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Mechanical evaluation of fourth-generation composite femur hybrid locking plate constructs

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Abstract Locking compression plates are routinely used for open reduction and internal fixation of fractures. Such plates allow for locking or non-locking screw placement in each hole. A combined use of both types of screw application for stabilization of a fracture is commonly applied and referred to as hybrid internal fixation. Locking screws improve the stability of the fixation construct but at the expense of significant additional cost. This study experimentally analyzes various combinations of locking and non-locking screws under simultaneous axial and torsional loading to determine the optimal hybrid locking plate—screw construct in a fourth generation composite femur. Clinically it is necessary to ensure adequate fixation stability in a worse case fracture-bone quality scenario. A locking screw near the fracture gap increased the axial and torsional strength of the locked plate system. Greater removal torque remained in non-locked screws adjacent to locked screws compared to an all non-locking screws control group.

1 Introduction:

Osteoporosis affects an estimated 24 million Americans. Women over 45 years of age are of particular risk [1]. Osteoporosis decreases the thickness of cortical bone and increases the porosity of cancellous bone. This results in poorer bone quality and an increased risk for fracture. Also, osteoporotic bone has been shown to have decreased strength for holding fixation devices (screws). Recent studies recommend the use of locking compression plates (LCP) for osteoporotic fractures [2, 3]. The LCP creates a toggle-free, fixed-angle construct which improves fixation strength in osteoporotic bone. A minimally invasive plate osteosynthesis (MIPO) technique allows an LCP to be inserted with limited soft tissue disruption, thereby minimizing additional damage during surgery to the blood supply which is so critical for healing [4]. LCPs have shown promise in reducing malunion rates in metaphyseal and diaphyseal fractures [5]. One specific LCP contains a combination-hole system which can house either locking or conventional non-locking screws. Other designs allow for placement of either locking or non-locking screws within the same circular hole. Frequently, LCPs are applied as a hybrid plate technique, which combines both locking and non-locking screws in different holes of a single plate. This allows for advantages of both types of screw application to be incorporated within the same construct. Additionally, our clinical experience shows that locking screws are approximately 5–10 times the cost of non-locking screws.

Several studies have been published examining LCP stability under axial and torsional loading [6–8]. Data on the biomechanical and clinical performance of LCPs are encouraging, though cases of malunions, nonunions and fixation failures have been reported [6–8]. This paper explores the relationship between the mechanical properties of a hybrid LCP system and its effects on fracture fixation. Specifically, this analysis was designed to determine the minimum number and optimal location for locking screw placement in the osteoporotic diaphysis of an unstable (comminuted) synthetic supracondylar femur fracture model.

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2 Background of locking compression plates

Internal fixation plate was first developed by Lane in 1895, but it failed because of corrosion [9]. Later in 1967, Schenk and Willeneggar developed the dynamic compression plate (DCP) modeled after Bagby and Jane's plate design [9]. Though the DCP plate proved better than previous designs, improvements were still needed [10]. DCPs do not fit the bone anatomically, which sometimes results in fracture displacement. Screw toggling can occur resulting in a secondary loss of fracture reduction under axial loading [10]. Additionally, the broad undersurface of DCPs compress the periosteum under the plate, thereby interfering with blood supply to the bone. The PC-Fix, developed by Tepic in 1995, was a narrow plate designed to limit contact on the bone through small points on its undersurface. Through this contact mechanism, periosteal damage was felt to be limited, thus fostering early bone healing [11]. The Less Invasive Stabilization System (LISS) plate was subsequently developed for application to the distal femur [12–14]. It was the first plate in the modern era to allow threaded screw heads to lock into the plate via matching threads within the screw hole.

In late 1990's, a group of surgeons from Davos, Switzerland developed the locking compression plate (LCP) which combined many of the concepts from the DC, PC-Fix and LISS plates [15, 16]. The LCP has a minimal contact undersurface like PC-Fix plates and threaded locking screws like LISS plates. To add versatility, a combination-hole system was designed in the LCP. It can house either locking or non-locking screws depending upon the fracture type, bone quality, and surgeon preference.

