Injury

# Early versus delayed weight bearing after intramedullary nailing for tibial shaft fracture: a multicenter, propensity score-matched study, the TRON study

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| **Abstract:** | Objectives: The purpose of this multicenter study was to assess the differences in the rates of implant failure and bone union by X-ray examination, and walking ability between an early weight-bearing group (EWB) and a non-weight-bearing group (NWB) following treatment with intramedullary nailing (IMN) for tibial shaft fractures with a propensity score-matching method. Material and Methods: We collected data from 336 patients with tibia fractures that were treated surgically. We excluded patients lost to follow-up and polytrauma patients. Finally, 263 patients were included who were divided into two groups, the early weight-bearing (EWB) group, in which partial weight-bearing walking within four weeks was encouraged, and a non-weight-bearing (NWB) group, in which no weight bearing was allowed for more than four weeks. To adjust for baseline differences between groups, a propensity score algorithm was used to match the EWB group with the NWB group in a 1:1 ratio of 75 cases each. After matching, we compared the rate of implant failure, the rate of bone union at six months and one year after surgery, and walking ability at the last follow-up between the two groups. Result: Implant failure occurred in 0 of 75 patients in the EWB group vs. 1 of 75 in the NWB group (P=1.0). Delayed bone union at six months occurred in 20 of 75 (26%) vs. 13 of 75 (17%) patients, and that at one year occurred in 5 of 75 (6.7%) vs. 3 of 75 (4%) patients. The median New Mobility Score was 9 (4-9) vs. 9 (0-9) points. Conclusions: There were no statistically significant differences in the rate of implant failure, the rates of the bone union at six months and one year after surgery, and walking ability between the EWB group and NWB group. We suggest that instruction in early weight-bearing after IMN nailing for tibial shaft fracture may not be harmful. |
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# Early versus delayed weight bearing after intramedullary nailing for tibial shaft fracture: a multicenter, propensity score-matched study, the TRON study

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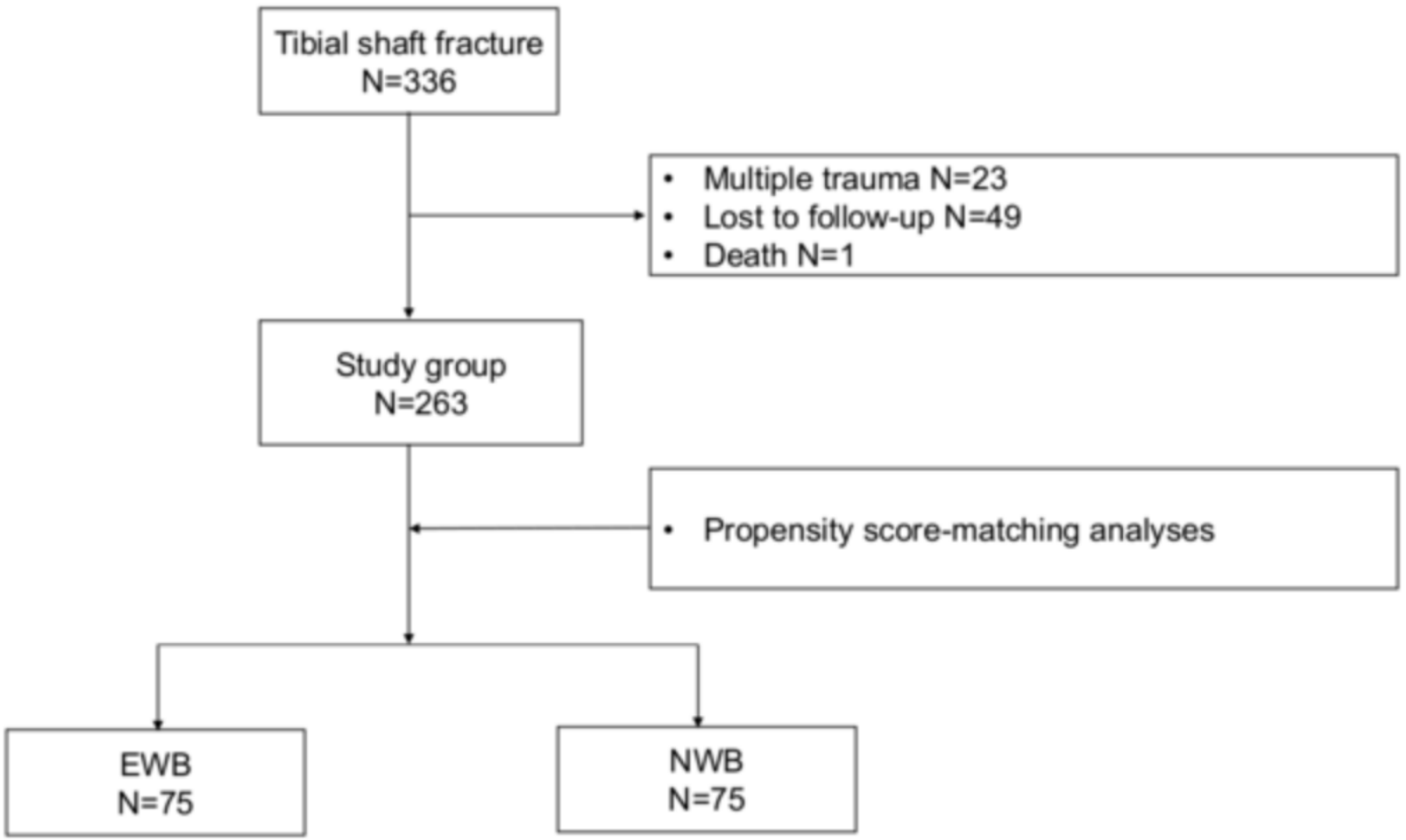
Figure


