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Original article

A novel adjustable dynamic plate for treatment of long bone fractures: An in vitro biomechanical study

Ahmet Karakasli [a], Nihat Acar [b,*], Ahmet Karaarslan [c], Fatih Ertem [d], Hasan Havitcioglu [a]

[a] Dokuz Eylul University, Faculty of Medicine, Department of Orthopaedics and Traumatology, 35340 Balcova, Izmir, Turkey
[b] Gazikent Medical Center, Department of Orthopaedics and Traumatology, 35340 Gazi Emir, Izmir, Turkey
[c] Şifa University Faculty of Medicine, Orthopedics and Traumotology Department, Sanayi St. No: 7, 35040 Bornova, Izmir, Turkey
[d] Dokuz Eylul University, Health Science Institute, Department of Biomechanics, 35340 Balcova, Izmir, Turkey

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ABSTRACT

Introduction: Locking compression plate (LCP) system was designed to provide bone stability and to enhance bone healing. However, implant failure, nonunion and instability are still frequently encountered complications. The purpose of this study was to assess and compare the biomechanical characteristics of a novel adjustable dynamic plate (ADP) with the commonly used LCP.
Materials and methods: Twelve 4th generation composite artificial femoral bones were used. Transverse fracture was created in all bones, 6 femurs were fixated using the novel ADP, whereas the other 6 femurs were fixated using the traditional LCP. All samples had undergone a non-destructive repetitive different forces (axial compression, bending and torsion), to evaluate the biomechanical differences between the two plating systems.
Results: Under axial load the mean stiffness value was 439.0 N/mm for the ADP and 158.9 N/mm for the LCP, ADP showed a statistically significant stiffness value than LCP with a P value of 0.004. There was no significant difference in flexion/extension bending strain values between ADP and LCP. However LCP provided significantly stiffer fixation in medial and lateral bending tests than ADP ($P = 0.037$) and ($P = 0.016$) respectively. But no significant difference was detected between the two plating system in the applied torsional stress.
Conclusion: These results do not show any significant biomechanical difference in the applied torsional and bending stresses between LCP and ADP. However the remarkably increased persistent compression effect of the ADP created a considerable stress on fracture edges which may accelerate bone healing.

1. Introduction

Absolute stability is essential for primary bone healing. Increased compression across a fracture site improves stability, allows pre-load to exceed dynamic load, prevents microinstability and resorption at the fracture site and, thus, enhances primary bone healing.[1,2] Locking compression plate (LCP) system was designed to improve the biology of bone repair and the mechanics of fracture stabilization.[3] Implant failures and nonunions are still frequently encountered in trauma practice.[3,4] Seventy-five percent of malunion and nonunion cases are caused mainly by inadequate initial fracture fixation.[5,6] The ideal treatment method should provide adequate stability, minimal gap and micromotion to permit early mobilization, preserve or optimize fracture biology, avoid serious complications, and achieve these goals in a cost-effective manner.[7–9]

The purpose of this study is to assess a newly designed adjustable dynamic plate (ADP) which provides an adjustable continuous compression on fracture edges and to compare it with the traditional commonly used LCP. The ability of the innovative ADP in minimizing fracture gap and its contribution on stability and micromotion were mechanically evaluated.

The hypothesis of this study was, due to the adjustability feature of the ADP, the fracture gap will be reduced and micromotion will be minimized when compared to the traditional LCP.

2. Materials and methods

4GC adult-sized left femurs (artificial) purchased from the same supplier (Model #3403, Sawbones, Vashon, WA, USA) were used. The femur cortical bones ($n = 12$) had a density of 1.64 g/cm^3 and

* Corresponding author.
E-mail address: eyad55_55@yahoo.com (N. Acar).

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cancellous bone density of 0.27 g/cm^3. The used artificial femurs have an intramedullary canal diameter of 13 mm, shaft diameter 27 mm and length 455 mm, were used to identically simulate transverse femoral fracture. Artificial femurs were used to ensure the same material properties and geometry and to enable standardization of the materials and structures for biomechanical comparative studies. The diaphyseal portion of femurs had cortices only. At the metaphyseal region, there were cortices and polyurethane foam simulating cancellous bone. A transverse osteotomy was performed on each bone with a saw to simulate a transverse femur fracture. In order to achieve a true transverse osteotomy, the roughened and irregular edges of the osteotomy margins were smoothened by a grinder to minimize friction between fracture edges.