2.1 Mechanics of the locking compression plate

Fixation using conventional plates and screws depends on the frictional force generated between the plate and bone. Conventional non-locking screws function by compressing the plate to the bone, creating friction at the interface of plate and bone. Locking screws do not compress the plate to the bone, and therefore, are subject to more bending loads than conventional screws [17]. The LCP applies two different anchorage technologies in one implant via minimally invasive surgery procedure. This provides flexibility in osteosynthesis. The conical screw threads provide the highest axial and angular stability to the construct and therefore, changes in the plate design do not influence the rigidity and stability [17]. Compressive load can be applied to a non-comminuted fracture through the plate using non-locking screws. If significant (absolute) stability is achieved, primary bone healing takes place with minimal callus formation [18]. If the plate is applied with less than rigid but adequate stability, a more flexible fixation construct (relative stability) is created which promotes callus formation. As shown in Fig. 1, a force (F1) is generated by tightening a screw. A subsequent compressive force (F2) is generated by the plate against the bone. From these two loads, a frictional force (F3) develops between the plate and bone leading to stable plate fixation. This friction force (F3) is equal to the sum of the torques on each of the screws. Fixation remains stable until axial force (F4) exceeds frictional force (F3). The axial load (F4) is proportional to the sum of torques in each screw. When the bone and plate are securely fastened, the F4 becomes equal to F3. As axial loads become repetitive and/or increase, screw insertion torque force decreases, causing screw to toggle that results in deterioration of fixation stability [19]. When a bone/plate construct is loaded, the bending forces applied to the screws generate shear force. The magnitude of toggle depends upon the contact between bone and plate, and the quality of the bone. Locking screws act as a fixed angle device within the bone when load is applied. The fixed angle is more protective against screw toggle [17].

Once locking screws are engaged within the plate, no further tightening is possible. This locks the implant to the bone at its applied position and prevents further efforts towards fracture reduction [20]. Locking screws are generally inserted perpendicular to the axis of the plate which allows transmission and distribution of axial loads over the full length of the plate. This eliminates toggling of the screws and improves stability. Additionally, locked screws work together collectively on each side of the fracture such that all must fail simultaneously for the construct to loosen. In comparison, once a single non-locking screw fails on one side of a fracture, the adjacent screw is subject to increased forces and a cascading failure pattern typically occurs. Recently, polyaxial locking has become available and allows for screws to lock at an angle. The main goal for fracture fixation is to achieve adequate stability and early mobilization as seen in Fig. 2.

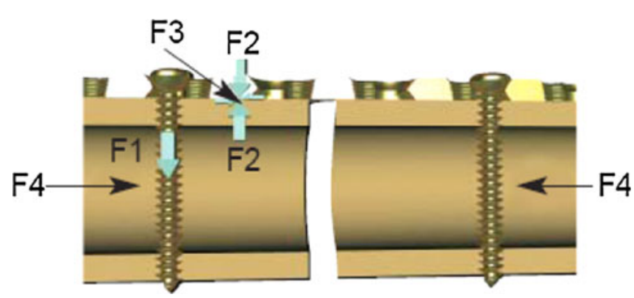

Fig. 1 Mechanics of the locking compression plate technology and forces generated as a result [12] where, F1 = Force to tighten the screw into a bone, F2 = Reaction force developed because of force F1, F3 = Friction force between the plate and bone due to F2, and F4 = Axial load.