Tibial shaft fracture
N=336
• Multiple trauma N=23
• Lost to follow-up N=49
• Death N=1
Study group
N=263
• Propensity score-matching analyses
EWB
N=75
NWB
N=75

**Highlights**:

1.We conducted a multicenter study to assess the differences between an early weight-bearing group (EWB) and a non-weight-bearing group (NWB) for tibial shaft fractures by a propensity score-matching method.

2. We compared an EWB group with a NWB group following IMN for tibial shaft fractures. There were no statistically significant differences among the rates of implant failure and bone union by X-ray examinations, and walking ability between the two groups.

3.We suggest that instruction in EWB after IMN for tibial shaft fracture may not be harmful.

# Early versus delayed weight bearing after intramedullary nailing for tibial shaft fracture: a multicenter, propensity score-matched study, the TRON study

Abstract

*Objectives:* The purpose of this multicenter study was to assess the differences in the rates of implant failure and bone union by X-ray examination, and walking ability between an early weight-bearing group (EWB) and a non-weight-bearing group (NWB) following treatment with intramedullary nailing (IMN) for tibial shaft fractures with a propensity score-matching method.

*Material and Methods:* We collected data from 336 patients with tibia fractures that were treated surgically. We excluded patients lost to follow-up and polytrauma patients. Finally, 263 patients were included who were divided into two groups, the early weight-bearing (EWB) group, in which partial weight-bearing walking within four weeks was encouraged, and a non-weight-bearing (NWB) group, in which no weight bearing was allowed for more than four weeks. To adjust for baseline differences between groups, a propensity score algorithm was used to match the EWB group with the NWB group in a 1:1 ratio of 75 cases each. After matching, we compared the rate of implant failure, the rate of bone union at six months and one year after surgery, and walking ability at the last follow-up between the two groups.

*Result:* Implant failure occurred in 0 of 75 patients in the EWB group vs. 1 of 75 in the NWB

group (P=1.0). Delayed bone union at six months occurred in 20 of 75 (26%) vs. 13 of 75 (17%) patients, and that at one year occurred in 5 of 75 (6.7%) vs. 3 of 75 (4%) patients. The median New Mobility Score was 9 (4-9) vs. 9 (0-9) points.