The fractures were reduced with a minimal osteotomy gap to simulate a transverse fracture pattern and instrumented by a single orthopedic surgeon under direct vision according to standard AO techniques. Two groups, each group composed of six femurs, were created. Two different fixation techniques were used to facilitate biomechanical comparison. In the first group the ADP plates were placed to the lateral side of femurs, whereas in the other group LCP plates were applied laterally to femoral bone models. In each group two bicortical, self-tapping and self-cutting locking head screws on either side of the fracture were used, the lengths of the screws for each specimen were chosen based on geometric bone measurements. The torque applied to each screw was standardized to 4 N m using a torque-controlling screw driver. Two kinds of plates were compared in a randomized pair-match design.

The newly designed plate; ADP (TipSan A. S. medical devices company, Izmir-Turkey) can generate a compression force up to 300 N. This compression is adjustable; can be adjusted by the surgeon intraoperatively. The ADP (Fig. 1), is composed of three main parts. The proximal part, consisted of a cylindrical hollow inside which there is a tube for the passage of the adjustable compression screw and wings with multiple holes on both sides for bicortical fixation. The distal part is consisted of an anatomical plate with natural holes for bicortical screws fixation. The third part (adjustable part) of the ADP is composed of a metal sheath hollow in the form of a tube containing a spring and an adjustable screw. Rotating the adjustable screw outward resulting in expansion of the spring and this is in term results in pulling the distal part of the plate toward the proximal part causing a continuous compression force of the distal part of the plate equivalent with the recoil strength of the spring. The dynamic adjustable screw system moves proximally and distally. The compression spring is adjusted using the proximal screw before the plate is placed to the lateral side of the femoral shaft. The Length of the plate increases by adjusting the proximal screw. Following the placement of the plate to the lateral side of femoral shaft, the screws are placed and a persistent compression is achieved on fracture ends by rotating the proximal adjustment screw outward. Mainly the ADP plate is composed of three parts, the proximal and distal parts can be modulated on each other's by a threaded locked system as demonstrated in Fig. 1. The size and the number of holes can be determined by the surgeon preoperatively. The newly developed adjustable dynamic plate is present in variable lengths, the distal part is 9 mm in width and 3.4 mm in thickness. Whereas the proximal part is 12 mm in width, 7.2 mm thick from the central part and 3 mm thick from the periphery.