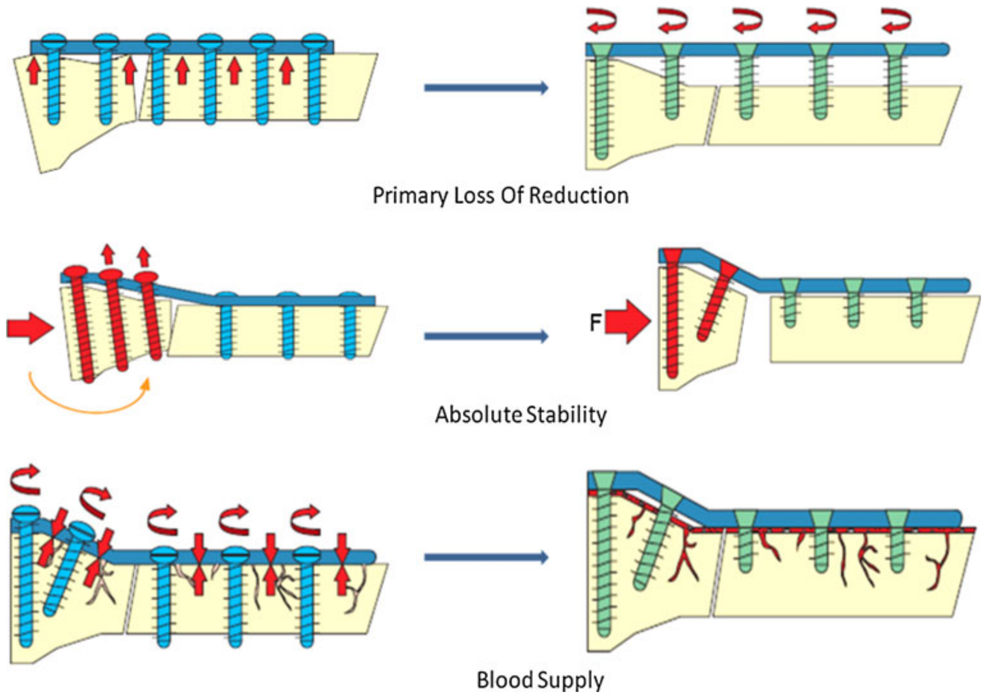

Fig. 2 Locking plates satisfy basic fracture stability principles. (1) Primary loss of reduction. (2) Absolute stability. (3) Preservation of blood supply under the periosteum [12]

3 Experimental methods and materials

Femoral shaft models, as shown in Fig. 3, contain epoxy glass fiber as shallow cylinders filled with polyethylene were purchased for this study (Model 3403, Pacific Research Laboratories, Vashon, USA). These synthetic femurs are used to simulate osteoporotic bone and have been seen in recent literature [21]. The distal part of the femur consisted of the condylar (articular) segment as shown in Fig. 3. It was made of similar material as the shaft but was not osteoporotic. Fracture comminution was created through a gap osteotomy of 2 cm in the metaphyseal region. Twenty 10-hole pre-contoured lateral distal femoral locking plate implants were supplied by Synthes (West Chester, PA) and were 4.5 × 10 mm in dimension. This enabled 4 groups of constructs that were tested.

Testing protocols for this study were developed based on other similar studies [7, 12]. Twenty synthetic femoral bone constructs were assembled to simulate fracture comminution. Osteoporotic diaphyseal segments were utilized in all groups. The specimens were equally divided into 4 groups according to screw type and placement. All screws were tightened to 4 Nm of insertion torque. As a result, there were two types of torques, (1) insertion torque, used to insert the screws on the cylinders, and (2) the remaining torque at the end of 50,000 cycles measured by torque meter, purchased for this study (Sharp, Mahwah, NJ). Axial loads of 50–700 N and rotational displacement of ±5° were applied. Axial load cycles were conducted in load control. However, rotational displacement was controlled

