

Acta Orthop Traumatol Turc 2015;49(5):552–557 doi: 10.3944/AOTT.2015.14.0439

# **Reliability of threaded locking screws**

## Ahmet Adnan KARAARSLAN<sup>1</sup>, Ahmet KARAKAŞLI<sup>2</sup>, Tolga KARCI<sup>1</sup>, Hakan AYCAN, Erhan SESLİ<sup>1</sup>

<sup>1</sup>Şifa University Faculty of Medicine, Department of Orthopedics and Traumatology, İzmir, Turkey <sup>2</sup>Dokuz Eylül University Faculty of Medicine, Department of Orthopedics and Traumatology, İzmir, Turkey

**Objective:** A frequent problem for interlocking nailing that affects the treatment of the fracture is locking screw deformation. The aim of this study is to determine whether bending resistance is different between high, low, and unthreaded locking screws of interlocking femoral nails.

**Methods:** Ninety screws were used in this experimental study, with 10 screws used in each of 9 groups. Three-point bending tests were performed on 6 groups of 5 mm screws (titanium, stainless steel, crossed with unthreaded, low threaded, and high threaded) and the same 3 thread types of 5.5 mm stainless steel screws in a 30-mm inner diameter steel tube, imitating the level of the lesser trochanter. An axial compressor was used to determine the yield points for permanent deformation in the locking screws by way of 3-point bending tests.

**Results:** The mean yield point value of the 3-point bending tests of 5-mm low threaded stainless steel locking screws was 2071 N, 53% less than that of unthreaded screws (3169 N). The mean yield point value of 5-mm high threaded stainless steel locking screws was 556 N, 272% less than that of low threaded screws (2071 N).

**Conclusion:** To avoid locking screw deformation, high threaded screws must not be used as locking screws. In cases of unreliable patients, 5-mm low threaded screws should not be used in the nailing of comminuted or oblique femur shaft fractures. All 5-mm unthreaded screws and 5.5-mm low threaded stainless steel screws can be used safely in full weight-bearing conditions of unreliable patients.

Keywords: 3-point bending test; femur nail; femur shaft fractures; locking screw.

Intramedullary nailing is a generally accepted treatment method for femoral fractures.<sup>[1,2]</sup> Because locking nails are load-bearing devices, this treatment method is vulnerable to locking screw failure in cases of comminuted fractures. Load transfer between fractured fragments is primarily via locking screws in load-bearing cases. Early failure of locking screws used for comminuted fractures may cause nonunion, malunion, delayed union, shortening, and nail migration.<sup>[3,4]</sup> Fatigue fractures of locking screws are reported with a high frequency of up to 50%. <sup>[5]</sup> This high rate of malunion in unreamed nails may be attributed to its correlation with frequent screw failure (52%) and nail failure (4%).<sup>[6]</sup>

The yield point of a material is described as the force at which a material starts to deform plastically. Prior to the yield point, when the applied force is removed, the material will deform elastically and return to its original form. Once the yield point is exceeded, some part of the deformation will be permanent and nonreversible. Thus, orthopedic implants must not be exposed to forces

> Available online at www.aott.org.tr

doi: 10.3944/AOTT.2015.14.0439

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Correspondence: Ahmet Adnan Karaarslan, MD. Şifa Üniversitesi Tıp Fakültesi, Ortopedi ve Travmatoloji Anabilim Dalı, İzmir, Turkey. Tel: +90 232 – 343 44 45 e-mail: aakaraarslan@yahoo.com Submitted: December 02, 2014 Accepted: April 25, 2015 ©2015 Turkish Association of Orthopaedics and Traumatology



greater than their yield points. It is reported that fatigue life is correlated with the yield point of screws in 3-point bending tests.<sup>[7,8]</sup> Another study reported that while walking there is a 2060 N (2.8 body weight [BW]) peak axial loading on the femur shaft and a 2280 N (3.1BW) peak axial loading descending stairs for a 75-kg person. <sup>[9,10]</sup> In comminuted femur fractures treated with locked nailing, for the proximal locking screws not to deform plastically, the yield points of the screws must be higher than 2060 N for early level walking (2.8 BW).

To our knowledge, no studies have compared 3-point bending yield points of unthreaded, low threaded, and high threaded locking screws with the same screw thread structure. Previous studies have investigated fatigue strength of different types of screws with different thread structures that were manufactured by different factories.<sup>[7,8]</sup> Early screw failure postoperatively is the most frequently seen clinical failure mode. The present study seeks to determine the appropriate screw thread structure (unthreaded, low threaded and high threaded) to avoid causing plastic deformation in 5-mm and 5.5mm locking screws (higher 3-point bending test yield point resistance) on level walking for comminuted and oblique femur diaphysis fractures. Thread height is the structural factor investigated in this study.