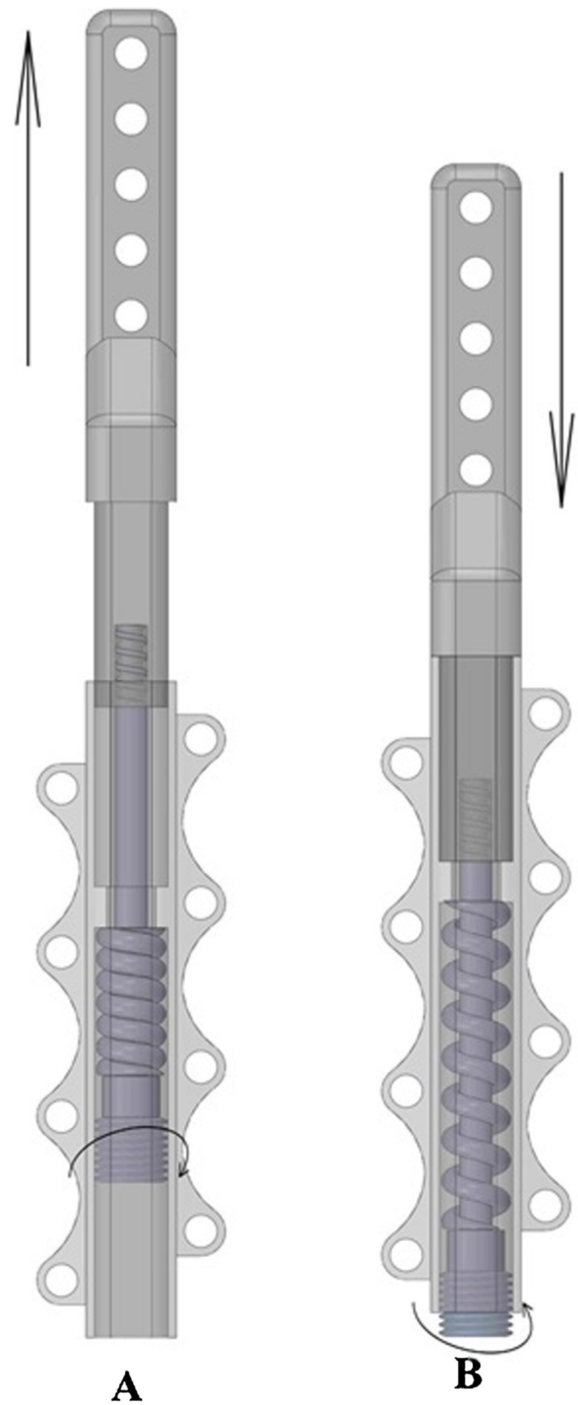

Fig. 1. Schematic drawings of plate mode of action. The view of established system before application (A). The view of plating system with its active persistent compression effect (B).

2.1. Mechanical tests

A uniaxial test setup was designed to allow the applied load direction to match with the mechanical axis of femur which passes through the center of the femoral head and the mid-intercondylar distance. The femoral bone models were fixed to the load cell of the testing machine. The vertical load was applied to the femoral head with hemicylindrical cup which allows a medial translation of the femoral head during loading (Fig. 2). Tests were undertaken to assess fatigue characteristics; axial compression load, bending load and torsional load. These tests were undertaken using AG-IS 10 kN, Shimadzu, Japan.

At first, a loading of 100 N was given with a loading rate of 10 mm/min; this was repeated several times until the load–deformation relationship was stabilized. Then the femur-plate constructs were loaded up to 750 N.[10,11] In all tests the change in

Fig. 2. Potted specimen prepared for mechanical tests. Figure showing the specimen placed in the load cell of the testing machine. Strain-gauges are placed on the sawbone femur's fracture contact points.

axial, bending and torsional angles were recorded both in loaded and unloaded states (Fig. 3).

The statistical analysis of this study was performed using the SPSS 15.0 software. Mann–Whitney *U* test was used to compare between results. We defined the level of significant difference as $P < 0.05$.

2.2. Axial compression testing

The plate-bone construct was tested under axial loading with the femoral head under compressive forces and the condyles were seated physiologically. Prior to the test, a CCD (Non-contact Video Extensometer DVE-101/201, Shimadzu, Japan) was used. In the axial test, a preload of 5 N and a maximal load of 750 N were applied, then reduced to 0 N while simultaneously the vertical displacement and the strain were recorded. Displacement was detected by the rotary linear variable differential transformer in the testing machine, and displacement was detected by an extensormeter. The test velocity was 0.1 mm/s. Each side was loaded for three cycles.

2.3. Four-point bending testing

A four-point bending model was used for the anterior posterior (AP), posterior–anterior (PA) (sagittal plane), medial–lateral (ML), and lateral–medial (LM) (coronal plane) testing. In each bending test, a maximal load of 300 N was applied at 0.1 mm/s. Centering the device with reference to the center of the fracture zone all the time ensured that the bending moment was applied to the same location in each specimen (Fig. 3). The test was repeated three times to ensure reproducibility of the results. Load versus displacement values were recorded to calculate the bending stiffness and flexibility.

2.4. Torsional testing

Torsion test was carried out with servo sync torque machine (SQM132, 245 N m 100 rpm, Turkey). The torsion tests were conducted in the displacement control mode with a constant axial load of 10 N to simulate resting muscle tension and a maximum moment of 8 Nm in both directions; the premoment as (m) and (e) as velocity/s. The testing cycle went from 0 to 8 N m and all the way through 8 N m in the other direction back to 0 N m. Torque versus the degree of angle deformation values were recorded.

3. Results

3.1. Axial compression test results

All mean values of stiffness results are shown in Table 1. Axial compression tests were carried out for the newly designed ADP and the LCP. Under axial load the mean stiffness value was 439.0 N/mm for the ADP and 158.9 N/mm for the LCP (Table 1). In addition, during axial compression, the mean values of displacement were 1.66 mm for the ADP and 4.65 mm for the LCP (Table 2). The ADP mean value of stiffness was higher than that of the LCP (Fig. 4). The difference was statistically significant ($P = 0.004$). The ADP showed a rigid performance than the LCP under axial load.