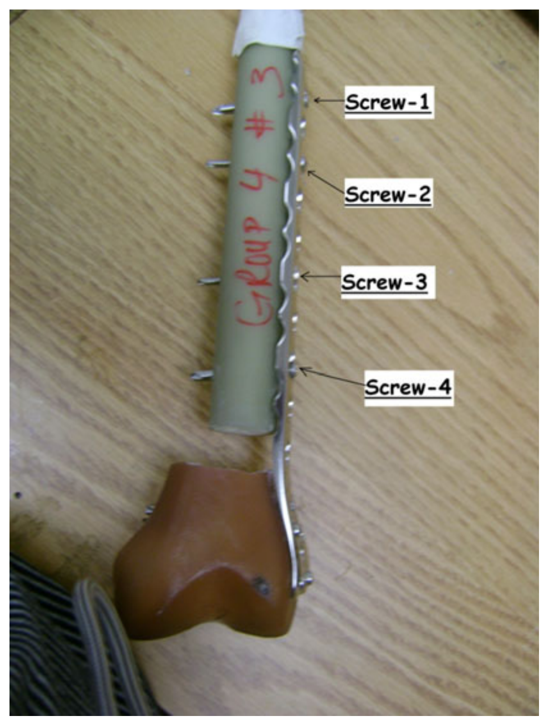

Fig. 3 For the femoral diaphysis (*shaft*), the most proximal (*top*) screw is designated as screw 1, and the most distal (*bottom*) screws as screw 4. The five locking screws in the condylar segment remained constant

for the torsion. Test frequency was kept at 2 Hz. The remaining torque, axial and torsional stiffness, and displacement in the osteotomy gap were measured for

Table 1 Twenty femoral constructs were divided in 4 groups according to their screw location and type

Group	# of specimens	Screw 1	Screw 2	Screw 3	Screw 4
Group 1	5	Non-locking	Non-locking	Non-locking	Non-locking
Group 2	5	Non-locking	Non-locking	Non-locking	Locking
Group 3	5	Locking	Non-locking	Non-locking	Non-locking
Group 4	5	Locking	Non-locking	Non-locking	Locking

two locking screws constructs and one locking screw constructs.

Experimental testing was conducted at the biomechanics laboratory of Miami Valley Hospital in Dayton, OH. The distal flared portion of the plate was fixed to the articular segment with five 5.0 mm cannulated locking screws. A combination of 4 mm locking screws and 4.5 mm cortex (non-locking) screws were arranged to plate to the diaphyseal portion.

The experimental groups and the screw positions (locking vs. non-locking) in the plate are listed in Table 1. After the tests the torque meter was used to determine the torque at which the screws loosened. From the insertion torque this value was subtracted to determine the remaining torque in each of the screws. From the test data, stiffness and displacement were calculated and plotted for all the groups.

The specimen was secured in an EnduraTEC machine (Minnetonka, MN) SmartTest Servo Pneumatic test frame. No preconditioning was required as the test samples were synthetic and did not contain any viscoelastic layers. Axial load was applied to the femoral shaft proximally while torsional load was applied through the femoral condyles at the distal end. The axial load application to the shaft was sinusoidal. The lower limit was maintained at 50 N of force while the upper limit was 700 N (to simulate weight bearing). Torsional load application was also sinusoidal applying ±5° cycles. Rotation of the condylar segment represented internal and external rotation forces on the femur during gait. Automatic testing shutdown limits were set to avoid significant displacement. Data was acquired at every 250 cycles by the Wintest data acquisition system. Scan points were examined at every 5000 cycles. Average stiffness and deformation were calculated using such data and plotted from selected scan points, presented else-where. Average loosening torque, average stiffness and average deformation were calculated for the 20 constructs. The data were analyzed statistically with the Kruskal–Wallis test, a one-way ANOVA test and the Tukey–Kramer HSD.

4 Results

Figure 4 shows the differences between the remaining torques of all four groups. After testing, the average

