EXPERIMENTAL STUDY

Biomechanical comparison of three different surgical methods in the surgical treatment of distal tibial metaphyseal fractures. An animal model study

Cem Yildirim, M.D.,[1] Osman Görkem Muratoğlu, M.D.,[2] Samed Ordu, M.D.,[3] Hasan Ceylan, M.D.,[1] Duran Can Muslu, M.D.,[4] Dogan Atlihan, M.D.[5]

[1]Department of Orthopaedic and Traumatology, Cam and Sakura City Hospital, Istanbul-*Türkiye*
[2]Department of Orthopedic and Traumatology, Medicana Avcılar Hospital, İstanbul-*Türkiye*
[3]Department of Orthopedic and Traumatology, Eskişehir Yunus Emre State Hospital, Eskisehir-*Türkiye*
[4]Department of Orthopedic and Traumatology, Brandenburg, Klinikum Dahme Spreewald Achenbach Krankenhaus, *Germany*
[5]Department of Orthopedic and Traumatology, Haseki Training and Research Hospital, İstanbul-*Türkiye*

ABSTRACT

BACKGROUND: The aim of this study is to investigate mechanical properties of minimally invasive plate osteosynthesis (MIPO), supracutaneousplating (SP), and unilateral external fixators (UEF) which can be performed for open tibial fractures.

METHODS: An unstable diaphysial tibia fracture was created in 60 fresh sheep tibia specimens by performing an osteotomy at the middle of bones. Specimens were divided into 3 groups. Specimens underwent fracture fixation with a standard MIPO technique, implanting the plate 15 mm from the bone for SP group. Unilateral uniplanar external fixators were achieved for UEF group. First, thirty specimens (10 specimen for each group) were loaded vertically along the tibial axis to 1800 N. Second, other 30 preperated bones were used for cyclical loading to avoid metal fatigue. For dynamic tests, a 350 N force was applied for 10,000 cycles.

RESULTS: In compression testing (vertical loading up to 1800 N) of the three fixation instruments; construct stiffness was highest in MIPO group when compared with SP and UEF groups. While the stiffness of the MIPO group was similar to SP group, it was statistically higher than UEF group (P=0.08 and P=0.002, respectively). SP group was significantly stiffer than UEF group (P=0.0021). The mean peak load was highest in SP group and lowest in UEF group. The peak load in SP group was similar to the MIPO group, it was statistically higher than the UEF group (P=0.743 and P=0.002, respectively).

CONCLUSION: Based on the biomechanical properties from this in vitro animal model study, SP technique was biomechanically stronger than UEF and has similar biomechanical properties with MIPO in terms of axial loading.

Keywords: External fixator; locked compression plate; minimal invasive plate osteosynthesis; open tibia fracture; supercutaneus plating.

INTRODUCTION

Severe soft tissue damage can be seen in open tibia fractures due to high-energy trauma.[1,2] In such cases, internal fixation can increase the risk of infection and even initiate the procedure that eventually leads to amputation. In the literature, there are studies suggesting that soft-tissue follow-up should be performed with temporary external fixation and then replaced with internal fixation for final healing.[1,3]

External fixators offer a satisfactory alternative in terms of controlling soft-tissue damage and protecting the periosteal circulation at the fracture line,[4,5] and they can be used as a temporary or permanent treatment in the fixation of open

Cite this article as: Yildirim C, Muratoğlu OG, Ordu S, Ceylan H, Muslu DC, Dogan Atlihan D. Biomechanical comparison of three different surgical methods in the surgical treatment of distal tibial metaphyseal fractures. An animal model study. Ulus Travma Acil Cerrahi Derg 2023;29:1091-1097.