3.2. Rotation test results

Rotation tests were carried out for ADP and LCP. At first a torsional force of +8 N/m was applied. The mean stiffness values of rotation was found to be 1.16 N m/° for ADP and 0.95 N m/° for LCP (Table 1). For ADP, the mean value of displacement under a torsional force of +8 N/m was measured as 7.23° for ADP and 8.96° for LCP (Table 2). These results demonstrated that ADP has lower rotational rigidity than the LCP. But this was not statistically significant. The results obtained after applying −8 N m rotational mean stiffness values were 1.24 N m/° for ADP and 0.82 N m/° for LCP (Fig. 5). In addition, the mean value of displacement under a torsional force of −8 N/m was measured as 6.63° for ADP and 10.1° for LCP. The rotational rigidity for the ADP was lower than that of LCP and this was statistically significant ($P = 0.013$).

3.3. Bending test results

Antero-posterior bending tests were carried out. The mean values of stiffness were measured as 500.0 N/mm, for ADP and 625.0 N/mm, for the LCP. The mean stiffness values of the posterior–anterior bending tests were measured as 681.81 N/mm for ADP and 666.66 N/mm for LCP. In the lateral bending tests the values of mean stiffness were 434.0 N/mm for ADP and 256.41 N/mm for LCP. In the medial bending tests the values of

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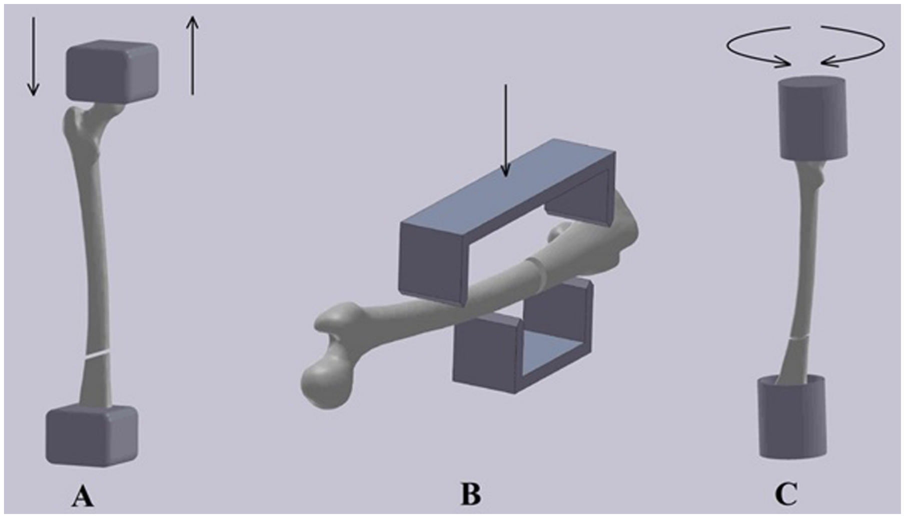

Fig. 3. Schematic drawings of the tests. (A) Testing of potted bone-implant axial compression and distraction (A), Testing of A–P, P–A, L–M, M–L bending (B) and testing of rotation (C). The arrow demonstrates the loading direction.

mean stiffness were maximum 600.0 N/mm for ADP and 357.14 N/mm for LCP (Fig. 6). All bending test results of ADP and LCP are shown in Table 1. In addition, in the displacement measurement there was no significant difference in the A–P and P–A directions bending between ADP and LCP. However, LCP stiffness values were found to be higher in bending tests of medial and lateral directions and this is statistically significant ($P = 0.037$) and ($P = 0.016$) respectively (Table 2).

The main compression values of ADP and LCP were measured by using strain gauges. Under axial loading the values of mean compression was 2218 μ-strain for ADP and 1915 μ-strain for LCP (Fig. 7). In addition, the value of ADP mean strain was 330 μ-strain without axial compression loading. But these values decreased to 0 μ-strain for LCP without axial compression loading. The mean compression value of ADP is higher than that of LCP. However there was no statistically significance.

Table 1
Mean value of stiffness.