*Conclusions:* There were no statistically significant differences in the rate of implant failure, the rates of the bone union at six months and one year after surgery, and walking ability between the EWB group and NWB group. We suggest that instruction in early weight-bearing after IMN nailing for tibial shaft fracture may not be harmful.

**Keyword: tibial shaft fracture, early weight- bearing**

## Introduction

Tibial shaft fractures are the most common long-limb fractures and are the most commonly encountered fractures for orthopedic surgeons [1]. Open reduction and internal fixation with intramedullary nailing (IMN) are useful for tibial shaft fractures and have been established as a standard treatment method [1,2].

Despite much research on tibial shaft fractures, that on postoperative management, including a weight-bearing protocol for tibial shaft fractures after IMN, is inadequate. There is concern that early weight bearing before bone union may lead to implant failure and decreased stability [3,4]. However, several reports showed that early postoperative weight bearing

accelerates bone union, leads to earlier return to work, and prevents muscle atrophy [3,5-7]. In a randomized controlled trial, Gross et al. compared an immediate weight bearing as tolerated group and a non-weight-bearing group after IMN for tibial shaft fractures. They showed that early weight bearing was safe and did not increase complications [3]. However, that study included only one multi-fragment fracture (AO/OTA type C) among 90 fractures. There is not enough evidence on the positive effects of early weight bearing in patients with unstable fractures such as those of type C.

The purpose of this multicenter study was to assess differences in the rates of implant failure and bone union by X-ray examinations, and walking ability, between an early weight-bearing (EWB) group and a non-weight-bearing (NWB) group following IMN for tibial shaft fractures by a propensity score-matching method.

## Material and Methods

This multicenter, retrospective study was approved by the ethics commission at each participating hospital. All patients provided informed consent to participate in the study. Hospitals of the Trauma research group of Nagoya (TRON) have registered orthopedic trauma surgery cases in the TRON database annually since 2014. The hospitals participating in the database are all associated with the Department of Orthopedic Surgery of Nagoya University, and orthopedic

surgeons perform the surgery at these hospitals located in Central Japan. From this database, we collected cases of tibial fractures that were treated surgically.

We extracted the data of 336 patients who underwent IMN from 2014 to 2019 from the database. We used five kinds of implants; Natural nail (Zimmer, Warsaw, IN, USA), Phoenix Nail (Zimmer Biomet, Warsaw, IN, USA), Trigen meta-nail (Smith and Nephew, Memphis, TN, USA), Expert tibia nail (Synthes GmbH, Oberdorf, Switzerland), T2 nail (Stryker, Mahwah, NJ, USA) (Supplemental table 1). We excluded 23 patients with multiple traumas, 49 who were not followed up postoperatively, and 1 patient who died after the operation because of myocardial infarction. Finally, we included 263 patients. We divided them into two groups, an EWB group and a NWB group. The subjects in the EWB group were encouraged to perform partial weight-bearing walking within four weeks after surgery. Those in the NWB group were not allowed weight bearing for more than four weeks after surgery.

To adjust for baseline differences between the groups, a propensity score algorithm was used to match the EWB group with the NWB group in a 1:1 ratio of 75 cases in each group. Propensity score matching is a well-validated statistical technique that creates comparable groups and allows for accurate assessment of treatment effect. Patients were matched for age, sex, body mass index, smoking history, general condition, fracture type (AO classification [8]), location of the fracture, nail diameter, operative time, injury mechanism, open fracture or not,

presence of fibula fracture, and presence of external fixation. After matching, demographics, presurgical comorbidities, and outcomes of interest were compared using $\chi 2$ (or Fischer's exact test when appropriate) and Student *t*-tests for categorical and continuous variables, respectively.

