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Innovative distal bolt-locking screw tibial nailing method and conventional nailing: A comparison of outcomes

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ABSTRACT

Objectives: Distal bolt-locking screw (DSBLS) tibial nailing offers an innovative method in which the nail is locked upon entering the screw. The current study compares the clinical, radiological, and functional outcomes of DSBLS tibial nails with conventional tibial nails.

Patients and Methods: We retrospectively evaluated 38 tibial fractures of 37 patients treated with intramedullary nailing. In Group 1, 21 fractures were treated with DSBLS nailing, while in Group 2, 17 fractures were treated with conventional nailing. Duration of surgery, time to weight-bearing, time to union, presence of deformity, return to work and sports, complications, American Orthopedic Foot and Ankle Society Score (AOFAS) and Olerud-Molander Ankle Score (OMAS) values were compared between the groups.

Results: Group 1 patients had significantly shorter time to full weight-bearing than patients in Group 2 (P=0.032). There was no significant difference between the groups in functional comparisons according to the AOFAS. In contrast, the outcomes of Group 2 were better than those of Group 1 according to the OMAS (P=0.475 and P=0.037). The outcomes for the other variables were similar.

Conclusion: In this method, patients can bear weight in a shorter time. The results of DSBLS nailing are as good as conventional nails, and it can be safely preferred in treating tibial fractures with intramedullary nailing.

Keywords: DSBLS, Distal bolt-locking screw, Tibia, Tibia nailing, Tibia fracture

1. INTRODUCTION

Among long bone fractures, tibia fractures are the most common [1]. The primary goal in treating tibial fractures is to achieve reasonable alignment and return the patient to daily life as soon as possible. Although, different implants such as plates and external fixators can be applied in treating tibial fractures, intramedullary nailing is also an effective option [2]. Intramedullary nails are preferred for tibial fractures due to essential advantages such as allowing stable fixation, causing less damage to soft tissue, allowing earlier weight bearing with weight sharing, and being linked to lower infection rates [3].

Tibial nails can be used in treating metaphyseal transition zone fractures and tibial diaphyseal fractures. As a result of the anatomical structure of the tibia expanding in the distal part, less bone-nail contact occurs in this region, and it is more difficult to obtain the desired stability. Therefore, distal locking screws are essential factors affecting stability [4]. Although, this problem has been tried to be overcome with various screw configurations or additional screws such as poller screws in classical nailing approaches, distal locking screws for the stable fixation of tibial fractures remain an important problem for orthopedic surgeons [5].

The distal bolt-locking screw (DSBLS) tibial nail was developed to address the problems caused by distal locking screws in the nail treatment of tibial fractures [6]. In the DSBLS method, in contrast to conventional nails, the nail is inserted into the bolt screw. This design allows for stability in different axes and axial compression [7]. In the current study, we compare the clinical, radiological, and functional outcomes of the DSBLS as an innovative method with the results of conventional intramedullary distal locking tibial nails. DSBLS is a method used in the current treatment of tibial fractures [6]. However, there needs to be a convincing study comparing the results of DSBLS and conventional nails in the literature. With this study, we aimed to contribute to the literature by comparing and evaluating the outcomes of the two methods.

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2. PATIENTS and METHODS

This study was carried out retrospectively with the approval of the ethics committee (approval number: 2019/0259). Patients who underwent surgery for tibial fractures between 2012 and 2018 and were treated by intramedullary nailing were evaluated. Patients who died in the postoperative period, underwent intramedullary nailing for the treatment of pseudoarthrosis, and did not attend regular follow-up visits were excluded. With these criteria, 38 tibial fractures of 37 patients were evaluated in the study. The patients were divided into two groups according to the type of nail used in treating their tibial fractures. Patients for whom DSBLS tibial nailing was used were considered Group 1, and patients for whom conventional tibial nailing was used were considered as Group 2. In the treatment of the 21 fractures in Group 1, intramedullary tibia nail with distal bolt-locking screw ''the TibiA" (TST, Istanbul, Türkiye) was used (Figure 1). The Trigen Meta-Nail (Smith & Nephew, Memphis, TN, USA), a conventional distal locking nail, was used in the treatment of the 17 fractures in Group 2.

