

# Outcome of Locked Compressive Nailing in Aseptic Tibial Diaphyseal Nonunions without Bone Defect

## Abstract

**Background:** Treatment of tibial diaphyseal nonunions are rather difficult. Plate-screw, intramedullary nailing and external fixation are the methods used for treatment. The aim of this study is to evaluate the treatment results of aseptic diaphyseal nonunions following tibia fractures by intramedullary compressive tibia nailing (IMCN) with or without bone graft. **Materials and Methods:** Twenty eight patients who had aseptic tibial nonunion without bone defects operated between 2005 and 2015 were included in the study. The mean age of our patients was 36.4 years (range 20–56 years). There were 22 males and 6 females. Fifteen of the patients exhibited hypertrophic nonunion and thirteen exhibited atrophic nonunion. The average time between fracture occurrence and presentation to our department was 1.6 years (range 1–20 years). All patients underwent fibular osteotomy by removal of a 2 cm bone block from the middle one-third of the fibulas. In all cases, IMCN was applied following the reaming procedure, then maximum bone contacts were achieved manually between proximal and distal bone fragments afterward, and dynamic compressive fixation with 1 mm of compression was performed by a single rotation of the compression screw at the top of the nail. Direct X-ray images were assessed according to the Rust criteria, and functional outcomes were assessed according to the Johner–Wrush criteria. Finite-element analysis was performed for 1 mm of compression. For statistical analysis, Fisher’s exact test, Pearson’s Chi-square test, and Mann–Whitney U-test were used. **Results:** Union was achieved in all patients. Radiological union was obtained at an average of  $15.5 \pm 1.86$  weeks. Functional results were found to be good or excellent in 25 (89.2%) patients and average or poor in 3 (10.8%) patients. One patient developed skin necrosis at the wound site, which was treated with rotational flap and skin graft. None of the patients developed implant failure, thromboembolism, deep-vein thrombosis, or infection. **Conclusions:** The use of compressive intramedullary nailing with or without bone graft is an effective method for the treatment of tibial nonunion.

**Keywords:** Autologous bone grafting, intramedullary compressive tibial nail, nonunion

## Introduction

Fracture healing is a progressive and dynamic process. In diaphyseal fractures of the tibia, the lack of radiological healing 3–5 months after the injury is identified as delayed union. The nonunion was described for those fractures that had not healed after 9 months.<sup>1,2</sup>

There are various reasons for fracture nonunion, and different nonunion types can develop due to different causes.<sup>3–5</sup> These should be accounted for when treatment is being planned. Systemic causes such as nutritional disorder, smoking, osteoporosis, diabetes mellitus, anticonvulsive and nonsteroidal anti-inflammatory medications, opioids, benzodiazepines, vitamin D

deficiency, and alcoholism, along with local causes such as infection, circulatory insufficiency, inadequate reduction, biomechanical imbalance, force of trauma, and open fracture, may cause nonunion.<sup>3–5</sup>

Conservative treatment of nonunion cases rarely results in full recovery. However, methods such as functional cast bracing, electromagnetic stimulation, and low-frequency ultrasound may be used in select cases.<sup>6–9</sup>

The type of nonunion must be taken into consideration when planning surgical therapy. Hypertrophic nonunions present with extensive callus formation and have a high chance for recovery. Application of a stable osteosynthesis is the best treatment course in this type of nonunion.<sup>10</sup> Atrophic nonunions are characterized with a low amount of callus formation, circulatory

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insufficiency of the bone, and low chance for recovery. This type of nonunion requires debridement of the necrotic tissue and additional biological stimulation. Various methods such as bone grafts – especially autografts, decalcified bone allograft, bone marrow injections, and/or the application of bone morphogenetic protein among other osteoinductive agents are used as biological stimulants.<sup>11-13</sup>

The surgical treatment of nonunions includes augmentative plating, compression plate, intramedullary nail (static/dynamic), exchange nailing, and external fixator application.<sup>14</sup>

The aim of the present study is to evaluate the treatment results of aseptic diaphyseal atrophic and hypertrophic nonunions following tibia fractures by intramedullary compressive tibia nailing (IMCN) with or without bone graft.