We used the ASA-PS (American Society of Anesthesiologists-Physical Status) classification to evaluate the patients' general condition. We classified injuries into low-energy injuries, such as falls on flat ground and from beds, and high-energy injuries, such as traffic accidents and falls from high places. After matching, we compared implant failure rate, bone union rate at six months and one year after surgery, and walking ability between the two groups. If bone union did not occur by six months after surgery, it was termed delayed union, and if bone union did not occur by one year, it was termed nonunion. We defined delayed union and nonunion as the absence of radiological signs of bone union and as pain in the fracture site [9]. Two observers evaluated the radiographs and assessed agreement of the diagnosis. The Kappa values were 0.89 (95% confidence interval: 0.84–0.93), and if the diagnoses differed, the results of the first author were used. Walking ability was evaluated with the New Mobility Score, which evaluates three items, able to get about the house, able to get out of the house, and able to go shopping, from 0 (not at all) to 3 (no difficulty), and the total score is nine points [10-12]. We evaluated the New Mobility Score one year after surgery. For statistical evaluation, categorical data were compared between the two groups using Fisher's exact test. All analyses of continuous variables

were performed using the *t*-test or Mann-Whitney U test as appropriate. The significance level was set at 0.05, and all statistical analyses were performed using EZR (Jichi Medical School, Tochigi, Japan [13]).

## Results

Table 1 shows the background of the patients. The numbers of A/B/C fracture types according to the AO classification in the EWB group were 24/32/19, and those in the NWB group were 26/31/18, respectively (P=0.96). There were no significant differences in patient background between the two groups.

The number of implant failures in the EWB group was 0 of 75, and that in the NWB group was 1 of 75 (P=1.0). Delayed union occurred in 20 of 75 (26%) patients in the EWB group and in 13 of 75 (17%) patients in the NWB group (P=0.24). Non-union occurred in 5 of 75 (6.7%) patients in the EWB group and in 3 of 75 (4%) patients in the NWB group (P=0.72). The median New Mobility Score was 9 (4-9) points in the EWB group and 9 (0-9) points in the NWB group (P=0.99) (Table 2).

## Discussion

To our best knowledge, this is the first study to evaluate EWB after IMN for tibial shaft

fractures, with a propensity score-matching method in a multicenter study. The strength of our study is that we used propensity score matching to equalize groups in the early weight bearing and non-weight bearing groups, with real-world data including type C fractures, distal end fractures, and open fractures. We found no significant difference in the complication rate, including implant failure, bone union rate, and walking ability by New Mobility Score between the EWB and the NWB groups.

In the present study, the number of implant failures was low (1 in 150, 0.07%) compared to the implant failure rate of about 6% reported in previous studies published from 1992 to 2003 [14-18]. Nails can obtain the same strength as double-plate osteosynthesis because of the improvements made in the material used in intramedullary nails in recent years [19]. However, the SPLINT study reported that after IMN for tibial shaft fractures, screw breakage and the rate of removal statistically increased because of full weight bearing immediately after surgery [1,20]. However, more than 90% of patients were restricted to partial or non–weight bearing postoperatively, so the immediate weight-bearing group was much smaller. It led to type I error. While, we matched the EWB group with the NWB group in a 1:1 ratio of 75 cases in each group. This procedure might decrease the statistical problems.

There was no significant difference in the bone union rate between the EWB group and the NWB group. Several studies reported that the time to bone union was shorter in the EWB group

[21-23]. In a retrospective study [22], delay in weight bearing after surgery for shaft fractures was associated with impaired healing. These results suggested that EWB had a positive effect on bone union. However, we did not show a difference in the bone union rate at six months or at one year, likely because 37 of the 150 fractures (24%) were multi-fragment fractures (AO/OTA type C) in our patients. The type C fracture is an independent risk factor of delayed union [24], and this might have affected our results.

There was also no significant difference in the New Mobility Score between the two groups. Gross et al. divided 90 patients treated by IMN for tibial shaft fracture into an EWB group and a NWB group and examined postoperative dysfunction. However, there was no significant difference between the two groups in their randomized clinical trial [3]. This suggested that the subjects treated with IMN could obtain a good outcome, which is shown by the New Mobility Score. However, most patients received full marks in the New Mobility Score, and the ceiling effect might have affected the outcome [25].