Address for correspondence: Osman Görkem Muratoğlu, M.D.
Department of Orthopedic and Traumatology, Medicana Avcılar Hospital, İstanbul, Türkiye
E-mail: osman.muratoglu@medicana.com.tr

Ulus Travma Acil Cerrahi Derg 2023;29(10):1091-1097 DOI: 10.14744/tjtes.2023.66304 Submitted: 08.06.2023 Revised: 24.07.2023 Accepted: 15.09.2023

Figure 1. Clinical example: A 30-year-old male patient with a Gustilo Anderson grade 3a open fracture of the distal metaphyseal tibia (a) treated with supercutaneous plating. (b) The anteroposterior X-ray image was taken 3 months after surgery and showed a healed fracture. The screw proximal to the fracture line was removed in the sixth postoperative week due to a pin site infection.

fractures.[5] However, traditional external fixator structures often cause difficulties in dressing and walking patients due to their large profile.[6-8] Interfragmentary motion is critical for the formation of callus tissue. It has been reported that interfragmentary movement may increase due to the lack of rigidity of the external fixator structures, which may cause insufficiency in forming callus tissue, delayed union, and even nonunion.[9,10]

Recently, satisfactory results of external locking plate application as an external fixator in open tibial fracture have been reported.[7,8,11,12] A clinical example is shown in Figure 1. Despite this, the use of locking plates as external fixators remains a generally unacceptable treatment.

There are limited studies in the literature comparing the biomechanical properties of minimally invasive plate osteosynthesis (MIPO), supercutaneous plating (SP), and unilateral external fixators (UEF).[11,13] Thus, this study aims to compare the mechanical properties (stability, stiffness, and loading up to 1,800 N) of MIPO, SP, and UEF in an unstable diaphyseal tibia fracture model using sheep bone. The first hypothesis of the study is to reveal that the application of SP may have similar biomechanical properties to MIPO. The second hypothesis was that SP may provide higher resistance to axial forces than UEF fixation.

MATERIALS AND METHODS

Preparation of the Specimens

In this study, 60 fresh sheep tibias of similar sizes were obtained from sheeps selected for slaughter. The bones were provided by an official veterinarian and harvested after animal death in the slaughterhouse. The dimensions of the bones of an adult sheep allow for testing the implants and prostheses used for the treatment of humans while its body weight is similar to that of an adult human.[14] Any soft tissues were cleaned off from the specimens, and the stripped bones stored frozen at −20°C. Each specimen was thawed at room temperature on the day of testing.

Evaluation of the Specimen's Bone Mineral Density (BMD)

Similar samples were used to increase the reproducibility of the data. To achieve this, BMD (FDX VISIONARY DR, Mauguio, France) was applied to sheep tibia samples. BMD of sheep tibia bone samples ranged from 1.426 g/cm³ to 1.523 g/cm³ (Mean 1.461 g/cm³, SD 0.025) and was approximately similar to human bone. There was no significant difference in BMD between the individual test groups.

Fracture Modeling and Construction

All specimens were transected from the proximal and distal tibial metaphysis to form bone fragments of equal length. The osteotomy was performed transversely in the middle of the specimens, and a 5-mm of bone fragment was removed to create an axially unstable fracture (Orthopedic Trauma Association type 42 A3 fracture).

The prepared constructs were sequentially tested in two modes: (1) loading up to 1800 N and (2) cyclical loading. Half of the preperated bone was used for loading up to 1800 N tests, and the other half was used for cyclical loading tests to avoid metal fatigue.[15] Specimens were randomly assigned to three fixation groups with similar mean BMDs:

In group 1 (MIPO), 3.5-mm six-hole low contact, titanium alloy LCP (Response Ortho, Istanbul) was placed on the anterior surface of the bone. Standard titanium 3.5-mm locked screws were inserted in slots 1 and 3 in the proximal bone fragment and slots 4 and 6 in the distal bone fragment (Fig. 2).

In group 2 (SP), 3.5-mm six-hole low contact titanium alloy LCP (Response Ortho, Istanbul) was placed 15 mm from the anterior surface of the bone. Standard titanium 3.5-mm locked screws were inserted in slots 1 and 3 in the proximal bone fragment and slots 4 and 6 in the distal bone fragment (Fig. 2).