*Figure 1. **a:** Coronal view of the DSBLS and the nail. **b:** The tibial nail in the sagittal plane and the entrance hole of the nail in the DSBLS. **c:** Locking of the tibial nail to the DSBLS in the coronal plane **d:** Locking of the tibial nail to the DSBLS in the sagittal plane*

The neurovascular status of patients admitted to the emergency department after trauma was evaluated. Patients with open fractures received antibiotic and tetanus prophylaxis. Anteroposterior (AP) and lateral (LAT) tibial radiographs were obtained, and temporary fixation was applied with a splint. The traumas that caused the fractures were analyzed. Fractures were classified by the Arbeitsgemeinschaft für Osteosynthesefragen/ Orthopaedic Trauma Association (AO/OTA) classification, and the Gustilo-Anderson classification was used for open fractures [8,9].

Patients received 1 g of first-generation cephalosporin preoperatively. The operation duration of the patients were recorded. Antibiotic prophylaxis was terminated at the 24th postoperative hour. Low-molecular-weight heparin was given to patients for prophylaxis of venous thromboembolism. On postoperative day 1, two-way (AP-LAT) radiography was performed with the ankle and knee joints visible. Patients with other concomitant fractures and those who could not be ambulated for other reasons were given in-bed exercises. Non-disabled patients walked on their feet.

After discharge, a routine outpatient follow-up program was applied, and the patients were evaluated at weeks 2, 4, 6, 8, 10, 12, and 16 and months 6 and 12 with control radiographs. Information about postoperative time to fracture union, time to weight bearing, return to work and sports were recorded in outpatient clinic visits. All participants were divided into four groups day 1, 1-20 days, 20-45 days, and >45 days according to time to weight bearing. Complications such as anterior knee pain, venous thromboembolism, infection, nonunion, malunion, heterotrophic ossification, reflex sympathetic dystrophy, and screw breakage were followed. The presence of varus-valgus deformity was evaluated on AP radiographs of the tibia, and the presence of antecurvatum-recurvatum deformity was evaluated on LAT radiographs. Angulation of more than 5° in any plane was considered malalignment [10]. Full weight bearing was regarded as the patient stepping on the foot without pain. Evaluation of union was performed radiologically. The Olerud-Molander Ankle Score (OMAS) and the American Orthopedic Foot and Ankle Society Score (AOFAS) were used for clinical evaluation [11, 12].

Surgical Technique

All patients were positioned supine. After sterile covering, the skin and subcutaneous tissues were cut with a 5-cm incision distally from the patella. The tibia was reached by passing through the center of the patellar tendon. The first entry site was determined and entered with fluoroscopic control at the point where the tibial plateau turned to the anterior cortex. The fracture was reduced, the guide wire was placed, and the tibia was reamed appropriately. After the nail was pushed to the location of the distal bolt screw, a Kirschner (K) wire was inserted from the medial of the tibia at the supramalleolar level, parallel to the joint in the coronal plane and to the midline of the tibia in the sagittal plane. After confirming position of the K-wire with the scope, the medial and lateral cortex were drilled sequentially with a 5-mm drill through the wire, and then solely the medial cortex was drilled with an 8.5-mm drill. The bolt screw was inserted into the drilled holes with its wide opening proximally facing the tibia. A nail was inserted into the placed screw, and locking was completed with a set screw. Proximal screws were placed using the guide (Figure 2).

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Marmara Med J 2023;36(3): 344-350

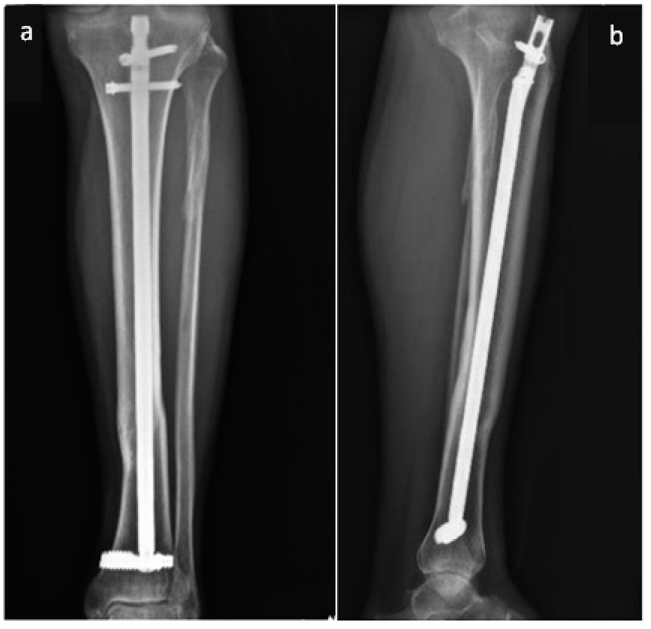

Figure 2. *X-ray images of a patient treated with DSBLS at 43 months postoperatively a: AP view b: LAT view*

In Group 2, the tibia was entered with the same approach used in the first group during intramedullary nailing applications. After reduction, the guide wire was placed, and reaming was performed. An intramedullary nail of appropriate length and thickness was placed. Distal locking screws were locked with a magnetically assisted system (Smith & Nephew, Memphis, TN, USA). Proximal screws were placed using the guide (Figure 3).

