstrated that there are young people who are at risk for high-energy trauma and elderly people at risk for low-energy fracture, which has significant functional and socio-economic impact [1, 2]. Key points of treatment include realignment, fracture stability, soft tissue preservation, and early ambulation. The aim of surgery in the treatment of displaced tibial fractures is to reduce the fracture and achieve fixation without compromising the periosteum and allowing early mobilisation without the need for prolonged cast immobilisation or plate fixation - which has led to the development of interlocking intramedullary nailing as the preferred operating technique for most displaced tibial fractures [3]. The SPRINT trial and the literature on nail techniques since then defined modern reamed and locked nail fixation as a reproducible standard and also highlighted the importance of a balance between mechanical stability and

biological stimulation for fracture healing [4, 5]. Although there have been improvements in implant design, the optimal time for postoperative weight bearing is still uncertain. In many of the more traditional patterns, loading is often limited for 6 weeks or more, especially when the fracture is a comminuted fracture, a distal-third fracture, or when the patient is complaining of pain. The nail-bone construct, however, has been engineered to withstand controlled axial loading and there may be mechanotransduction promoting callus production in a stable fixation [6]. On the other hand, overloading or over-ambitious loading can potentially increase micromotion, malalignment, screw breakage, pain, and so forth, particularly if the reduction is not ideal.

Recent clinical trials have cast doubt on the routine use of delayed weight-bearing. In a randomized trial, Gross et al. showed that immediate weight-bearing after tibial nailing did not result in more adverse events in OTA 42-A and 42-B fractures [7]. Greenhill et al. reported that there was a lack of independent effect on the healing of simple closed fractures by postoperative weight bearing [8]. Observational studies, on the other hand, have suggested that delayed weight-bearing may be related to poor healing but because there is likely some confounding by fracture severity and pain, this remains speculative [9].

Comparable union and implant failure rates were determined between early and delayed protocol in a multicentre propensity-matched study by Uemi et al after tibial intramedullary nailing [10]. Recently, a systematic review and meta-analysis found that early weight-bearing could potentially shorten time to union and reduce the overall complication rate in certain patients and suggested that there was limited and less than ideal prospective data and variability in the definitions of early loading [11]. This study reinforces the need for centre-specific, prospective comparative data both functional and radiological.

The research gap is especially pertinent in tertiary hospitals with high prevalence of road traffic injuries where extended non-weight-bearing could be a risk to return to work, leading to dependency and poor compliance to rehabilitation. The purpose of the present study was to compare the functional and radiological results of early versus delayed weight bearing of tibial shaft fractures after locked intramedullary nailing. The main aim was to evaluate time to full weight bearing/fracture union. Secondary goals included pain, LEFS score, range of motion at the knee and ankle, RUST score progression and complications.

Materials and Methods

The study was a prospective comparative study in Department of Orthopaedics of a Tertiary care teaching hospital for 18 months. The adult patients who were seen with an acute fracture of the tibial shaft and treated with reamed statically locked intramedullary nailing were selected for the study after obtaining their informed written consent.

The number of patients in the sample was determined based on the mean time to full weight-bearing. Based on a clinically relevant difference of 2.5 weeks between groups, a pooled SD of 3.5 weeks, an alpha error of 5%, and an 80% power, a minimum of 31 patients per group was needed. Allowing for possible follow-up loss, 35 patients were recruited in each group, giving a final sample of 70 patients.

Patients of AO/OTA 42A, 42B, or selected 42C tibial shaft fractures who have a closed injury or had aGustilo-Anderson type I open injury, and accepted reduction in the postoperative anteroposterior and lateral radiographs were included. The exclusion criteria included intra-articular extension, segmental bone loss, Gustilo open fracture type II or III, pathological fracture, polytrauma which precluded mobilisation, fractures of the same limb (femur and foot), neurovascular injury, uncontrolled diabetes, chronic steroid therapy, and non-compliance with rehabilitation.

Patients were evaluated in a routine manner before surgery, both clinically and radiographically. The surgery was performed under spinal or general anaesthesia according to the level of the fracture and the surgeon's preference, and using a reamed interlocking nail via an infrapatellar or semi-extended approach. Nail length and diameter were chosen depending on the size of the canal and the contralateral templating. In all cases, static proximal and distal locking was used. Radiographs were taken after surgery and examined for coronal, sagittal alignment, apposition and screw position.