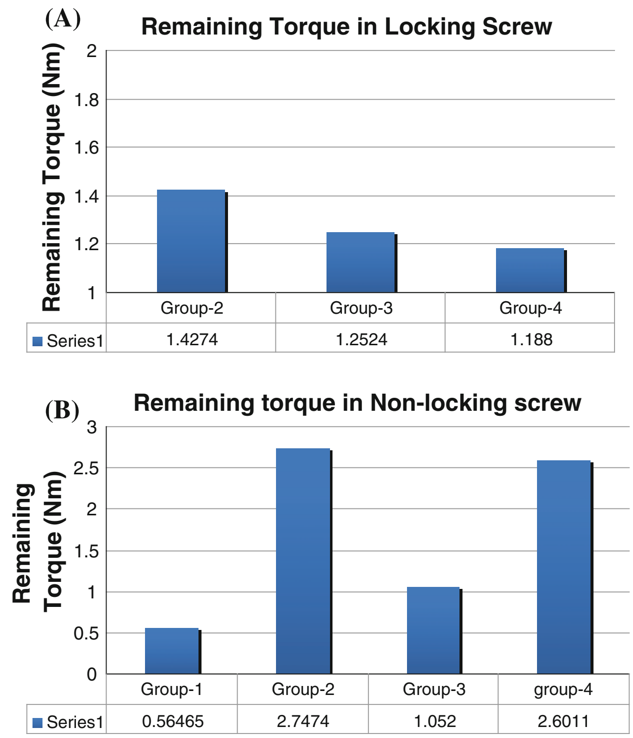

Fig. 4 Average remaining torque in Groups 2, 3 and 4 (**a**), and Average remaining torque in the non-locking screws in all 4 groups (**b**)

remaining torque in group 1 (4 non-locking screws) was 0.56 Nm whereas in group 2 and group 3 (1 locked screw and 3 non-locked screws), it was 2.72 and 1.48 Nm, respectively. Group 4 (2 locked and 2 non-locked screws) demonstrated 2.67 Nm of remaining torque. Test results were tabulated in Table 2. Comparable results were obtained with one-way ANOVA. The Tukey–Kramer HSD results suggest similarities between groups 2 and 4 but significant differences between groups 3 and 4. The screw torque mechanics of non-locking and locking screws differ, so comparison of loosening torque for both types of screw application were also done separately. Figure 4a shows the average remaining torque of the locking screws in groups 2, 3 and 4. Group 4 locked screws demonstrated the least amount of torque, 2.81 Nm remaining, whereas the group 2 locked screws had the 2.57 Nm remaining. Maximal deterioration in screw torque was seen in group 1 with 0.56 Nm remaining. The reduction of screw torque for

Table 2 Summary of statistical analysis of the experimental results

Group	Mean loosening torque (Nm)	Significance groups[a]	Axial stiffness[b]	Torsional stiffness[b]	Deformation[b]
			$\chi^2 = 1.72$ Prob $> \chi^2 = 0.6314$	$\chi^2 = 1.33$ Prob $> \chi^2 = 0.72$	$\chi^2 = 3.22$ Prob $> \chi^2 = 0.3577$
Group-1	0.5646	C	65	42	38
Group-2	2.7037	A	56	51	52
Group-3	1.4759	B	34	42	49
Group-4	2.3967	A	55	75	71

[a] Based on Tukey–Kramer Test Results of Mean Loosening Torque

[b] Kruskal–Willis Test Method; Mean Rank Score (Out of 100)

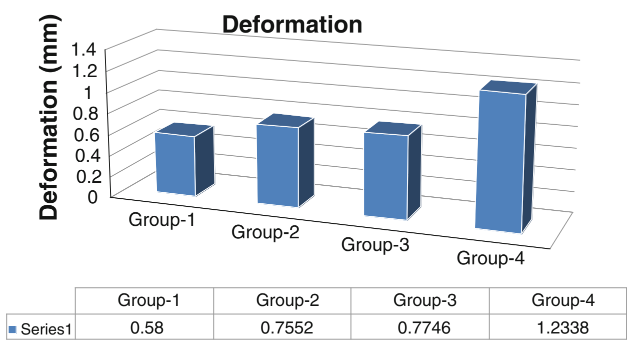

Fig. 5 Average deformation for all metallic constructs by group

non-locking screws was in group 2 was 2.75 Nm remaining. Non-locked screws in group 3 lost an average of 2.95 Nm of torque (1.05 Nm remaining). This was statistically significant compared to group 2. The group 4 non-locked screws lost 1.65 Nm of torque (2.35 Nm remaining), which was not significantly different from group 2. The presence of a single locking screw adjacent to the osteotomy (group 2) offered a protective effect compared to a single locked screw placed furthest from the osteotomy (group 3).