In group 3 (UEF), 3.5 mm partially threaded Schanz pins (with 4.5 mm shaft) were placed similarly to the other groups on the anterior surface of the bone (using two bicortical Schanz pins on either side of the fracture), and each segment was connected 15 mm from the bone with carbon fiber rods (Response Ortho, Istanbul) (Fig. 2).

According to the AO external fixation principles, at least three locking screws/half pins are required per fracture fragment to achieve stable fixation on either fragment of the fracture, but considering the size of the sheep bones used in

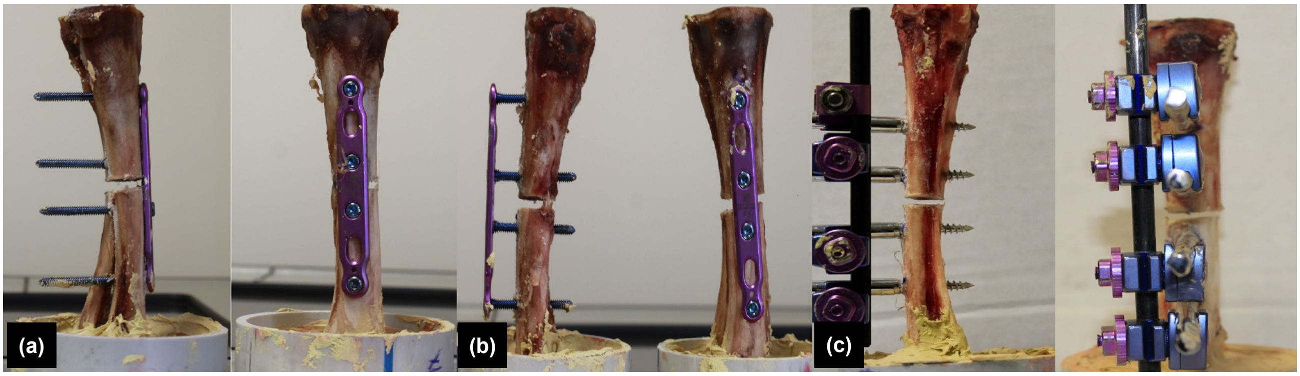

Figure 2. (a) In the minimal invasive plate osteosynthesis group, locking compression plates were applied flush to the bone with standard locking screws; **(b)** in the Supercutaneous plating group, plates were applied 15 mm from the bone; **(c)** in the Unilateral External fixator group, each fracture segment was connected 15 mm from the bone with carbon-fiber rods.

our study, we applied two screws per fracture fragment. We acknowledge that this represents a limitation of our study. However, in our study, we adhered to the AO external fixation principles, which suggest that there should be a screw near and a screw far from the fracture gap in both fracture fragments.

Internal locking screws/pins were placed at a distance of 5 mm from the fracture gap. It was ensured that all applied locking screws/pins were bicortical. The distance between the bone surface and the plates/rods was limited to 15 mm in the SP and UEF groups to allow for post-operative care, soft-tissue swelling, and adequate fixation stability of the constructs.[5,16]

Test Setup

All the biomechanical tests were conducted at the Response Ortho Research and Development Laboratory (Tuzla, Istanbul) using a servohydraulic materials testing machine (MTS Acumen™ Electrodynamic Test Systems, Eden Prairie, MN, USA). The two ends of the bone-plate and bone-external fixator constructs were mounted in a circular custom-made cup: The distal part of the models was fixed in dental plaster. The 5-mm spacer was removed after each specimen was stabilized.

The proximal part of the final testing construct was fixated on the actuator of a material test system. The distal part of the final testing construct was firmly placed and fixed to the base of the test system. The final constructs were loaded vertically along the mechanical axis of the tibia.

Failure is defined as fracture displacement >5 mm in space and/or >5° angle between tibial segments, sudden decrease in the force at the load-displacement curve, fracture anywhere in the specimens, and screw loosening.

Loading Protocol

The bone-plate constructs were sequentially tested in two ways: (1) loading of up to 1,800 N and (2) cyclical loading. First, the constructs were loaded to 350 N (half of the bodyweight of a 71.4 kg person) at a speed of 10 mm/min. Afterward, the specimens that survived from the initial loading test were loaded to 1800 N at a rate of 10 mm/min for assessment of construct stiffness.