	Locking compression plate		Adjustable dynamic plate	
	Stiffness	±SD	Stiffness	±SD
Axial compression (N/mm)	158.9	41.8	439	93.6
Distraction (N/mm)	49.4	7.21	100.5	30.38
Rotation (+8) (N m/°)	0.95	0.2	1.16	0.2
Rotation (−8) (N m/°)	0.82	0.18	1.24	0.2
Bending AP (N/mm)	638	139.2	218	54.5
Bending PA (N/mm)	682.1	161.1	269.7	179.8
Bending lateral (N/mm)	321.3	144	250.1	198.7
Bending medial (N/mm)	375	87.5	194.3	250.2
Strain max. (μ-strain)	1915		2218	
Strain min. (μ-strain)	0		330	

Table 2
Mean value of displacement.

	Locking compression plate	Adjustable dynamic plate
Axial compression (mm)	4.65	1.66
Distraction (mm)	2.06	1.08
Rotation (+8) (°)	8.96	7.23
Rotation (−8) (°)	10.1	6.63
Bending AP (mm)	0.48	0.6
Bending PA (mm)	0.45	0.44
Bending lateral (mm)	1.17	0.69
Bending medial (mm)	0.84	0.5

4. Discussion

Plate fixation techniques are used in various bone fractures to provide stabilization and bone healing. Compression and stability are necessary for bone healing. With the original AO/ASIF technique, screws or tension devices were used to achieve a good compression. Later on, the specially designed screw hole of the dynamic compression plate (DCP) allowed axial compression of the fracture zone.[9,10] Recently, locking plates, have been developed to obtain a more stable fixation. However, by applying the locking screws, an excessive pressure does not develop between the plate and the bone. These plates were developed to have a more stable fixation in osteoporotic bone fractures.[3,11,12]

One of the main disadvantages of the traditional plating systems is the inability to maintain their compression effect after fracture site bone resorption, which is one of the leading causes of non-unions and delayed unions in fracture fixation.[13,14]

The main aim of this novel plate design is to apply a continuous persistent compression effect on the fracture edges with a sufficient mechanical stability even after fracture site bone resorption.

In this study, higher stiffness values were obtained in axial compression loading with ADP construct compared to the LCP construct and this was statistically significant ($P = 0.004$). Under axial loading, the mean values of displacement were 1.66 mm for the ADP and 4.65 mm for the LCP. The ADP construct can provide continuously persistent compression at the fracture ends. Therefore, the gap between the fracture ends will be minimal. Due to this continuous persistent compression, the displacement is reduced with ADP constructs. The newly developed ADP ensures a suboptimal stability at fracture ends by providing continuously persistent compression. This novelty may induce osteoconduction at fracture ends.

Uhl et al.,[14] showed that the construct gap had some permanent gap narrowing during cyclic loading at physiologic levels for LC-DCP and LCP constructs; hence, cyclic gap strains were higher for LCP constructs. Gap narrowing resulted from the screw heads sliding in the LC-DCP and DCP plate holes because the screws were inserted in neutral position. Permanent gap closure did not occur in LCP constructs because the screw heads were locked into the plate. There are two important factors in bone healing; osteoconduction

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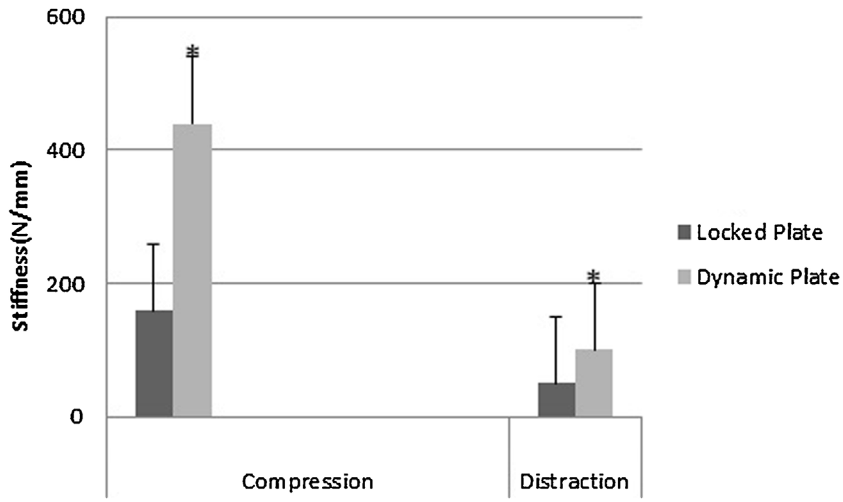

Fig. 4. The mean stiffness of ADP and LCP in axial compression-tension, and different types of nailing techniques.