Total deformation was measured by subtracting the displacement value measured at the end of the cyclic testing from the initial actuator position. Figure 5 shows the mean deformation for each group. Group 4 had the greatest mean displacement at 1.23 mm. The non-locked screw construct (group 1) showed the lowest at 0.58 mm. Average axial and torsional stiffness for the constructs was calculated with applied load and displacement. Axial stiffness was greatest in group 4 at 1231.3 N/mm and lowest in group 1 at 745.3 N/mm, respectively (Fig. 6a). Torsional stiffness was highest in group 4 at 219.5 N/mm and lowest in group 1 at 154.7 N/mm (Fig. 6b), respectively. Femoral axial stiffness was found directly proportional to torsional stiffness based on this experimental program. The mean stiffness was compared between groups statistically through the Kruskal–Wallis method. The average stiffness among all groups remained near the standard mean. Group 1 constructs demonstrated the highest mean axial stiffness and group 3 the lowest. Group 1 and Group 3 constructs demonstrated the lowest mean torsional stiffness where as Group 4 demonstrated the highest mean torsional stiffness.

Under rotational forces, the mean loosening torque was compared for different screw positions from the osteotomy gap (Fig. 7a). Screws adjacent to the osteotomy gap retained the lowest insertion torque at 1.46 Nm. Screws farthest from the osteotomy retained the greatest amount of original insertion torque at 2.16 Nm. The screws second closest to the osteotomy gap retained more original insertion torque than did the screws third closest. The average torque of locking screws farthest from and closest to the osteotomy

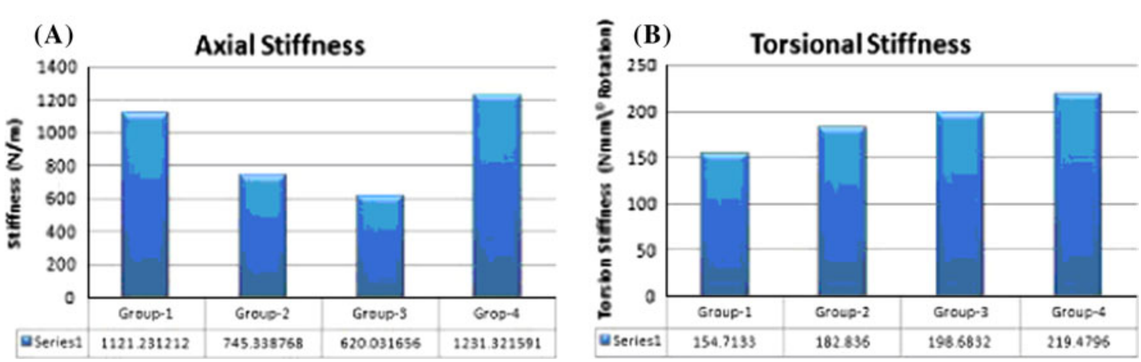

Fig. 6 **a** Axial Stiffness for each group, **b** Torsional Stiffness calculated from the load and displacement data for each group