The hypothesis of this study was that the presence of threads on proximal locking screws lowers the bending resistance of the screw. This study aimed to determine whether there is a significant difference of locking screw bending resistance between unthreaded, low threaded, and high threaded screws, as well as which thread types (high threaded, low threaded, or unthreaded) of proximal locking screws are able to resist up to 2060 N (2.8 BW) of load in full load-bearing conditions in level walking, with the goal of identifying the most appropriate locking screw geometry and thickness to prevent locking screw failure of an intramedullary nail.

## Materials and methods

In this experimental study design, 3-point bending tests were conducted to evaluate the bending strengths of different types of screws with different thread geometries. Ninety screws were used in this experimental study, with 10 screws used in each of 9 groups. The independent variable of this study was the screw thread geometry, and the dependent variable was the bending strength of the screws, determined by the yield point of a screw on the applied 3-point bending test. Three-point bending tests were performed on 6 types of 5 mm screws (titanium, stainless steel, unthreaded, low threaded, and high threaded) and 3 types of 5.5-mm stainless steel screws with 3 different thread depths (unthreaded, low threaded and high threaded) in a steel tube with an inner diameter of 30 mm and an outer diameter of 45 mm, which imitates the level of the lesser trochanter (Figure 1). According to the manufacturer's catalog, the 5-mm low-profile high-pitch thread (low threaded) screws are used as transverse proximal locking screws. The results of this study indicate that high-profile low-pitch (unthreaded and high threaded) screws may also be used as locking screws.

We used 30 titanium (Hipokrat Medical Devices, Izmir, Turkey) and 60 medical stainless steel of grade 316L (Hipokrat Medical Devices, Izmir, Turkey) proximal locking screws for 9 groups, with 10 screws for each group (Table 1). All screws were 5 mm or 5.5 mm in diameter and 55 mm in length. The high threaded and low threaded screws were only threaded in the middle 27 mm of the shaft. The smooth screws had no thread in their shaft. The low threaded screws had a low-profile high-pitch thread. High threaded screws had a high-profile low-pitch thread (Figure 1). The same 3-point bending experiment assembly used by previous researchers was used in the present study. Chao et al. and Hou et al. described the experimental design for 3-point bending test to evaluate the bending resistance of locking screws



Fig. 1. 5-mm unthreaded, low threaded, and high threaded titanium locking screws. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

Screw groups (n=90)	Thread diameter (mm)	Core diameter (mm)	Stiffness (N/mm) Mean±SD; 95% Cl	Deformation (mm) at yield point, Mean±SD; 95% Cl
5-mm titanium unthreaded	_	5	3348±117 (3264–3432)	0.77±0.03 (0.75–0.80)
5-mm titanium low threaded	5	4.2	2180±128 (2088–2272)	0.71±0.03 (0.69–0.74)
5-mm titanium high threaded	5	3.5	1547±141 (1446–1649)	0.62±0.05 (0.58–0.66)
5-mm stainless steel unthreaded	_	5	3662±170 (3541–3784)	1.01±0.05 (0.97–1.05)
5-mm stainless steel low threaded	5	4.2	2398±249 (2219–2576)	1±0.08 (0.94–1.06)
5-mm stainless steel high threaded	5	3.5	1963±482 (1618–2308)	0.4±0.04 (0.37-0.42)
5.5-mm stainless steel unthreaded	_	5.5	4479±289 (4272–4685)	0.82±0.08 (0.76–0.89)
5.5-mm stainless steel low threaded	5.5	4.7	2727±449 (2405–2049)	1.08±0.14 (0.97–1.18)
5.5-mm stainless steel high threaded	5.5	4	2740±318 (2512–2968)	0.53±0.05 (0.49–0.57)

 Table 1.
 The thread diameter, core diameter, stiffness (N/mm) and deformation (mm) on yield point at 3-point bending test of locking screws (n=90).

in their 30-mm inner diameter, 40-mm outer diameter polyethylene cylindrical tubes. To eliminate the effect of polyethylene deformation, the same experimental design with a stainless steel tube with the same inner diameter was used in the present study.<sup>[7,8]</sup> Previous researchers determined the average inner and outer femoral cortex diameters as 30 mm and 45 mm, respectively, on the level of the lesser trochanter.<sup>[11-14]</sup> A metal cylinder representing the lesser trochanteric level was used, and its inner and outer diameters were designed according to femur measurements reported by previous studies. Two centimeters below their tip were 2 opposite holes with a diameter of 8 mm. A locked nail (Tipsan Medical Devices Company, Izmir, Turkey) 380 mm in length, the proximal part of which was 13 mm in diameter with a 12-mm body diameter, was used for the 3-point bending test. An oblong proximal locking screw hole, 12 mm long and 6 mm wide, was located 60 mm distal from the locked nail proximal edge. The nail was supported by 2 rings proximally and distally to prevent the locking nail from shifting in the metal cylinder (Figure 2). The rings, of which the outer diameter was 2 mm smaller than that