Construct stiffness was calculated by dividing each load step by the average displacement of the loading actuator. Moreover, the other 30 prepared bones were used for cyclical loading to avoid metal fatigue. For dynamic tests, a 350-N force was applied at a frequency of 5 Hz for 10,000 cycles. This is the proximate step number performed over a 4–6 week period and the expected interval for postoperative non-weight bearing. Furthermore, construct durability was defined as the number of loading cycles that the specimens tolerated before the failure. Data collection and analysis were done by two mechanical engineers (EB, CK) who were not included in the study and were blinded to the treatment groups.

Statistical Analysis

A sample size of 60 (ten subjects per group) was calculated using G*Power 3.0 (Heinrich-Heine Universität Düsseldorf, Düsseldorf, Germany) program to provide ≥80% power and 5% alpha error to compare the peak load and stiffness of three fixation method for open tibial fracture. The results were statistically evaluated using the Statistical Program for the Social Sciences (SPSS) 15.0 software. To analyze the data, the Kruskal–Wallis test, and Bonferroni-corrected Mann–Whitney tests were used within the SPSS 15.0 program. One-way analysis of variance with post hoc testing was performed to determine between-group significant difference. P<0.05 were considered statistically significant.

RESULTS

In the MIPO group, eight out of ten samples failed during incremental loading up to 1800 N. All eight specimens failed through bending of the plate, and >5° of angulation occurred (Fig. 3a). All samples in the SP group survived after incremental loading up to 1800 N.

In the UEF group, two specimens failed by valgus collapse although the carbon fiber rod was intact (Fig. 3b).]. Table 1 shows the biomechanical parameters of the three groups.

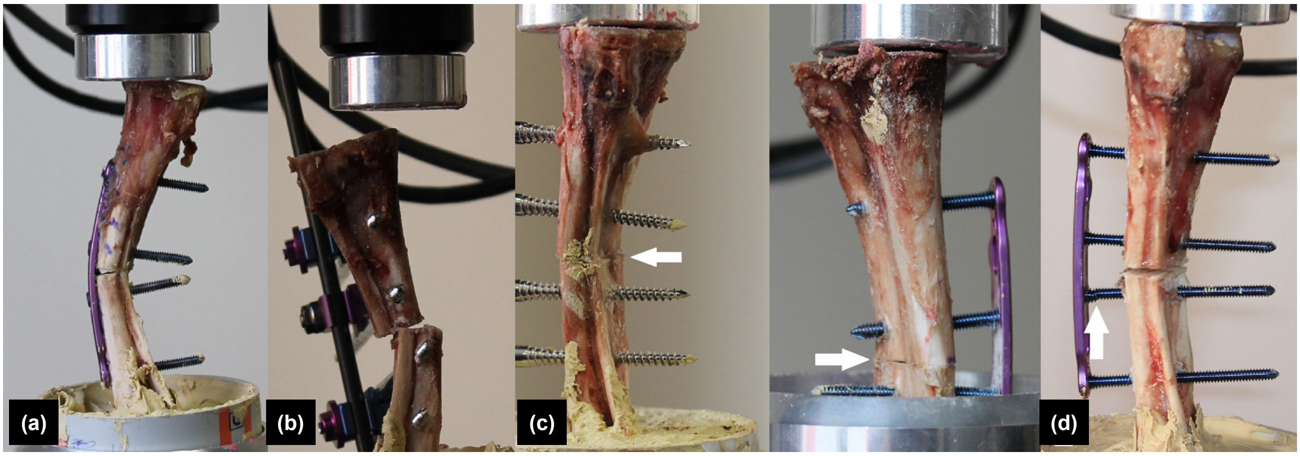

Figure 3. (a) In the Mipo group, plastic deformity developed in the plates due to asymmetric closure of the osteotomy gap in loading tests up to 1800 N. (**b)** Failed sample due to distal fixation loss in Unilateral External fixator (UEF) group in loading tests up to 1800 N. **(c)** In axial loading tests up to 1800 N, no deformity was observed in the implants due to symmetrical closure of the osteotomy line in all specimens of the supercutaneous plating (SP) group, except for 2 specimens in the UEF group. **(d)** A sample that completed the cyclic loading test despite the breakage of the 3rd screw in the SP group.