Figure 3. *X-ray images of a patient treated with the conventional nail at 36 months postoperatively a: AP view b: LAT view*

Statistical Analysis

The collected data were evaluated using IBM SPSS Statistics for Windows 20.0 (IBM Corp., Armonk, NY, USA). Descriptive analyses were used for the groups. Data for categorical variables were presented as number (%); data for continuous variables were presented as mean ± standard deviation or mean (standard deviation). Since parametric test conditions were not met in general, differences in value between groups for continuous and discrete variables were evaluated with the Mann-Whitney U test. Chi-square independence test was applied to analyze the significance of differences between groups in terms of qualitative variables. The relationships among quantitative variables were evaluated with Spearman's correlation coefficients. P value <0.05 was accepted as a sign of statistical significance.

3. RESULTS

Twenty-three (62,1%) of the patients were male, and 14 (37,9%) were female. The mean age of Group 1 was 47.48±17.71 years, and that of Group 2 was 42.35±17.12 years. (P=0.332). The mean follow-up period of all participants was 37.6 (12-84) months. The mean follow-up period was 30.19±9.04 months for Group 1 and 46.76±19.94 for Group 2. The follow-up period of Group 1 was statistically significantly shorter than Group 2 (P=0.005).

The tibial fractures of the patients were due to non-vehicular traffic accidents (NVTAs), vehicular traffic accidents (VTAs), falls, gunshot wounds (GSWs), and sports injuries. Tibial fractures were classified according to the AO/OTA classification, and the Gustilo-Anderson classification was used to evaluate open fractures [8,9]. Traumas causing fractures and the classifications of the fractures are given in Table I.

The mean operative duration of the patients in Group 1 was 125±30.28 min.; in Group 2, this duration was 124±32.45 min. Statistically, the difference between the groups was not significant. (P = 0.714). Time to union was 8.11±1.83 weeks in Group 1, and 9.75±3.35 weeks in Group 2, the difference between them was not statistically significant (p=0.289). The time to return to work was 9.09±8.21 months in Group 1 and 8.06±3.31 months in Group 2. The time to return to sports was 9.79±7.91 months in Group 1 and 9.53±4.95 months in Group 2. In terms of time to return to work or time to return to sports there was no statistically significant difference between the groups. (P=0.422 and P=0.470, respectively). the American Orthopedic Foot and Ankle Society Score (AOFAS) and Olerud Molander Ankle Score (OMAS) values and times to weight bearing for the two patient groups are given in Table II.

In the coronal plane, 15 patients (71.4%) in Group 1, 12 patients (70.6%) in Group 2 had neutral alignment. In Group 1, 2 (9.5%) patients had varus alignment; no varus alignment was seen in Group 2. Valgus alignment was seen in 4 (19%) cases in Group 1, 5 (29.4%) in Group 2. Thus, there was no statistically significant difference between the groups for coronal plane alignment (P=0.36). In Group 1, alignment in the sagittal plane was neutral in 16 (76.2%) cases, antecurvatum in 2 (9.5%), and recurvatum in 3 (14.3%). In Group 2, it was neutral in 15 (88.2%) cases

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Marmara Med J 2023;36(3): 344-350

and antecurvatum in 2 (11.8%). No recurvatum alignment was observed in Group 2. In the sagittal plane, no statistically significant difference was found between the groups (P=0.267). Other complications seen in these cases are given in Table III. All complications were evaluated together and compared in the groups, there was no statistically significant (P=0.75).