This study had several limitations. First, the study design was retrospective. Although confounding factors are excluded as much as possible by performing propensity score matching in a multicenter study, it is possible that unknown confounding factors were not excluded. Second, although many cases were collected in this multicenter study, the number of cases may not be large enough to result in significant differences due to the low rates of implant failures,

delayed union, and nonunion. However, based on the results of this study, the number of cases needed to find a significant difference in complications with power analysis is 2600. It is practically difficult to collect this many cases in each group. Finally, we assessed the patients' outcomes only by walking ability. We did not evaluate their length of hospital stay or the period until they returned to work.

We demonstrated no significant difference in the complication rate, including implant failure, bone union rate, and walking ability by New Mobility Score between the EWB and the NWB groups with a propensity score-matching method in a multicenter study. We suggest that a prospective study focusing on postoperative management of tibial fractures with intramedullary nails should be conducted in the future.

**Conclusions**

There were no statistically significant differences in the rate of implant failure, rates of bone union at six months and one year after surgery, and walking ability between the EWB group and NWB group. We suggest that instruction in EWB after IMN for tibial shaft fracture may not be harmful.

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Table 1

Patient demographics.

| | Early weight-bearing group | Non-weight-bearing group | P value |
|---|---|---|---|
| Number, n | 75 | 75 | |
| Age, years, mean±SD | 48.8±17.8 | 47.3±16.5 | 0.608 |
| Sex, M/F, n | 53/22 | 55/20 | 0.856 |
| BMI, kg/m$^2$, mean±SD | 23.7±3.7 | 23.4±3.9 | 0.597 |
| Smoking, n (%) | 26 (34.7) | 27 (36.0) | 1.00 |
| ASA I/II/III, n (%) | 48 (64)/25 (33)/2 (3) | 53 (71)/18 (24)/4 (5) | 0.386 |
| AO classification A/B/C, n (%) | 24 (32)/32 (43)/19 (25) | 26 (35)/31 (41)/18 (24) | 0.956 |
| Location of fracture, n(%) | | | 0.422 |
| Proximal third | 5 (6.7) | 9 (12.0) | |
| Midshaft | 29 (38.7) | 24 (32.0) | |
| Distal third | 41 (54.7) | 42 (56.0) | |
| Nail diameters (mm) median, (range) | 10.0 (8.5-13.0) | 10.0 (7.5-13.0) | 0.577 |
| Operative time (min), mean, (range) | 120 (41-224) | 118 (41-271) | 0.794 |
| Injury mechanism, n (%) | | | 0.831 |
| Low energy | 22 (29.3) | 18 (24.0) | |
| High energy | 53 (70.7) | 57 (76.0) | |
| Open fracture, n (%) | 23 (30.7) | 24 (32.0) | 1 |
| Gustilo classification | | | 0.214 |
| Type I, n (%) | 10 (43.4) | 5 (20.8) | |
| Type II, n (%) | 7 (30.4) | 6 (25) | |
| Type IIIA, n (%) | 4 (17.4) | 10(41.7) | |
| Type IIIB, n (%) | 2 (8.7) | 3 (12.5) | |
| Fibula fracture, n (%) | 61 (81.3) | 63 (84.0) | 1.00 |
| External-fixation, n (%) | 26 (34.7) | 27 (36.0) | 1.00 |

BMI - body mass index, ASA - American Society of Anesthesiologists-Physical Status.

Table 2

Postoperative findings in the early and non-weight-bearing groups.

| | Early weight-bearing group | Non-weight-bearing group | P value |
|---|---|---|---|
| Implant failure, n (%) | 0 | 1 (1.3) | 1.00 |
| Delayed union, n (%) | 20 (26.7) | 13 (17.3) | 0.237 |
| Non-union, n (%) | 5 (6.7) | 3 (4.0) | 0.719 |
| New Mobility Score, median (range) | 9 (4-9) | 9 (0-9) | 0.988 |