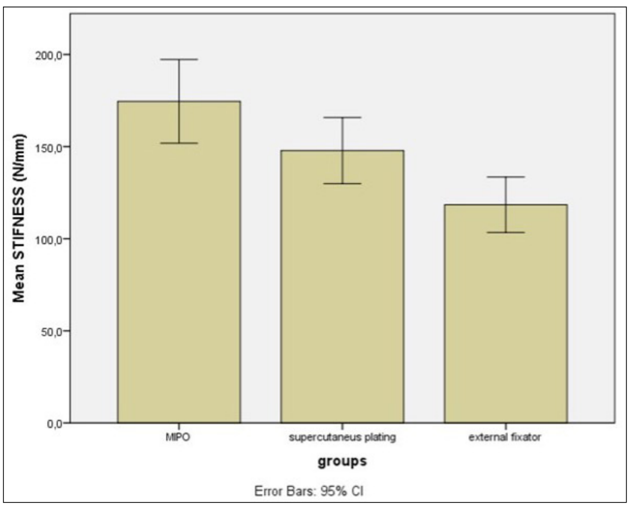

Figure 4. Graphic illustration of mean stiffness values (N/mm) of 3 groups.

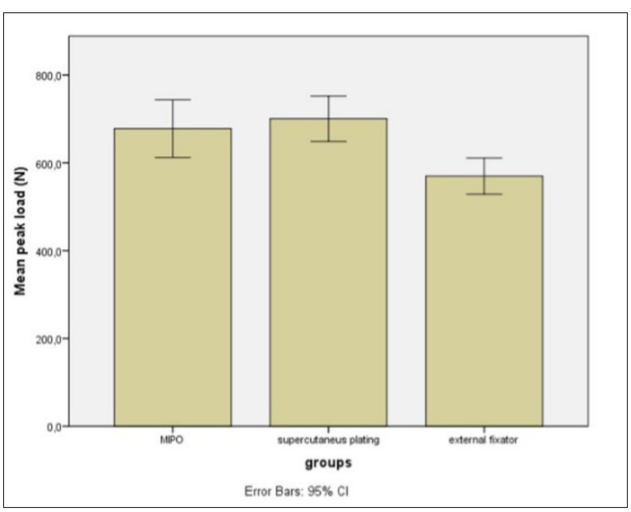

Figure 5. Graphic illustration of mean peak load values (N/mm) of 3 groups.

Construct stiffness was highest in the MIPO group when compared with the SP and UEF groups (Fig. 4). While the stiffness of the MIPO group was similar to the SP group, it was statistically higher than the UEF group (P=0.08 and P=0.002, respectively). The SP group was significantly stiffer than the UEF group (P=0.0021). Moreover, the MIPO group also demonstrated significantly greater displacement when compared with the UEF group (P=0.008). The mean peak load was highest in the SP group, and lowest in UEF group. The peak load in SP group was similar to the MIPO group, it was statistically higher than the UEF group (P=0.743 and P=0.002, respectively) (Fig. 5).

During axial loading of up to 1,800 N, the fracture gap closure in the MIPO constructs was asymmetric, and the fracture gap was noted to not completely close toward the near cortex. Thus, the bending of MIPO constructs occurred. The fracture gap closure of SP and UEF constructs was nearly parallel (Fig. 3c). No deformation of these constructs after gap closure was observed.