***Table I**. Types of trauma causing fractures and fracture classifications according to AO/OTA*

	Group 1 n (%)	Group 2 n (%)	χ^2	p
Trauma				
Fall	8 (38.1)	7 (41.2)		
GSW	1 (4.8)	1 (5.9)		
Sports	0 (0)	1 (5.9)		
VTA	3 (14.3)	1 (5.9)		
NVTA	9 (42.9)	7 (41.2)	2.094	0.853*
Type of fracture				
Closed	16 (76.2)	13 (76.5)		
Type 1 open	1 (4.8)	0 (0)		
Type 3 open	4 (19)	4 (23.5)	0.913	0.529*
Fracture classification				
42A1	4 (19.0)	9 (52.9)		
42A2	0 (0)	2 (11.8)		
42A3	2 (9.5)	2 (11.8)		
42B2	9 (42.9)	3 (17.6)		
42C2	1 (4.8)	0 (0)		
42C3	1 (4.8)	0 (0)		
43A1.1	3 (14.3)	0 (0)		
43B1.3	1 (4.8)	0 (0)		
43C1.3	0 (0)	1 (5.9)	17.168	0.024*

**Fisher's Exact/Fisher-Freeman-Halton Test*

***Table II**. AOFAS /OMAS values and times to weight bearing*

	Group 1 (n=21)		Group2 (n=17)			
	Mean (SD)	median	Mean (SD)	median	U	p*
AOFAS	91.86 (6.67)	90	93.71 (5.83)	95	154.500	0.475
OMAS	83.90 (11.30)	85	91.18 (11.66)	95	108.500	0.037
Postop. full weight bearing (day)	n (%)		n (%)		χ^2	p**
<1	2 (9.5)		0 (0)			
1-20	4 (19)		2 (11.8)			
20-45	5 (23.8)		0 (0)			
>45	10 (47.6)		15 (88.2)		7.753	0.032

**Mann-Whitney U test **Fisher Exact test/Fisher-Freeman-Halton Test , AOFAS: The American Orthopaedic Foot and Ankle Society Score, OMAS: The Olerud-Molander Ankle Score*

***Tablo III.** Complications in the groups*

Complication	Group 1 (n=21) n (%)	Group 2 (n=17) n (%)	χ^2	p
Anterior knee pain	9 (42.9)	4 (23.5)	1.559	0.212
Irritation	5 (23.8)	7 (41.2)	1.311	0.252
Emboli	2 (9.5)	0 (0)	1.709	0.492*
Infection	1 (4.8)	0 (0)	0.831	0.362*
Nonunion	1 (4.8)	0 (0)	0.831	0.362*
Heterotrophic Ossification	0 (0)	0 (0)	-	-
Sudeck atrophy	0 (0)	1 (5.9)	1.269	0.447*
Screw breakage	0 (0)	1 (5.9)	1.269	0.447*

** Fisher Exact / Fisher-Freeman-Halton Test*

4. DISCUSSION

There are different options for the treatment of tibial fractures, but intramedullary nailing is primarily recommended because of its superiority over other methods [13]. Especially for fractures in the distal third of the tibia, it is challenging to maintain proper alignment, reduction, and stable fixation. Conventional nailing has overcome these difficulties by placing multiple screws on different planes. Mohammed et al. stated that one distal locking screw is insufficient for fractures in the distal region, and if more than one screw cannot be placed, the choice of implant type should be changed [14]. Vallier et al., reported a malalignment rate of 23% after intramedullary nailing in the treatment of distal tibial fractures [10]. Richard et al., similarly reported a malunion rate of 25% in their study [15]. We evaluated the locations of the fractures in our study and found that the number of distal third fractures in Group 1 was statistically significantly higher than in Group 2. Despite this difference between the groups, there was no statistically significant difference between them in terms of malalignment, and the results were similar to the literature.

The most crucial difficulty in intramedullary nailing is the placement of distal locking screws in the nailing [16]. Previously, distal locking screws were placed with fluoroscopy, but later electromagnetic methods started to be used, and operation durations were shortened thanks to that development [17]. Uruc et al., concluded in their study that the duration of surgery with the electromagnetic locking method was significantly shorter, and Langfitt et al., reported that surgical durations were shorter when the electromagnetic locking method was used for distal locking in their study compared to conventional nails [18,19]. In our study, there was no significant difference between the groups with regard to the surgical duration (P=0.714). Although, a magnetically assisted locking system (Smith & Nephew Trigen Sureshot) was used in Group 2, we think that the application technique applied for DSBLS nailing was the source of similar results being obtained between the two groups. With conventional nails, the distal locking screw is placed inside the nail, whereas with DSBLS nailing, the nail is placed inside the screw, providing ease of application for distal locking.