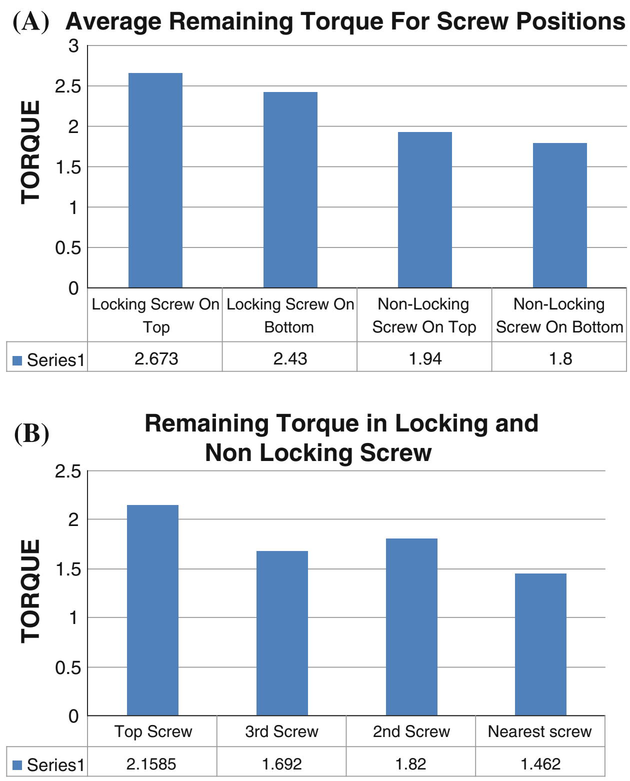

Fig. 7 Average remaining torque (Nm) for individual screw positions (**a**) and average remaining torque for locking and non-locking screws (**b**)

had been calculated separately to analyze loosening under axial and torsional loading conditions. A similar analysis was performed for the non-locking screws. Figure 7b shows the comparison of all calculated average torque values. The locking screws farthest from the gap had the lowest loosening torque compared to locking screws closest to the osteotomy gap. Similarly, the non-locking screws furthest from the gap demonstrated lower loosening torque compared to the non-locking screws nearest to the fracture gap. Additionally, locking screws in general had less deterioration of original torque compared to non-locking screws. Finally, the locking screws closest to the fracture gap showed better retention of original torque than the closest non-locking screws. During the entire test program 3 failed from group 1, 1 from group 2 and 2 from group 3. The remaining constructs successfully completed 50,000 cycles.

5 Discussion

A number of studies provide evidence that locking plates with locking screws are stable under axial and torsional loading [3, 7, 9, 22–30]. This information is of significant importance to clinicians for preoperative planning. Both traditional non-locking and locking screws are available for use. The use of locked screws generally improves the mechanical properties of the fixation construct (especially with osteoporotic bone or fracture communion) but come at a greater financial expense. Little information exists to guide a surgeon as to the minimum number and location of locked screws when applying a fixation construct. This study provides such information for the osteoporotic diaphysis of a supracondylar femoral fracture model.

Stoffel and associates recommended that screws be placed near a fracture gap when the gap exceeded 2 mm [24]. They also suggested that the working length (distance between the first screws on each side of fracture gap) be kept to a minimum as the fracture gap increased. In the case of torsional loading, 3–4 screws are recommended on each side of the fracture [24]. The plate-screw density, the number of screws inserted divided by the number of holes available in the plate contributes to fracture stability. Gautier and associates [25] suggested that plate-screw density be maintained at a minimum of 0.4–0.5. The use of bicortical screws over unicortical screws also increases stability under torsional loading of bone. Taking this information into consideration, our femoral constructs were designed such that they maintained a plate-screw density of 0.5 in the diaphyseal portion and that each fragment would contain a minimum of 4 screws on each side of the osteotomy gap. In this study the osteotomy (simulated comminuted fracture) gap was consistent between groups and specimens as was the material properties of the bone by using the synthetic models. This eliminated bone quality and fracture inequality as variables in the metallic construct performance between groups.

Results from this program demonstrated that the maximum deterioration in screw torque from the original 4 Nm occurred in group 1 (84% reduction) with all non locking screws (Table 1; Fig. 3). The least deterioration of original screw torque was in group 2 (29.7% reduction), with one locking screw at the distal end. Group 2 and 4 (with two locking screws at the proximal and distal ends, Table 1; Fig. 3) screws had similar average remaining torque values after testing. In group 3, with one non-locking screw nearest to the osteotomy gap loosened the most and affected the overall performance of the construct significantly. The proximal locking screw in group 3 maintained its original torque for the most part while the other non-locking screws deteriorated substantially during torsional loading. Group 1, with all non-locking screws, demonstrated poor stability as only 16% of its average screw torque remained after 50,000 cycles of the testing. Based on the performance of the group 2 constructs, it appears that a single locking screw adjacent to the osteotomy (simulated fracture communion) is sufficient to protect construct stability under axial and torsional loading.