Fig. 2. Photography and schema of the 3-point bending test used. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]



Fig. 3. Post- (left) and pre- (right) bending of 5-mm unthreaded stainless steel locking screws. [Color figure can be viewed in the online issue, which is available at www.aott.org.tr]

of the inner diameter of the cylinder, had a 15-mm inner diameter and a height of 10 mm. After the 2 rings were secured on the nail by 3 screws, their free movement distally and proximally in the cylinder was measured. The screws to be tested were passed through metal cylinder holes, 8 mm in diameter, and the proximal locking screw hole of the nail (Figure 2). The whole load was transferred from the proximal to distal in this experiment assembly through the proximal locking screw. There was no load-sharing situation; instead there was a loadbearing condition that imitated comminuted or oblique femur fractures.

The study was conducted at the University of Dokuz Eylül, Institute of Health Science, and Biomechanics Laboratory. The biomechanical tests were performed using an axial compression testing machine (AG-I 10 kN, Shimadzu Scientific Instruments, Kyoto, Japan). In this study, the loading rate was 1 mm/min in displacement control mode.<sup>[7,8,15]</sup> The loading was made on the head of the nail (Figures 2). The locking screws were preloaded with a load of 100 N. The yield point of the locking screws (unthreaded, low threaded, and high threaded) were studied in this experimental design. The machine output force-displacement graphs were viewed on a computer monitor. During the biomechanical test period, bending on the elastic-plastic deformation border was determined by the force-strain graph. By visualizing the graphs, the yield point was detected after the straight line began to curve, at which point the test was stopped. Following every experiment, all screws and nails were checked macroscopically. All screws were bent in the middle on the compression site and did not have any fractures (Figure 3).

The data of the yield point values from the 3-point bending test were evaluated using the Mann-Whitney test. The level of significant difference was defined as p<0.05.

#### Results

The yield point values of the 5-mm unthreaded titanium and stainless steel screws were found to be 73% and 53%, respectively, more than those of 5 mm low threaded screws (p=0.000) (Table 2, 3). The yield point values of the 5-mm low threaded titanium and stainless steel screws were found to be 62% and 242%, respectively, more than those of 5-mm high threaded screws (p=0.000) (Table 2, 3).

The yield point values of the 5-mm unthreaded titanium and stainless steel screws were found to be 2.8 times and 5.6 times, respectively, more than those of 5-mm high threaded screws (p=0.000) (Table 2, 3). The

Table 2. Yield points (N=Newton) in 3-point bending test comparing low threaded and unthreaded screws (n=90).

Screw groups	Low threaded screws (N) Mean±SD; 95%Cl	Unthreaded screws (N) Mean±SD; 95%Cl	%	p value increase
5-mm titanium	1413±109 (1334–1491)	2453±52 (2415–2490)	73	=0.000
5-mm stainless steel	2071±250 (1892–2250)	3169±248 (2991–3346)	53	=0.000
5.5-mm stainless steel	2699±3123 (2474–2922)	3506±245 (3331–ö3682)	30	=0.000

Table 3. Yield points (N=Newton) at 3-point bending test comparing high threaded and low threaded screws (n=90).

Screw groups	High threaded screws (N) Mean±SD; 95%Cl	Low threaded screws (N) Mean±SD; 95%Cl	%	p value increase
5-mm titanium	874±94 (806–942)	1413±109 (1334–1491)	62	p=0.000
5-mm stainless steel	556±83 (496–616)	2071±250 (1892–2250)	272	p=0.000
5.5-mm stainless steel	1327±136 (1229–1425)	2699±3123 (2474–2922)	103	p=0.000

yield point values of the 5.5-mm unthreaded stainless steel screws were found to be 2.6 times more than those of the 5.5-mm high threaded screws (p=0.000) (Table 2, 3).

Via 3-point bending test, the yield points of the 5-mm low threaded locking screw group and all 3 high threaded screw groups were determined to be approximately or just below 2060 N (2.8 BW) (Table 3). The yield points of all 3 unthreaded screw groups and the 5.5-mm low threaded stainless steel screw group were determined to be above 2060 N (Table 2, 3). As a result of deep groove (notch sensitivity), the bending resistance all high threaded locking screws sharply decreased below 2060 N (Table 3).

The stiffness of unthreaded screws was higher than that of low threaded screws, and the stiffness of low threaded screws was higher than that of high threaded screws in all groups (Table 1).

## Discussion

According to our findings, 5-mm unthreaded titanium and stainless steel screws have 73% and 53% more bending resistance, respectively, than low threaded screws, and 5-mm low threaded titanium and stainless steel screws have 62% and 272% more bending resistance, respectively, than high threaded screws.