There are different results in the literature regarding the union time of tibial fractures after intramedullary nailing. Robertson et al., reported the mean time to union of tibial fractures as 20.9

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Marmara Med J 2023;36(3): 344-350

weeks [20]. In the first of two studies in which the results of DSBLS nailing alone were given, Küçükdurmaz et al., reported a mean union time of 9 weeks, and Atiç et al., reported a mean union time of 20.9 weeks [6,21]. In our study, there was no significant difference between the groups with regard to union time, and the results were compatible with those of Küçükdurmaz et al. Although, the same type of nail was used, we think that the difference between the results of Küçükdurmaz et al. and Atiç et al. was related to the time to weight bearing of their patients. Küçükdurmaz et al., allowed their patients to bear weight on the first postoperative day, while Atiç et al., allowed weight bearing to begin in the 9th week. In the literature, it has been shown that early weight bearing accelerates fracture union [22,23]. In our study, we aimed to have our patients bear weight as soon as possible in the postoperative period. In the comparison between the two groups in terms of time to weight bearing, we concluded that DSBLS nailing allowed for a shorter time to weight bearing compared to conventional nails (P=0.032).

The primary goal in the treatment of tibial fractures is to return the patient to daily life with a pain-free and fully functional limb. In their study, Dogra et al., reported an average time to return to work of 5 months, while Arangio et al., reported an average time to return to work of 11 months [24, 25]. In our study, the average time to return to work was 9.09±8.21 months in Group 1 and 8.06±3.31 months in Group 2, and there was no significant difference between the groups. In a systematic review of 16 studies by Robertson et al., the average time to return to sports after tibial fracture was 10.25 months [20]. In our study, the average time to return to sports was 9.79±7.91 months in Group 1 and 9.53±4.95 months in Group 2. There was no significant difference between the two groups, and the results were similar to the literature.

Ankle movements may be affected, especially in cases of distal tibial fractures. Therefore, ankle function should also be considered in the evaluation of clinical results of tibial fractures. Guo et al., reported the mean AOFAS of 89.1 among their patients treated with intramedullary nailing [26]. In their study, Kariya et al., reported that the mean AOFAS was 82.1 [27]. Matthew et al., found the mean OMAS of 91.4 as clinical outcomes of their patients [28]. Ibrahimi et al., reported a mean OMAS of 87.9 in the study [29]. In our study, the mean AOFAS was 91.86±6.67 and 93.71±5.83 with no significant difference between the groups. When OMAS criteria were considered, the mean value of Group 1 was found to be 83.90±11.30, while this value was 91.18±11.66 in Group 2. The results of Group 2 were statistically significantly better in terms of the OMAS. We think the larger number of distally located fractures in Group 1 and the shorter follow-up period compared to Group 2 may have been effective for this situation.

Anterior knee pain is the most common complaint after treatment of tibial fractures with intramedullary nailing [30]. Keating et al., reported that anterior knee pain occurred in 53% of the patients in their study [31]. Court-Brown et al. reported this rate as 56.2% in their study[32]. In a meta-analysis, Katsoulis et al., found the average incidence of anterior knee pain to be 47.4% [33]. In our study, the most common complication that we observed in patients was anterior knee pain, reported by 34.2% of our patients. There was no statistical significance between the groups and our results are consistent with the literature. In our study, five patients in Group 1 and seven patients in Group 2 complained of screw irritation. Although, there were more patient complaints in Group 2, there was no significant difference between the groups. Superficial skin infection was observed in two patients in Group 1 and was treated with oral antibiotics. Reflex sympathetic dystrophy was observed in one patient in Group 2. Venous thromboembolism was detected in two patients in Group 1. The distal locking screw broke in one patient in Group 2. In Group 1, nonunion was observed in the left tibia of a patient with bilateral tibial fractures, and the union was achieved by applying exchange nailing. When all complications were considered together, the results were similar between the groups.

The first limitation or our study is its retrospective structure. The fact that a single surgeon did not perform the operations is another limitation. We think that different results could be obtained in a homogeneous group with a higher number of patients with fractures located in the distal tibia.

Conclusion

In conclusion, DSBLS nailing is a method for solving the problems encountered with distal locking screws. With DSBLS nailing, patients can bear weight earlier. The radiological and functional results and complications of DSBLS nailing are similar to conventional nails. This approach can be safely preferred in the treatment of tibial fractures with intramedullary nails.

Compliance with Ethical Standards

Ethical Approval: The study was approved by the Medeniyet University, Goztepe Training and Research Hospital Ethics Committee (approval number: 2019/0259).

Conflict of Interest: The authors declare that they have no conflicts of interest.

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Marmara Med J 2023;36(3): 344-350