This study demonstrates the importance of insertion torque with other mechanical parameters, namely stiffness, rigidity and displacement. Torsional rigidity (GJ) is proportional to insertion torque of a screw. As insertion torque decreases, so does the construct's rigidity and also the holding power of the screw [4, 25]. Group 4 showed the highest rigidity without any screw failure. Three femurs in group 1 and two femurs in group 3 failed. These results support that with increase in angle of twist the remaining torque decreases. The most proximal screw faces the lowest angle of twist while the screw closest to the gap (fracture) faces the most. Thus, one could argue that the screw nearest the fracture gap should be inserted with higher insertion torque. A potential downside is that inserting non-locking screws with higher insertion torque in osteoporotic bone will likely strip the threads. Stripping torque is the maximum torque that a screw can be inserted with that a bone can withstand [30]. Once a screw surpasses stripping torque, it begins to toggle and can be easily pulled out. Non-locking screws have a stripping torque of approximately 4.5 Nm in osteoporotic bone [4].

This behavior was experimentally supported by the biomechanical testing results from our study. Figure 4 showed that the screw torque in groups 2 and 4 (Table 1; Fig. 3) remained the highest after testing, presumably secondary to the "protective" effect of the locking screws. In comparison, group 1 screws (all non-locking) lost most of their original torque after testing (Fig. 4b). Interestingly, for locking screws, the greatest loosening was in group 2. Locking screws nearest the osteotomy gap loosened 8% more than those furthest from the osteotomy gap. Similar results were reported by others [7, 23, 27]. Yet the locking screw near the osteotomy gap seemed to "protect" the adjacent proximal non-locking screws from loosening. The non-locking screws near the osteotomy gap loosened 52% more than non-locking screws furthest away from the osteotomy gap. Therefore, locking screws near the osteotomy gap maintained more of their original insertion torque than non-locking screws in the same location. Figure 5 shows the average displacement accrued per group at the end of the testing. It is quite clear that two locking screw constructs, one at each end, provide the largest displacement. Accordingly, the axial stiffness in group 4 was higher than other groups as well as the torsional stiffness. Figure 7 demonstrates similar findings. Non-locking screws nearest the osteotomy gap loosened 15% more than locking screws in the same location. Therefore, locking screws provide better angular stability over non-locking screw and can resist more torsional load, also found by others [22–30]. Based on these findings, placing a locked screw nearest to the osteotomy (fracture) gap is recommended. As insertion torque decreases, the construct's rigidity also decreases resulting in reduced screw holding power [25–27]. Screws begin to toggle and affect the stability of the LCP under both axial and torsional loading. Both hybrid and fully locked constructs exceeded the average stiffness of non-locked constructs by 23 and 53%, respectively. The group of construct with two locking screws (group 4) demonstrated the highest torsional stiffness among all groups. Axial stiffness was also highest in group 4 (Fig. 6a, b). Thus, stiffness was co-related with screw torque.

6 Conclusion

Biomechanical evaluation of LCPs with both locking and non-locking screws (hybrid plating) constructs secured with locking screws provide higher axial and torsional rigidity. During conduction of the experimental testing, several behaviors of the LCP were recognized: (1) There was more remaining torque in locking screws near the osteotomy (fracture) gap compared to that of non-locking screws, (2) The presence of a locking screw increased the torsional rigidity of adjacent non-locking screws, (3) In hybrid plated constructs, plates with two locking screws showed higher remaining torque, increased stiffness and deformation compared to constructs with one or no locking screws, (4) One locking screw near an osteotomy (fracture) gap and other at the proximal end provide sufficient axial stiffness and torsional rigidity, (5) The use of more than one locking screw in a construct does affect the biomechanical results, (6) Screws nearest the osteotomy gap demonstrated the greatest loss of original screw insertion torque. (7) Deformation among locking screw constructs was seen more than non-locking screw constructs, and (8) Torsional stiffness was higher in locking screw constructs.

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