## Materials and Methods

Twenty eight patients who were diagnosed with aseptic tibial nonunion without bone defect, between 2005 and 2015, were included in the study. Infected nonunions, lower extremity compartment syndrome cases, those who had history of malignancy, and those under 2 years of followup were excluded from the study. The mean age of the patients was 36.4 years (range 20–56 years). A total of 22 patients were male while 6 were females. Fifteen patients had presented with hypertrophic nonunion and thirteen had presented with atrophic nonunion. Patient characteristics are shown in [Table 1]. The average time between

fracture occurrence and presentation to our department for surgery was 1.6 years (range 1–20 years). The initial treatments of patients were external fixation for fractures in four, expandable intramedullary nail in two, plate-screw fixation in sixteen, and conservative in the remaining six patients. Due to nonunion during followup, compressive intramedullary tibial nail was utilized in all cases. The fractures were closed in all cases, except for the four patients who had Gustilo–Anderson type 2 open fractures. First, fibula osteotomy was performed in all patients by the removal of a 2 cm bone block. Dynamic compressive fixation was performed with reaming and compressive intramedullary nail (C75 IMCN, Hipokrat, İzmir, Turkey) in 15 hypertrophic nonunion cases. On the other hand, the 13 patients who had atrophic nonunion were treated with dynamic compressive fixation by reaming and compressive intramedullary nail, along with the implementation of autogenic bone graft from the iliac crest. Among our patients, 12 were smokers, 2 of these also had diabetes mellitus and were using insulin, another patient was an alcohol abuser along with being a smoker, and 1 patient had osteoporosis due to surgical oophorectomy. A 48-h treatment regimen of 1 g of cefazolin sodium four times a day was started on all patients 1 h before surgery. After surgery, all patients received low-molecular-weight heparin for 21 days. X-ray images were ordered, and clinical evaluations were performed for all patients during post surgery followup. Weight bearing was not allowed until the callus was seen on plain X-ray. Followup period was 3.2 year (2–6 years). Direct X-ray images were assessed according to the Rust criteria,<sup>15</sup> and functional outcomes were assessed according to the Johner–Wrush criteria.<sup>16</sup> Finite-element (FE) analysis was performed for 1 mm of compression.

## Statistical analysis

Descriptive statistics were presented as “mean ± standard deviation,” “median (min-max),” and “*n* (%)” values, where appropriate. Fisher’s exact test and Pearson’s Chi-square analysis were performed for categorical variables. Mann–Whitney U-test was used for comparison of quantitative variables with non normal distribution. Statistical analysis was made using the computer software Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, version 21.0. released 2012, IBM Corp., Armonk, New York, USA). *P* < 0.05 was considered statistically significant.

## Finite-element analysis

Two types of material were used in the analysis. The first is the cortical bone material which was identified according to bone data. The mechanical properties of the bone material were determined as follows: elasticity module 20 GPa, Poisson ratio 0.15, and density 1650 kg/m<sup>3</sup>. The material of the nails and screws was titanium. The mechanical properties of titanium were determined as follows:

**Table 1: Patient characteristics (n=28)**

Patients characteristics	<i>n</i> (%)
Age (mean±SD)	36.4±9.4
Gender	
Female	6 (21.4)
Male	22 (78.6)
Fracture type	
Open	4 (14.3)
Closed	24 (85.7)
Diabetes	
Negative	26 (92.9)
Positive	2 (7.1)
Smoking	
Negative	16 (57.1)
Positive	12 (42.9)
Osteoporosis	
Negative	27 (96.4)
Positive	1 (3.6)
Alcoholism	
Negative	27 (96.4)
Positive	1 (3.6)
Nonunion type	
Atrophic	13 (46.4)
Hypertrophic	15 (53.6)

SD=Standard deviation

elasticity module 96 GPa, Poisson ratio 0.36, and density 4620 kg/m<sup>3</sup>.

FE modeling and analysis were performed using ANSYS® 16.2 (NASDAQ: ANSS). The FE model was constructed with the bone, intramedullary compressive nail, and screws.

As a result of the FE analysis for the tibia screw that we used, the strain distribution shown in Figure 1 was obtained. The 1 mm displacement value applied by the nail screw appears to be the result of moment and axial force. The average stress is around 34 MPa.

### Operative procedure

All patients were in the supine position when the fracture line was accessed. Necrotic tissue was removed. Osteotomy was performed from the middle one-third of the fibulas with a lateral incision, and 2 cm of bone was excised. A midline incision on the anterior aspect of the knee was used as entrance. Reaming was performed through superior access from the proximal tibia. The appropriate length and diameter of the nail were determined, and then nailing was performed in all cases. Having achieved maximum bone contacts manually between proximal and distal bone fragments, two locking screws were used to obtain distal

locking, and one screw was used for locking through the proximal dynamic hole. 1 mm compression was performed by a single rotation of the compression screw at the top of the nail.<sup>17,18</sup> Locking was achieved without fluoroscopy in a short time, using one or more combining techniques described in our previous article.<sup>17</sup> With these techniques, the surgeon was protected from radiation exposure.<sup>17</sup> Grafts obtained during reaming were placed in the site of nonunion. In patients who had atrophic nonunion, autogenic grafts acquired from the iliac crest and fibula segment were used as bone grafts.

