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ÖZGÜN ARAŞTIRMA/ORIGINAL RESEARCH

Comparison of the Resistance of Proximal Locking Screws in Tibia Nailing System – A Biomechanical Study

Tibia Intramedüller Çivileme Sisteminde Proksimal Kilitleme Vidalarının Dirençlerinin Karşılaştırılması: Biyomekanik Çalışma

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Öz

Amaç: Parçalı tibia kırıklarınnın tedavisinde kullanılan intramedüller çivinin kilitleme vidalarında deformasyon sıklıkla görülmektedir. Bu çalışmanın amacı tibia intramedüller çivileme sisteminde beş farklı proksimal kilitleme vidasının bükülme dirençlerini karşılaştırmaktır. **Gereç ve Yöntemler:** 50 adet vida üç farklı çapta(4.5 mm, 5 mm ,5.5 mm) ve 2 farklı yiv şeklinde(yivli ve yivsiz)olacak şekilde beş farklı gruba ayrıldı. 34 mm iç çapa sahip bir paslanmaz çelik tüp tibiayı temsil etmek üzere hazırlandı. Tüm vidalara uygulama sonrası üç nokta bükülme testi yapıldı. **Bulgular:** Yivsiz 4.5 mm ve yivli 5mm vida gruplarının ortalama değerleri yivsiz 5 mm, yivli 5.5 mm ve yivsiz 5.5 mm gruplarına gore anlamlı derecede düşük bulundu(p=0.000) **Sonuç:** Proksimal kilitleme vidasının deformasyonundan kaçınmak için yivsiz 4.5 mm ve yivli 5 mm vidaların kullanılması uygun olmayabilir. Yivsiz 5 mm, yivli 5.5 mm ve yivsiz 5.5 mm vidaların kullanılması daha güvenli olabilir.

Anahtar Kelimeler: Parçalı tibia kırığı, tibia çivisi, kilitleme vidası, bükülme testi

Abstract

Purpose: Locking screw deformation is common in nailing of comminuted tibia fractures. The aim is to compare five different proximal locking screws bending resistance in tibia nailing system. **Methods:** 50 screws were divided into five groups. A stainless steel tube which has a 34 mm internal diameter was prepared representing the proximal tibia. A 3-point bending tests were performed on locking screws for determining their yield points with 3 different dimensions (4.5 mm, 5 mm and 5,5 mm) and with 2 different screw thread (low threaded and unthreaded). **Results:** The mean yield point values of smooth 4.5 mm and threaded 5 mm low locking screws were statistically significant less than that of smooth

5 mm, low threaded 5.5 mm and smooth 5.5 mm(P=0.000). **Conclusions:** To avoid proximal locking screw deformation, using of smooth 4,5 mm and low threaded 5 mm locking screws should be avoided in nailing of comminuted tibia fractures of unreliable persons. Smooth 5 mm, low threaded 5.5 mm and smooth screws 5.5 mm may be used safely.

Keywords: Tibia comminuted fractures, tibia nail, locking screw, bending test

Introduction

Intramedullary interlocking nailing has been considered by many trauma centres to be the gold standard surgical option for comminuted shaft fractures of the tibia [1-4]. In comminuted fractures, during full-weight bearing, the mechanical load is transferred from the proximal locking screw to the distal locking screws through the nail body. The mechanical load applied over locking screws and nail is well known to be supreme around the contact points between them [2, 3]. Single or cyclic loading may cause locking screw failure. It has been demonstrated that, early failure of locking screws may result in non-union, mal union, delayed union, shortening and nail migration in comminuted tibia fractures [2, 3, 5, 6]. Locking screw failure incidence was estimated to range from 6 % to 14 % [1,2,6].

As a material feature, the yield point is defined as the stress at which a material starts to deform plastically. The metallic materials first deform elastically and then returns to its previous shape as soon as the stress is removed before reaching the yield point. When the yield point of a material is exceeded, the failure will be irreversible. That’s why the implants used at orthopaedic practices should have higher bending yield point and should not be exposed to stress higher than their yield points [2,3, 6]. Searching the literature strangely did not reveal any well- structured biomechanical study comparing the yield point of proximal locking screws of tibia nailing system groups at three-point bending tests.

The hypothesis of the study was that 3 point bending resistance of some tibia proximal locking screws was lower than the peak physiological loading on tibia (3.2 BW) and some was higher than the peak physiological loading. A 3-point bending tests were performed on locking screws with 3 different dimensions (4.5 mm, 5 mm and 5,5 mm) and with low threaded and unthreaded screw groups. The aim of this study is to compare five different proximal locking screws bending resistance in tibia nailing system.