After the confirmation of stable fixation, the patients were randomly divided into early weight-bearing or delayed weight-bearing groups according to a departmental protocol and surgeon's preference. Early group started toe-touch to no more than half weight within 48-72 hours and progressed to weight-bearing as tolerated based on pain/swelling/gait. The delayed group was allowed to ambulate without weight bearing or toe touching until 6 weeks, then progressive partial and full weight bearing. All of them were treated with the same analgesia, as indicated thromboprophylaxis, wound care, quadriceps exercises, ankle mobilisation and physiotherapy.

Assessment was repeated at 2 weeks, 6 weeks, 3 months and 6 months. Functional outcomes were

time to full unsupported weight-bearing, VAS pain score, LEFS, knee range of motion, ankle dorsiflexion-plantarflexion arc, and return to work or daily activity. Assessment of radiological outcome was carried out by measuring the bridging callus in at least three cortices and the RUST score on standard AP and lateral radiographs. Full weight-bearing with radiological bridging callus was considered to be painless and was defined as union. Delayed union was considered as lack of progressive healing at 24 weeks and nonunion was when union was not achieved at 9 months or if a secondary intervention was required. The data were entered into the computerised micro Excel and analysed using SPSS version 26. The continuous variables were presented as mean +/– SD and compared by independent t-test or Mann-Whitney U-test depending on the distribution. Categorical variables were presented as frequencies and percentages and compared using chi-square or Fisher exact test. Repeated measures were analysed by repeated measures ANOVA. Results with a p value < 0.05 were deemed statistically significant.

Results

Seventy patients completed six-month follow-up and were included in the final analysis. The early and delayed weight-bearing groups each included 35 patients. Baseline demographic, injury, and operative variables were comparable between groups, indicating acceptable clinical matching before rehabilitation exposure.

Table 1: Baseline Demographic and Fracture Characteristics

Variable	Early WB (n=35)	Delayed WB (n=35)	p-value
Age (years), mean +/- SD	39.8 +/- 11.6	41.2 +/- 12.4	0.626
Male sex, n (%)	26 (74.3)	25 (71.4)	0.786
Road-traffic injury, n (%)	23 (65.7)	22 (62.9)	0.806
AO/OTA 42-A, n (%)	16 (45.7)	15 (42.9)	0.811
AO/OTA 42-B, n (%)	14 (40.0)	15 (42.9)	0.808
AO/OTA 42-C, n (%)	5 (14.3)	5 (14.3)	1.000
Closed fracture, n (%)	31 (88.6)	30 (85.7)	0.718
Middle-third fracture, n (%)	20 (57.1)	19 (54.3)	0.810
Time to surgery (days)	2.1 +/- 0.9	2.3 +/- 1.0	0.382
Operative time (minutes)	76.4 +/- 12.7	78.2 +/- 13.1	0.560

There was no statistically significant difference in age, sex distribution, injury mechanism, fracture type, soft-tissue status, fracture level, timing of surgery, or operative duration between groups.

Table 2: Functional Outcomes After Intramedullary Nailing

Outcome	Early WB (n=35)	Delayed WB (n=35)	p-value
Time to full unsupported WB (weeks)	4.1 +/- 1.3	9.6 +/- 2.1	<0.001
VAS pain at 6 weeks	3.1 +/- 1.0	4.2 +/- 1.1	<0.001
VAS pain at 6 months	1.1 +/- 0.7	1.4 +/- 0.8	0.101
LEFS at 3 months	61.8 +/- 8.9	55.2 +/- 9.6	0.004
LEFS at 6 months	73.4 +/- 7.5	69.1 +/- 8.2	0.026
Knee ROM at 6 months (degrees)	132.6 +/- 8.4	128.3 +/- 10.2	0.059
Ankle arc at 6 months (degrees)	57.1 +/- 6.3	53.8 +/- 7.1	0.044
Return to work/activity (weeks)	13.6 +/- 4.2	17.8 +/- 5.1	<0.001

The early weight-bearing group demonstrated faster unsupported ambulation, lower six-week pain, higher LEFS at 3 and 6 months, improved ankle motion, and earlier return to work or routine activity.

Table 3: Radiological Union and Complications

Outcome	Early WB (n=35)	Delayed WB (n=35)	p-value
RUST score at 6 weeks	6.3 +/- 1.2	5.7 +/- 1.1	0.033
RUST score at 12 weeks	9.7 +/- 1.8	8.6 +/- 1.9	0.015
RUST score at 24 weeks	11.7 +/- 0.9	11.3 +/- 1.2	0.121
Mean union time (weeks)	17.2 +/- 3.8	19.4 +/- 4.2	0.024
Delayed union, n (%)	3 (8.6)	5 (14.3)	0.452
Nonunion, n (%)	1 (2.9)	2 (5.7)	0.555
Malalignment >5 degrees, n (%)	1 (2.9)	2 (5.7)	0.555
Superficial infection, n (%)	2 (5.7)	2 (5.7)	1.000
Implant failure, n (%)	0 (0)	1 (2.9)	0.314