During dynamic loading, all samples in the MIPO group survived 10,000 loading cycles. In the SP group, six of ten samples failed because of screw breakage between the plate and the bone due to repetitive screw bending during cyclical loading. In two of the four surviving constructs, 10,000 cycles are completed even though the third screw broke during the 2300 cyclical loadings (Fig. 3d). More failure was observed in the SP group compared to the other groups under cyclic loading because bending stress occurred at a distance between the plate-screw interface and the screw-to-bone contact. The increased strain and bending moment in this region caused bending fatigue, leading to fractures at the unprotected part of the screw between the bone and the plate. In addition, two of the ten UEF constructs failed due to loss of fixation distal to the fracture line, while the proximal fixa-

Table 1. Comparison of the biomechanical measurements between groups

	Groups			p-value†	Intergroup Comparisons‡		
	MIPO Mean±SD (min-max)	SP Mean±SD (min-max)	UEF Mean±SD (min-max)		MIPO versus SP	MIPO versus UEF	SP versus UEF
Stiffness (N/mm)	174.56±18.31 (148.8-191)	147.83±14.44 (126-161.4)	118.44±12.11 (102-130.2)	0.006	0.08	0.002	0.021
Peak Load (N)	678±52.98 (610-745)	700.6±41.76 (655-765)	570±33.16 (520-610)	0.010	0.743	0.016	0.002

†Kruskal-Wallis test; ‡Games-Howell test. N/mm: Newton/millimeters; SD: Standard deviation; MIPO: Minimal invasive plate osteosynthesis; SP: Supercutaneus plating; UEF: Unilateral external fixator.

tion remained completely intact.

DISCUSSION

The biomechanical results of this study showed that there was no significant difference between MIPO and SP techniques in terms of axial stiffness and peak load. In addition, both techniques have been shown to contribute more to the axial stability of structures than UEF. Accordingly, these findings support our hypotheses that SP and MIPO exhibit similar biomechanical properties under axial load and that UEF causes less rigidity than these two techniques.

The management of severe open tibial fractures is one of the most troublesome issues challenging trauma surgeons for a long time because healing periods are longer with high rates of complications compared to the typically encountered for other common fractures.[17] Several typical complications exist, including wound complications, infection, or malunion.[18,19] Treatment protocols for open tibial fractures include MIPO, UEF, and SP. In this study, the authors aimed to biomechanically compare these three structures under axial load in a diaphyseal tibia fracture (AO classification 42-A3) model.

While rigid fixation produces good clinical results, studies have shown that more rigid fixation may adversely affect fracture healing. If the implant covers the load and the healing bone is overprotected, the union is adversely affected by causing defects in the remodeling process and resorption at the fracture line.[20,21] Many studies have reported that poor healing of fractures stabilized by periarticular locking plates is due to the high stability caused by locking plates. In their retrospective cohort studies, Lujan et al.[22] found that patients with supracondylar femur fractures who were treated with periarticular locking plates had asymmetric callus formation and nonunion at a rate of 18.6%. Many methods have been proposed to reduce this stability in cases of concern that locking plating may be too stable to affect fracture healing adversely.[16,23]

In our study, the stability of the MIPO group was found to be superior to the other groups, supporting the literature. More minor changes in the osteotomy gap were observed when similar axial loads were applied in the MIPO group compared to the other groups. Interestingly, the mean peak load, which indicates the deformation point of the structure in the load-displacement graph before the osteotomy gap was closed, was found to be higher in the SP group than in the MIPO group, although it was not statistically significant. We attributed this to the symmetric closure of the osteotomy gaps of the structures in the SP group during axial loading. Thus, the applied force is evenly distributed in the bone-plate system, and therefore, deformation occurs in the load-displacement graph under higher loads. Besides, SP may allow for flexible fixation and parallel movement between fracture fragments, enhancing fracture healing. In light of this information, the relationship between flexible fixation, which accelerates the formation of callus formation and the healing process, and unstable fixation, which causes nonunion and implant failure, should be considered.[15]