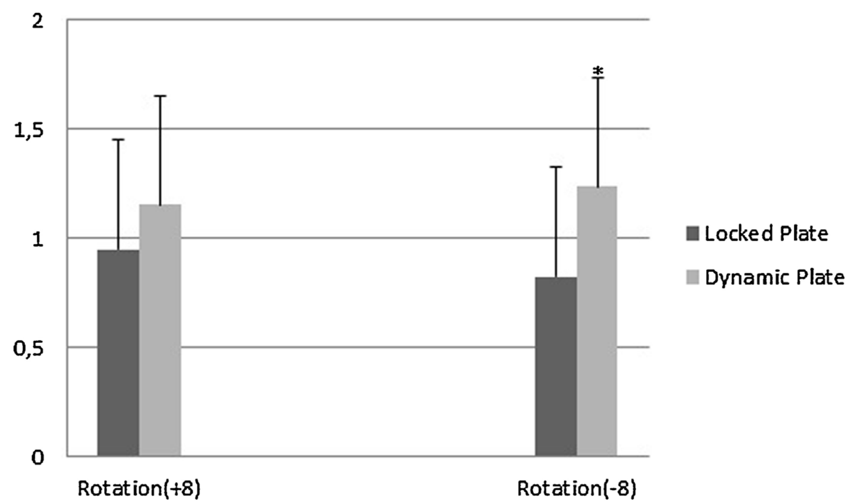

Fig. 5. Torsional stiffness during rotational loading in clockwise and counter-clockwise of femur-plate constructs.

and osteoinduction. Osteoconduction consists of physical and mechanical fixation. The fixation, contact and continuity of the fractured bone ends are important for bone healing. Compression by internal fixation devices at bone ends is desirable. A small gap at fracture site may delay union or may cause nonunion. Compressive tension at fracture site are necessary for successful bone healing.[15,16] Hardware failure is a complication that has been reported to occur in 7% of plate fixations, although clinical experience with non-contact fixation has shown that loosening of the implant by bone resorption in the area of the screw-bone

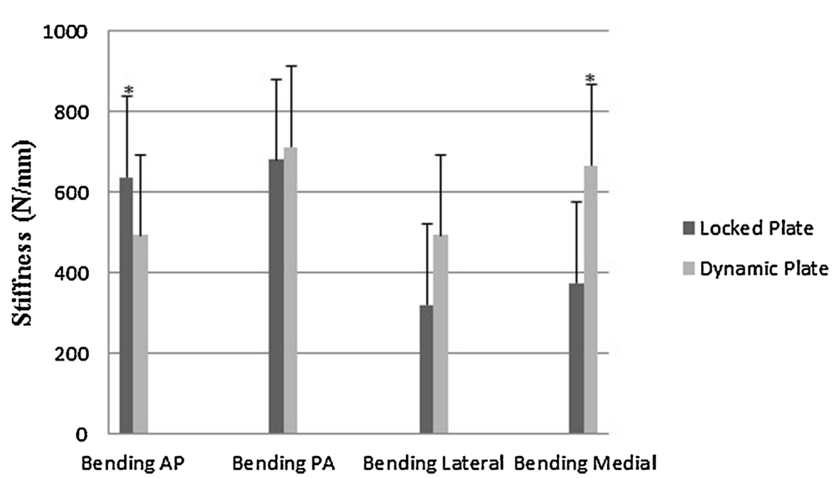

Fig. 6. Bending stiffness in different position of femur-plate constructs. Bending stiffness measurements for all femural models showed no statistically significant differences between measured data.

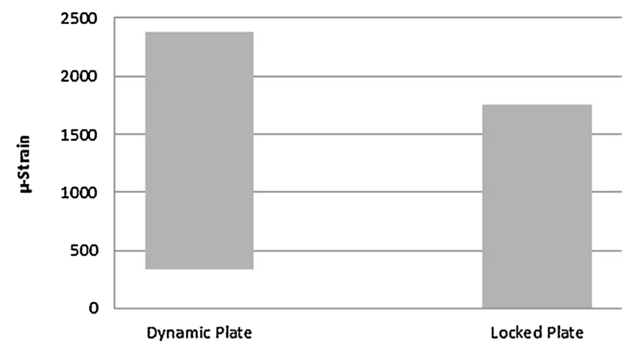

Fig. 7. ADP and LCP strain during loading between two groups of femur-nail constructs. The space under the strain of ADP bar represents the strain of the ADP without applied force.