Radiological progression favoured early weight-bearing at 6 and 12 weeks, while final 24-week RUST score and complication rates were comparable between groups

Discussion

This prospective comparative study demonstrated that early protected weight bearing after stable intramedullary nailing of the tibial shaft fracture had greater functional outcome and was not associated with increased complications, but rather slightly quicker radiological healing. The most clinically significant difference was in time to unsupported ambulation, which was over 5 weeks shorter in the early group. Early return to activity is a critical factor since tibial shaft fractures are often seen in the economically active population and a prolonged stay in bed can affect physical and psychosocial recovery.

The results are in accordance with load sharing theory of intramedullary nailing. Modern locked nails enable controlled axial loading and help to prevent bending and rotational forces. Reamed intramedullary nailing was first demonstrated by Bone and Johnson to be a means of achieving reliable stability of tibial fractures, and subsequent long-term follow up studies have reported long term functional outcomes after union [12, 13]. Thus, rehabilitation after surgery should be directed not just towards achieving a radiographic consolidation, but towards returning the patient to his/her normal gait, ankle motion, quadriceps strength, and confidence when walking.

These results are consistent with the randomized study by Gross et al. in which they found no difference in complications in patients permitted immediate post-operative weight bearing following IM nailing of OTA 42-A or 42-B tibial fractures [7]. Likewise, Greenhill et al. showed no change in healing of tibial shaft fractures with weight-bearing assignment [8]. The slight higher union rate seen in the early group in the current study is probably not due to a purely biological effect, but also due to mechanical stimulation of the callus, increased blood flow in the lower limbs and prevention of stiffness due to disuse.

The study is also consistent with the findings of Houben et al., which found that delayed weight bearing was an independent risk factor for poor healing of tibial shaft fractures that were surgically treated [9]. The interpretation of causality should however be taken with caution as the delayed weight bearing is frequently given to patients with more severe fracture patterns, higher level of pain or less secure fixation. This bias was minimised by excluding unstable fixation, significant soft tissue damage, segmental bone loss and polytrauma that was a contraindication to mobilisation. Baseline fracture morphology was similar, but this was a non-randomized study, which may have residual selection bias. In this study, the radiological results showed that the early group had higher RUST scores at week 6 and week 12, but they were similar at the end of the study at week 24. This pattern indicates that early loading may not always alter the ultimate union status, but can help to improve early callus maturation. There were also comparable rates of union and implant failure following propensity matching reported by Uemi et al. [10]. Bhanushali et al. performed a systematic review and demonstrated potentially decreased union time and total complications with early weight bearing, but noted a need for further prospective studies with consistent definitions of weight bearing [11].

Both groups experienced improvements in pain and function; early weight-bearing resulted in greater 3-month LEFS and less 6-week pain. Such differences could be due to early recovery of gait cycle and decreased fear avoidance behaviors. Anterior knee pain following tibial nailing has been recognized as a complication that is dependent on the approach, nail entry and soft tissue irritation [14, 15]. In the current study, the anterior knee pain was mild in the majority of participants and was not significantly different according to loading protocol at six months. Modestly more ankle motion was observed in the early group, favoring early supervised mobilisation to address stiffness.

There were no significant differences in complication rates. The early weight-bearing group did not have a significant increase in malalignment, nonunion, infection or implant failure. The results may not be extrapolated to all tibial fractures. Early loading should be tailored to each case and be avoided or deferred if fixation is unstable, reduction is poor, fracture is highly comminuted, bony loss is present, soft-tissue envelope is compromised, or patient compliance is questionable. Rather than just providing freedom of motion in the post-op prescription, progression criteria should be outlined.

The advantages of this study are that it is prospective, that all follow-ups are standardized, that the functional and radiological outcome measures are used, and that the clinically relevant complications are evaluated. The limitations include single-centre setting, sample size (small), non-randomized allocation and six-month follow-up. Further follow-up is necessary to assess late anterior knee pain, return to heavy work activities, removal of implants, and ongoing gait abnormalities. Randomized future studies should be performed on patients with fractures stratified by fracture pattern, nail diameter, locking configuration, and bone quality.

Conclusion

After the selection of tibial shaft fractures, early protected weight-bearing following stable locked intramedullary nailing of the fracture led to improved early ambulation, functional outcome, ankle range of motion, return to activity, and early radiological progression.

It did not result in malalignment, nonunion, infection or implant failure. A stable reduction and fixation can be safely achieved with a supervised, criteria based early weight-bearing protocol.

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