The aim of our study was to confirm that there is significant bending resistance difference between unthreaded, low threaded, and high threaded proximal locking screws. To allow early weight-bearing in femur comminuted or oblique fractures of unreliable patients, proximal locking screws must be 5.5-mm low threaded stainless steel or unthreaded 5-mm screws. Five-millimeter low threaded screws must not be used in weight-bearing conditions in unreliable patients, and all high threaded locking screws must not be used as locking screws.

In the test with the polyethylene cylinder, it was not possible to determine the yield point because of the pull-out and holding power of the locking screw. The locking screw 3-point fatigue life tests were performed primarily instead of yield point determination.<sup>[16,17]</sup> In the cylinders most researchers used, the holes were not bigger than the screw diameter. Consequently, the pullout and holding power of the locking screws could not be disregarded. The force of 1-mm deformation, defined as "yielding strength" instead of "true yield point," was measured.<sup>[7,8,15]</sup> It was determined that the holes in the metal cylinder began to apply a holding power effect on the thread of locking screws when the screw bent. We concluded that due to the trapping of bent screws within the holes, the diameter of the smallest metal cylinder screw hole must be 8 mm in order to clearly determine the yield point.

On comminuted oblique femur fractures and highenergy fractures in which bone resorption on the fracture site is frequently seen, locking nails work as full load-bearing implants. For early weight-bearing in these fractures, proximal locking screws must resist body weight-loading. It was reported that there is peak axial load of 2280 N (3.1 BW) on the femur during descending stairs and a peak axial load of 2060 N (2.8 BW) on the femur during level walking for a 75 kg person. <sup>[9,10]</sup> To avoid proximal locking screws deforming plastically in level walking for comminuted femur fractures, the yield points of these locking screws must be greater than 2060 N.

It was reported that thread depth and geometry may affect the fatigue life of locking screws.<sup>[7,8,15]</sup> It was reported that implants (especially titanium) tend to suffer from notch sensitivity in fatigue strength, and the notch reduces the fatigue life of the implant significantly when there are substantial stress concentrators.<sup>[18]</sup> If there is no thread at the contact location between the nail and locking screw-where the load is transmitted to the locking screw and where the locking screw breaks-fatigue life can be increased by avoiding the notch effect of the screw's thread.<sup>[16]</sup> Notch sensitivity is particularly evident at the regions with sharp geometrical change, such as the thread of the locking screw and the nail hole.<sup>[7]</sup> Increasing the diameter of the nail in order to use larger diameter screws may cause nail fatigue fracture by weakening the nail. Nail fracture is a more serious complication than locking screws fractures.<sup>[3,7]</sup>

In an experimental assembly imitating physiological nonvertical or angled forces, it is not possible to determine the exact yield points of a locking screw due to slippage between the locking screw and nail. That we did not use composite femur may appear to be a limitation of our study, but in a test assembly with that material, we found that it is not possible to determine to which locking screw deformation (1 proximal and 2 distal locking screws) the sudden deformation that appears on the force-deformation graph belongs. During the 3-point bending tests, we determined that deformations appear on the screw fixation points of composite femur; thus, it was uncertain if the deformation that appears on the force-deformation graph belonged to these deformations or the screw deformation itself. We discovered that a very small deformation-even 0.1 mm-affects the test significantly and makes it impossible to determine the exact yield point. Materials such as cadaver femur, polyethylene, or aluminum cylinders could be used for this study. However, holes of polyethylene cylinder or cadaver femur can be deformed during 3-point bending tests, making it impossible to clearly understand the difference between screw deformation and the cylindrical material deformation. For this reason, we used stainless steel cylinders, which—along with the holes in them are resistant to deformation. Another limitation of our study was that rotational forces could not be applied to screws by this experimental assembly; a further study may be designed to evaluate the effect of these kinds of nonvertical forces.

The results of this study demonstrate that the 3-point bending resistance of some locking screws groups (all 5-mm low threaded screws and all 5-mm and 5.5-mm high threaded screws) is approximately or just below 2060 N. According to our results, there may be failure in locking screws in level walking for load-bearing nails in unreliable patients. The reduction of the fractures may eventually fail. Deformity, shortness, and nonunion may be result. We determined that all 5-mm or 5.5-mm unthreaded locking screws and 5.5-mm low threaded stainless steel locking screws could resist over 2060 N of axial loading.

To avoid locking screw deformation in clinical application, high threaded screws must not be used as locking screws. Five-millimeter low threaded screws should not be used in the nailing of comminuted or oblique femur shaft fractures of unreliable patients. All unthreaded 5-mm screws and 5.5-mm low threaded stainless screws can be used safely in full weight conditions of unreliable patients.

Conflics of Interest: No conflicts declared.

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