### Results

Union was achieved in all patients [Figures 2a-d and 3a-d]. Radiological evaluations were done according to the Rust criteria, and we found that average union time was 15.5 ± 1.86 weeks. There was no statistically significant difference in union time between males and females (*P* = 0.712). However, union time was found to be significantly different in regard to fracture type; open fracture union times were significantly longer (*P* = 0.007). Smokers' union time was found to be significantly longer than those who did not smoke (*P* < 0.001). We also found that union time was longer in patients who had atrophic nonunion compared to hypertrophic nonunion (*P* < 0.001) [Table 2 and Figure 4].

Clinical and functional outcomes were assessed according to the Johner–Wrush scale. Functional results were determined as good or excellent in 25 (89.2%) patients and fair or poor in 3 (10.8%) patients. At final followup, in good and excellent group, mean shortening in the limb was 8.36 mm (range 5 mm–10 mm) and in the fair and poor group it was 20 mm (range 18 mm–22 mm). Skin necrosis around the wound site was seen in one patient, which was treated with rotational flap and skin graft. None of the patients developed implant failure, thromboembolism, deep-vein thrombosis, or infection.

### Discussion

Many systemic and local factors have been proposed to cause tibial nonunion.<sup>3</sup> Twelve of our patients were

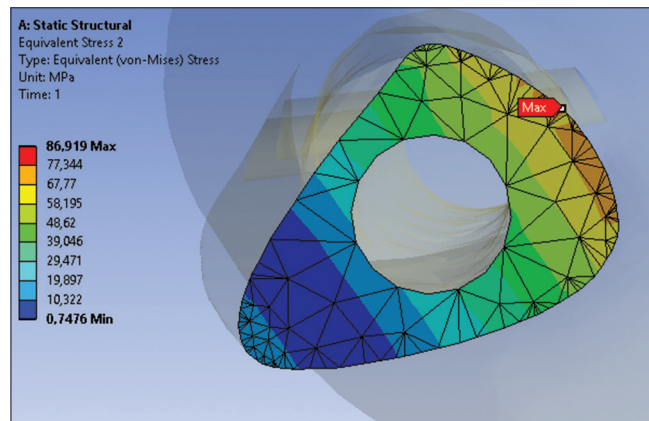


Figure 1: The surface stress of the bone when the screw was pressured for 1 mm. To see the stress distribution at the fracture site, the lower part of the bone was hidden after analysis and the von Mises stress values are given as MPa



Figure 2: (a-d) Presurgery and 20-week postsurgery images from AP and lateral viewpoints of a 47-year-old patient who was conservatively treated after a traffic accident 20 years ago

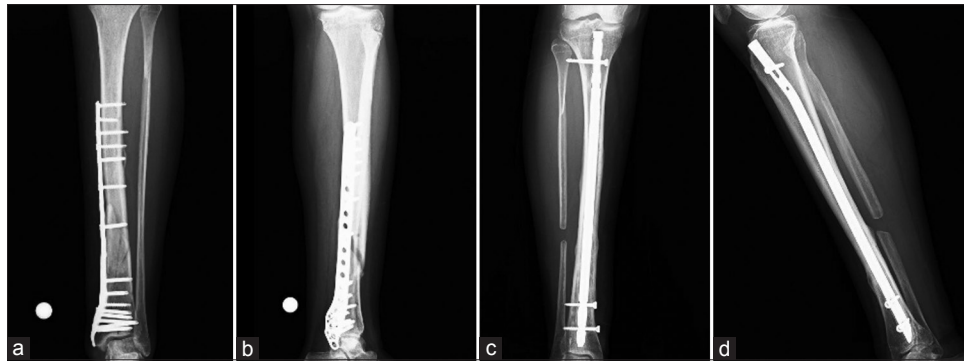


Figure 3: (a-d) Presurgery and 20-week postsurgery images from AP and lateral viewpoints of a 35-year-old female patient who received plate and screw osteosynthesis

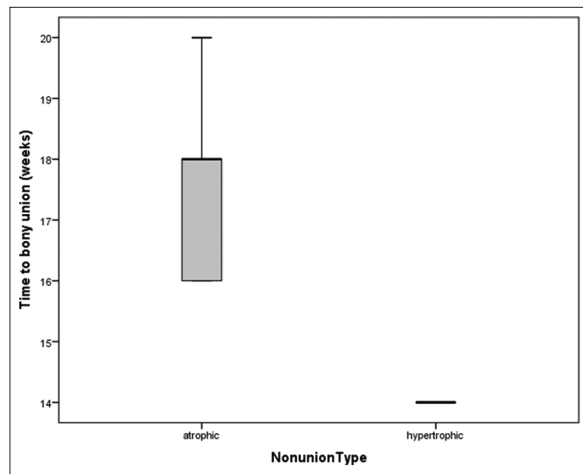


Figure 4: The relationship between nonunion type and time to bone union

smokers, two of these had diabetes, one was alcoholic, and one was diagnosed with osteoporosis. Four patients were treated with external fixator due to open fractures. The patients who had open fractures, smoked, abused alcohol, and had diabetes or osteoporosis were found to have the longer union times reported in our series. This finding is in parallel with the systemic and local factors listed in the literature.<sup>3,19,20</sup>