Shi et al.'s[13] biomechanical study examined the plate-type external fixator in treating tibial fractures from a biomechanical perspective. They showed that the plate-type external fixator was biomechanically stronger and more rigid than the conventional one. The results of this study were like the present study; however, Shi et al.[13] have designed and used the plate-type external fixator, a new prototype of the external tibial fixation device, in their study. In addition, they have mentioned that it is necessary to produce new fixators in different sizes for people of different heights, which will increase the cost. We used standard LCP plates, which are widely used today. Furthermore, we compared percutaneous plating with the standard MIPO technique in our study. These are superiorities of our study to the study of Shi et al.[13] In another study, musing the metaphyseal locked plate as an external fixator in biomechanical evaluation, internal locked plate fixation, external locked plate fixation, and conventional external fixation were compared, and five fourth-generation composite tibias were used in each group.[24] However, power analysis needed to be specified for the number of samples in the study. In this study, unlike our study, the fracture line was formed in the proximal metaphyseal region. Moreover, Ma et al.[24] have not specified the distance of the plate to the bone in the external locking plate fixation group in their study. However, in a recent clinical study,[25] the authors have emphasized that the distance between the plate to be used as an external fixator and the bone is essential, and they have recommended keeping this distance as close as possible. In conclusion, our study is the study that best imitates percutaneous plating in clinical practice in terms of sample size, similarity to surgical technique, and accessibility to the plate used in surgery.

In conventional compression plates, the stability of the structure is based on friction at the plate-bone interface, whereas in locking plating, there is a fixed connection of the locking screws and the load carrier (plate). Because this connection is similar to the external fixator, the locking plates are seen as internal-external fixators. However, in a biomechanical study investigating the effect of the distance between the bone and the implant on the construct stability, it has shown that the distance between the bone and the implant is inversely proportional to the construct stability.[15] Increasing the distance between the plate and the bone will reduce the stability of the structure, causing fixation failure and ultimately increasing nonunions. On the other hand, there are also publications reporting a high rate of nonunion and suppression of callus formation due to the high stiffness of locking plating.[22] According to the biomechanical data from our study, despite its low profile, external fixation with the LC-DCP plate appears strong enough to withstand the acting axial forces. Ma et al.[24] have reported a high rate of union when using a locking plate as a temporary and definitive external fixator; similarly, some surgeons have reported similar experiences too.[6,11,12] We believe it may be advisable to use external locked plating fixation to reduce the stiffness of the plating constructs and promote secondary fracture healing. To reduce the risk of failure of this new external locked plating technique, clinical studies are needed to provide recommendations for its practical use.

Finally, some significant limitations of this study need to be considered. First, none of the structures used in our study had soft tissue, so the effects of muscle and ligamentous structures could not be examined biomechanically. Second, this study is performed on sheep bones. Ideally, old human cadavers should be used as osteoporotic specimens, as hardness and strength are highly affected by bone quality. However, in our study, we used fresh sheep bones, whose bone mineral composition was reported to be not significantly different from humans, except at early stages of physiological growth.[26,27] Third, a torsional test setup was not performed because of technical insufficiency. However, in clinical practice, patients are only allowed partial weight bearing under axial load in the early postoperative period. Our study mimics the early postoperative rehabilitation period. Finally, since we could not predict the risk of infection, the data from our study cannot confirm the significance of SP in clinical practice due to the increased infection rates after the fixation of open tibial metaphyseal fractures. For this purpose, prospective randomized clinical studies with many sample groups should be planned. Despite these limitations, this research expands orthopedic surgeons' knowledge of SP for fracture fixation in treating open tibial distal metaphyseal fractures.

CONCLUSION

This study concluded that SP use instead of standard locked plating for open tibial fractures enables more flexible fixation without requiring additional procedures. The axial stiffness and peak load of SP constructs were found to be similar to MIPO constructs. However, SP constructs were biomechanically stronger than UEF constructs. SP constructs were not found to be as durable as standard locked plating, according to the findings of this study. However, the difference was not statistically significant. Therefore, the SP technique may be an attractive alternative treatment method for open tibial fractures.

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: C.Y., O.G.M.; Design: C.Y., D.A.; Supervision: C.Y., D.A.; Materials: C.Y., D.A.; Data collection and/or processing: C.Y., S.O., D.C.M.; Analysis and/or interpretation: C.Y., S.O., D.C.M.; Literature search: C.Y., H.C.; Writing: C.Y., H.C.; Critical review: C.Y., O.G.M., D.A.