Materials and Methods

In this experimental biomechanical study, the 3 -point bending tests were submitted on 5 types of standart locking screws on market with 3 different diameters (4.5 mm, 5 mm and 5,5 mm) and 2 different screw body structure (1/3 (Low) threaded and unthreaded). We used 50 medical stainless steel (316 L) (produced by Hipokrat Medical Devices, İzmir- Turkey) proximal locking screws 55 mm in length divided into five groups (Table 1). Three groups of the screw bodies were unthreaded, whereas two groups of screw had low- profile high pitch threads on their shafts (Figure 1). The core diameter of low threaded screws was 0.5 mm thinner than the unthreaded screws of the same diameter.

A questionnaire was conducted by our research team included orthopaedic trauma surgeons and companies producing orthopaedic implants regarding the most frequently used lengths of tibia proximal locking screws. A mean of 50 mm long screws was the most commonly used screw length as a proximal locking screw in the interlocking nailing of tibia (between 45 mm and 55 mm, mean 50 mm). Then we calculated the inner and outer diameter of the stainless steel tube used in the experiment. We used a stainless steel tube (inner diameter of 34 mm, outer diameter 39 mm and 420 mm in length) that represented the level of proximal tibia, like the same test system used by previous studies [7-12]. 18 mm below of the stainless steel tube upper tip were two opposite holes in diameters of 7 mm.

For three point bending test, we used interlocking tibia nail (Tıpsan Medical Devices, İzmir-Turkey) which had 10 mm body diameter, 420 mm length and 12 mm proximal part diameter. On the tibia interlocking nail there is one proximal locking screw oblong hole 6,5 mm in diameter and 16 mm in length. The tibia interlocking nail was supported from its proximal and distal part by two metal ring shaped devices that don't allow movement of the nail to sides on the stainless tube [10-12]. Metal rings had external diameter of 32 mm and internal diameter of 14 mm and were 12 mm high simulating the cross sectional area of a standart tibia. After rings were screwed to the nail, free passage of the nail distally and proximally in the tube was controlled. The screws passed through the metal tube holes of 7 mm diameter and proximal locking screw oblong hole of the tibia nail. The speed of loading on 3 -point bending tests was 1 mm/ minute resampling previous studies [7-12]. Loading was conducted from the upper tip of the tibia nail by axial compression machine (Figure 2).

Figure 1 : Samples of proximal tibia locking screws (Above:Low threaded, Below: Unthreaded).

Figure 2 : Photography of the 3-point bending test of proximal tibia locking screws.

The biomechanical tests were conducted in University of Dokuz Eylül, Biomechanics laboratory by using the universal axial compression testing machine (Shimadzu, AG-I 10 kN, Japanese). We determined yield point of stainless steel locking screws in this experimental test and the machine output stress -strain graphs on computer monitor. We determined the yield point by the straight line changing to a curve in the elastic-plastic deformation border. After every test we checked all locking screws and nail. All of the screws bent in the mid portion of the compression location with no screw fracture and no nail deformation. The data of the yield point values of tibia proximal locking screws at the 3-point bending test were evaluated using the Mann-Whitney U test. The level of significant difference was defined as p<0.05.

Results

The mean yield point values of 4,5 mm smooth and 5 mm low threaded locking screws were respectively 1693± 117 (1522-1755) N (Mean± SD , CI) and 1644± 131 (1452-1712) N below the peak physiological loading on tibia (3.2 Body Weight(BW)= 2352 N for 75 kg person (Table 1). On the other hand the mean yield point values of 5 mm smooth, 5.5 mm low threaded and 5.5 mm smooth locking screws were respectively 2452± 204 (2171-2578)N, 2356± 312 (1962-2585) N and 2871± 285 (2481-3049) N above peak physiological loading on tibia (Table 1).

Table 1: The 3 point yield points of tibia proximal locking screws

Screw Groups (Diameter, thread)	**Yielding point (N: Newton)** **Mean±SD (CI: confident interval)**
group : 4,5 mm smooth screws (n=10)	1693± 117 (1522-1755)
group : 5 mm threaded screws (n=10)	1644± 131 (1452-1712)
group : 5 mm smooth screws (n=10)	2452± 204 (2171-2578)
group : 5,5 mm threaded screws (n=10)	2356± 312 (1962-2585)
group : 5.5 mm smooth screws (n=10)	

The mean yield point values of 4,5 mm smooth and 5 mm low threaded locking screws were statistically significant less than 5 mm smooth, 5.5 mm low threaded and 5.5 mm smooth locking screws (P=0.000, Mann-Whitney test) (Table 2).