The intramedullary nailing method is widely used in aseptic tibial nonunions without bone defect. Two of our patients had developed nonunion following treatment with expandable nails for their tibia shaft fractures. Steinberg *et al.*<sup>21</sup> report that they obtained satisfactory results with expandable nailing in tibia nonunions; however, Smith *et al.*<sup>22</sup> do not recommend expandable nailing even in acute tibia shaft fractures. We did not use expandable nails in either acute or nonunion cases.

Varying values for the duration and rate of union are reported in the literature. Niedźwiedzki<sup>23</sup> utilized intramedullary nailing in tibial nonunion cases and reported the rate of union as 94% and time until union as 9.2 months. On the other hand, Faisham *et al.*<sup>24</sup> used static

Table 2: Union time in regard to gender, fracture type, smoking status, and nonunion type

Patients characteristics	Time to bone union	P
Gender, median (minimum-maximum)		
Female	14 (14-18)	0.712
Male	15 (14-20)	
Fracture type, median (minimum-maximum)		
Open	18 (16-20)	0.007**
Closed	14 (14-18)	
Smoking, median (minimum-maximum)		
Negative	14 (14-16)	0.001***
Positive	18 (14-20)	
Nonunion type, median (minimum-maximum)		
Atrophic	18 (16-20)	0.001***
Hipertrophic	14 (14-14)	

\*\*P<0.05; \*\*\*P<0.001

intramedullary nailing and found union rate to be 100% within 4 months.

In a study focused on cases which developed tibia nonunion after intramedullary nailing, Hsiao *et al.*<sup>25</sup> achieved 100% union rate within 4.7 months when they replaced the nail with dynamic locked nails.

Swanson *et al.*<sup>26</sup> replaced the nail and performed overreaming by 1 mm or more in their cases. They reported a 98% rate of union achieved in 4.8 months.

In a study based on literature review by Brinker and O'Connor,<sup>14</sup> aseptic tibial nonunion cases (without segmental defect) treated with intramedullary nailing were evaluated. They found that, when replacement was done with augmentative plate and bone graft or reamerized nail, a high rate of union was achieved. They also report that aseptic nonunion cases which were previously treated with plates showed high success rates with revision plate-screw fixation and bone graft or other biological implants. We didn't study the difference in union rate depending on primary fixation.

In contrast with these authors, in our study, we used the dynamic compressive implementation of locked compressive nailing in all our cases, and fibula osteotomy was performed on all patients. None of our patients needed revision or augmentative plates. In atrophic nonunions, autogenic grafts obtained from the iliac bone and fibula osteotomy and spongy tissue obtained during reaming were used as grafts, whereas only the spongy tissue was used in hypertrophic nonunions. A rate of 100% union was obtained in  $15.5 \pm 1.86$  weeks on an average.

In addition to being a lockable nail, the nail we use is an intramedullary nail which makes compression possible through its proximal dynamic screw. Baki *et al.*<sup>18</sup> in their experimental study on rabbits have shown the effect of compression and its amount on union. In this study, they evaluated the stress put upon the fracture site with 0.5 mm and 1 mm compression. They report that 0.5 mm of compression results in a stress value of 34.5 MPa and 1 mm of compression results in 88 MPa. They also found that union was histologically better and was obtained sooner in the 34.5 MPa group. In our study, through FE analysis, we found 1 mm of compression yielded 34 MPa of stress on average [Figure 1]. This result concurs with the 34.5 MPa stress distribution value proposed by Baki *et al.* This feature of our study may explain the relatively shorter union time reported by us in comparison to other studies. In the literature, Gupta presented a study on active compression through intramedullary compression nailing, which is applied for treating nonunions. He concluded that this may prove greatly advantageous to the fracture union through increased stability and the osteogenic potential.<sup>27</sup>

Compressive intramedullary nailing with or without bone graft in the treatment of aseptic tibial diaphyseal nonunion without bone defect is an effective method offering significantly shorter union times and outstanding clinical and functional results

### Limitations

The low number of patients, the lack of different compression values, and the retrospective nature are limitations of our study. However, to the best of our knowledge, this is the first study where compression and surface stress values in the treatment of tibial nonunion are evaluated in conjunct. Although application of a stable osteosynthesis is the best treatment course in the hypertrophic type of nonunion, 15 of 28 patients had hypertrophic nonunion in the present study. Even in these cases, stabilized osteosynthesis with dynamic compression was applied, and this could be considered as a limitation of the study.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information

to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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### Conflicts of interest

There are no conflicts of interest.

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