interface is the most frequent complication.[3] The newly developed adjustable dynamic plate minimizes micro motion at fracture site. Stiffness at fracture ends was found to be higher with ADP compared to that of LCP under axial loads. The stiffness with ADP construct was 439.0 N/mm and 158.9 N/mm with LCP. ADP, by producing a continuous compressive effect at fracture ends, increases stiffness and load sharing between the bone and the implant and may prevent implant failure. The reported axial stiffness of the locked plating construct was (2.9 kN/mm) compared with that of the broad 4.5-mm conventional plating constructs stiffness (2.6–3.2 kN/mm) and locked plating constructs stiffness (2.1–2.7 kN/mm).[17,18]

Under +8 N/m torsional loading, the mean stiffness value for ADP was 1.16 N m/° and 0.95 N m/° for LCP. In terms of plate torsional rigidity, ADP and LCP mean values were close to each other and the difference was not significant statistically. Under −8 N/m torsional loading, the mean stiffness value for ADP construct was 1.24 N m/° and 0.83 N m/° for LCP construct. Torsional rigidity of ADP under −8 N/m torsional loading was higher and the difference was found to be statistically significant (P = 0.013).

Stoffel et al. reported that locked constructs had a 26% lower torsional rigidity than non-locked constructs while the axial stiffness did not significantly differ between the two constructs.[3] Doornink et al. found that in torsion, the hybrid construct was significantly stronger than the locked construct. In the locked construct, locking screws failed by screw breakage between the plate and bone because the elevated plate was free to toggle around the single plane of screw fixation.[20,21] In four point bending loads ADP showed a higher stiffness value than LCP in medial–lateral direction. However, in other directions the two plates showed similar values of stiffness. The non-locked construct tolerated a higher bending stiffness compared to any of the locking constructs. This reduced bending strength of locked constructs relative to the conventional construct. This reduction is likely caused by stress concentration at the end screw.[18] Fitzpatrick et al. reported a 16% higher bending strength for conventional nonlocked constructs compared to locked constructs.[19] The strain at fractured bone fragment ends was measured. Under compressive loading, 330 to 2218 μ-strain was recorded at the synthetic bone fracture site with ADP. This value is compatible with literature. In LCP the strain was between 0 and 1915 μ-strain. Maximum strain values were similar. Without load the strain of the LCP construct was zero. Whereas, without load the strain of the ADP construct was measured to be 330 μ-strain. It is well known that a zero strain at the fracture edges might cause a delayed in union or non-union sometimes in LCP fixation. While the patient is in lying or sitting position, there is no strain at the fracture ends with LCP. However the remarkably increased persistent compression effect of the ADP creates a considerable stress on fracture edges which may accelerate bone healing. It is reported in literature that mechanical strain should be in the range of 100–2000 μ-strain for bone healing.[15,16,22]

Theoretically, during clinical application, the proximal part of the ADP contains wings with natural holes which are designed to be countered before application to match the anatomical shape of the bone segment to be applied on, and to allow oblique bicortical screws application and this in term may result in a minimal soft tissue exposure when compared to LCP application. On the other hand reaching the proximal end of the proximal part may also require further proximal soft tissue exposure to allow the manipulation of the adjustable screw.

Before conducting this study, the main aim was to provide a new plate design that can be able to apply a persistent fracture edge compression despite of the fracture edge bone resorption phenomenon which almost takes place in all fracture patterns.

However, this study like other studies, has some limitations. The novel plate design can be modified and compared in future studies with other traditional plates like DCP and LC-DCP designs. Besides being an in vitro biomechanical study, additional clinical studies should be submitted in the future to address its clinical feasibility and usefulness in fracture healing.

5. Conclusion

In vitro, ADP is found to be biomechanically slightly more advantageous than LCP in favor of axial compression. The continuous persistent compression provided by ADP, besides other important factors like micromotion and adequate bone edges contact, may clinically provide a persistent fracture edge compression effect despite of the fracture site resorption, which in term may enhance bone healing capacity, however further clinical studies should be submitted to study the effect of such a plate design on bone healing process.

Conflicts of interest

The authors have none to declare.

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