Discussion

The aim of the study was to find out which kind of tibia proximal locking screws could resist the peak physiological loading on tibia (3.2 BW= 2352 N for 75 kg person) to allow early mobilization in tibia comminuted fractures of unreliable patients. According to our findings, the mean yield point values of 4, 5 mm smooth and 5 mm low threaded locking screws were respectively 1693 N and 1644 N below the peak physiological loading on tibia. The mean yield point values of 5 mm smooth, 5.5 mm low threaded and 5.5 mm smooth locking screws were respectively 2452 N, 2356 N and 2871 N above the peak physiological loading on tibia.

The same experimental design was used by many researches with polyethylene tube [7-9], aluminium tube [13] and stainless steel tube [10

-12] to obtain yield strength and yield point. With the polyethylene tube and aluminium tube to obtain true yield point was not likely as it was unreliable if the deformation that appears on the stress-strain graph belonged to polyethylene tube and its holes deformations or the locking screw deformation itself [10-12].

In the tests without big holes of the test tube, it was also unlikely to obtain the true yield point due to the pull-out and holding power of the locking screw. Therefore previous researches determined 3-point bending fatigue life of the screws instead of true yield point with tube holes not bigger than the locking screw diameter. It was stated that the stress on 1-mm deformation was defined as "yielding strength" instead of "true yield point [7-9, 14, 15]. It was concluded that due to the trapping of screws within the tube holes, the diameter of the metal tube hole must be 7 mm in order to clearly determine the true yield point [10-12].

It was reported that, the mean yield point value of 5 mm smooth locking screws applied 20 mm proximal of lesser trochanter (45 mm medullary diameter) was 1164 N and 3190 N on the lesser trochanteric level (30 mm medullary diameter) [12]. It was stated that the greatest factor which determines the locking screw three-point bending strength was the bone canal diameter (i.e., transcanaliculer working length of the locking screw) [16,17]. The test design we used was a stainless steel tube (inner diameter of 34 mm)

Table 2: Comparison of 3 point yield points of tibia proximal locking screw groups

Screw group Yielding point, mean(N)	**Screw group Yielding point, mean(N)**	**P value**
4,5 mm smooth screws, 1693 N	5 mm smooth screws, 2452 N	P=0,000
	5,5 mm threaded screws, 2356 N	P=0,000
	5,5 mm smooth screws, 2871 N	P=0,000
5 mm threaded screws, 1644	5 mm smooth screws, 2452 N	P=0,000
	5,5 mm threaded screws, 2356 N	P=0,000
	5,5 mm smooth screws, 2871 N	P=0,000

that represented the level of proximal tibia. We found 2452 N as mean yield point value of 5 mm smooth locking screws The thread depth of locking screw with sharp geometrical change was found to reduce the fatigue life of locking screws at 3 point bending tests because of being substantial stress concentrators [7- 9, 11, 18]. Use of high threaded locking screws was not recommended because of very low three point bending resistance [11].

The metal tube instead of cadaver tibia and composite tibia may appear to be a limitation of the study. It has been reported that cadaveric tibia is not suitable for biomechanical tests due to the difficulty of finding a tibia bone in terms of same bone mineral density and same biomechanical resistance [19, 20]. In the test design with composite tibia, it is unlike to determine which locking screw (one proximal and two distal) deformation occurs purely. Cadaveric tibia or composite tibia itself or their locking screw holes could be deformed during 3-point bending tests, making it impossible to notice the original deformation source.

On comminuted or oblique tibia fractures, interlocking nails work as full load-bearing implant instead of load sharing implant. For early patient mobilization with these fractures, tibia proximal locking screw should resist peak full weight bearing of unreliable patients. It was reported that the physiological loading on tibia was 2.5-3.2 BW, being peak axial load of 3.2 BW (2352 N for 75 kg person) [21]. To avoid plastic deformation of proximal locking screw in comminuted tibia fractures of unreliable patients, the yield points of tibia locking screws should be greater than 2352 N. Otherwise deformity and shortness of tibia may occur. We found that the mean yield point values of 5 mm smooth,

5.5 mm low threaded and 5.5 mm smooth locking screws were above peak physiological loading (2352 N) on tibia.

Conclusions: To avoid proximal locking screw deformation in comminuted tibia fractures of unreliable patients, the use of smooth 4,5 mm and low threaded 5 mm locking screws should be avoided, whereas smooth 5 mm, low threaded

5.5 mm and smooth 5.5 mm locking screws can be used safely.

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