Conflict of Interest: None declared.

Financial Disclosure: The author declared that this study has received no financial support.

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DENEYSEL ÇALIŞMA - *ÖZ*

Distal tibia metafiz kırıklarının cerrahi tedavisinde üç farklı cerrahi yöntemin biyomekanik olarak karşılaştırılması. Bir hayvan modeli çalışması

Dr. Cem Yıldırım,[1] Dr. Osman Görkem Muratoğlu,[2] Dr. Samed Ordu,[3] Dr. Hasan Ceylan,[1] Dr. Duran Can Muslu,[4] Dr. Dogan Atlıhan[5]

[1]Çam ve Sakura Şehir Hastanesi, Ortopedi ve Travmatoloji Kliniği, İstanbul, Türkiye
[2]İstinye Üniversitesi, Ortopedi ve Travmatoloji Anabilim Dalı, İstanbul, Türkiye
[3]Eskişehir Yunus Emre Devlet Hastanesi, Ortopedi ve Travmatoloji Kliniği, Eskişehir, Türkiye
[4]Klinikum Dahme Spreewald Achenbach Krankenhaus, Ortopedi ve Travmatoloji Kliniği, Brandenburg, Almanya
[5]Haseki Eğitim ve Araştırma Hastanesi, Ortopedi Ve Travmatoloji Kliniği, İstanbul, Türkiye

AMAÇ: Bu çalışmanın amacı, açık tibia kırıklarında uygulanabilen minimal invaziv plak osteosentezi (MIPO), subkutan plaklama (SP) ve unilateral eksternal fiksatörlerin (UEF) mekanik özelliklerinin araştırılmasıdır.
GEREÇ VE YÖNTEM: 60 adet taze koyun tibia örneğinde kemiklerin ortasından osteotomi yapılarak stabil olmayan diyafiz tibia kırığı oluşturuldu. Örnekler 3 gruba ayrıldı. SP grubu için numunelere standart bir MIPO tekniği ile kemikten 15 mm implante edilen kırık fiksasyonu uygulandı. UEF grubuna unilateral uniplanar eksternal fiksatörler uygulandı. İlk olarak, otuz numune (her grup için 10 numune) tibial eksen boyunca dikey olarak 1800 N'ye yüklendi. İkinci olarak, metal yorgunluğunu önlemek için döngüsel yükleme için önceden hazırlanmış diğer 30 kemik kullanıldı. Dinamik testler için 10.000 döngü için 350 N'lik bir kuvvet uygulandı.
BULGULAR: Üç fiksasyon aletinin sıkıştırma testinde (1800 N'ye kadar dikey yükleme); yapı sertliği SP ve UEF grupları ile karşılaştırıldığında MIPO grubunda en yüksekti. MIPO grubunun sertliği SP grubuna benzer iken UEF grubuna göre istatistiksel olarak daha yüksekti (sırasıyla p=0.08 ve p=0.002). SP grubu, UEF grubuna göre anlamlı olarak daha sertti (p=0.0021). Ortalama pik yük SP grubunda en yüksek, UEF grubunda en düşüktü. SP grubunda tepe yük MIPO grubuna benzer, UEF grubundan istatistiksel olarak yüksekti (sırasıyla p=0.743 ve p=0.002).
SONUÇ: Bu in vitro hayvan modeli çalışmasından elde edilen biyomekanik özelliklere dayanarak, subkütan plaklama tekniği biyomekanik olarak UEF'den daha güçlüydü ve eksenel yükleme açısından MIPO ile benzer biyomekanik özelliklere sahipti.

Anahtar sözcükler: Açık tibia kırığı; eksternal fiksatör; kilitli kompresyon plaklama; minimal invaziv plak osteosentezi; süperkütanöz plaklama.

Ulus Travma Acil Cerrahi Derg 2023;29(10):1091-1097 DOI: 10.14744/tjtes.2023.66304