NEW COUPLING SYSTEM FOR INTERFERENCE SCREWS: BIOMECHANICAL RESISTANCE TO TORSION

Aloísio Fernandes Bonavides Júnior, Rodrigo César Rosa, Antônio Carlos Shimano, José Baptista Volpon, Maurício Kfuri Júnior

ABSTRACT

Objective: To introduce a new coupling system between screw driver and interference screw, and biomechanical tests that validate the safety of its application. Methods: The new system was submitted to biomechanical torsion assays. Two types of analysis were performed: maximum torque of manual insertion of the screws into bovine bone; destructive assays of torsion of the system using an INSTRON 55MT machine. The same tests were also performed on a control group, using a commercially available interference screw coupling system (Acufex®). Results: In the tests on manual insertion of screws in bovine femurs, the average values found with a digital torque meter were 1.958 N/m for Acufex® and 2.563 N/m for FMRP. Considering $p>0.05$, there were no statistical differences between the two groups ($p=0.02$) in the values for maximum torque of insertion, in the two systems studied. The average values for maximum torque of torsion resisted by the screw were 15N/m for the Acufex® screw and 13N/m for the FMRP screw, again with no statistical differences between the two groups ($p>0.05$). In the evaluation of angular deformation, there was also no significant difference between the two screw types ($p=0.15$). Conclusion: The new coupling system for interference screws developed at FMRP-USP revealed a torsion resistance that is comparable with the system already available on the market and regulated for international use.

Keywords: *Knee/surgery. Bone screw. Biomechanics.*

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INTRODUCTION

Lesions of the anterior cruciate ligament (ACL) have significant importance in clinical practice. From the clinical point of view, the lesion can promote instability and secondary lesions in the joint, posing a challenge to the orthopedist in search of the best treatment and of the fastest return to sports of their patient. One of the techniques used the most for ligament reconstructions is the one that associates the use of an interference screw with the central third of the patellar ligament with bone at its ends as a replacement for the torn ACL.

Several factors contribute to the significant popularity of the use of the patellar ligament graft among orthopedists. These include: the subcutaneous location of the graft, a fact that facilitates its removal; the stiffness of the initial fixation with the use of interference screws and the possibility of healing through bone consolidation of the bone block of the graft in the ligament insertion tunnel. In spite of theoretical advantages associated with the use of the patellar ligament graft fixed by means of interference screws, some problems are described with the use of this technique, such as: disconnection of the screwdriver upon insertion or removal of the screw, with consequent loss of the screw in the intra-articular region; partial or total iatrogenic laceration of the graft fibers or of the posterior cruciate ligament upon the fixation of the graft; interposition of Hoffa's fat pad and of the synovium at the time of screw penetration, precluding visibility upon femoral fixation; breakage and deformity in the guide pin with the impossibility of removing it and divergence or convergence of the direction of the screw in relation to the bone tunnel, leading to insufficient graft fixation and non-visibility of the graft in the tunnel upon insertion of the femoral screw.[1,2]

These complicating factors determine an increase in surgical time, greater morbidity for patients and intraoperative stress for the surgical team. The perception of these practical difficulties prompted us to seek alternatives to facilitate the use of interference screws in arthroscopically-assisted knee ligament surgery.

One of the authors of this study (MKJ) idealized a method of supportive coupling between the interference screw and its respective screwdriver. The hypothesis is that this deve-

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lopment results in greater control during the screw insertion or removal procedure in the joint, preventing it from working loose inadvertently or from getting lost inside the knee.

OBJECTIVE

The aim of this study is to present a new screwdriver-interference screw coupling system, as well as the safety of its use, adopting in vitro biomechanical torsion assays as parameters.

MATERIALS AND METHODS

MATERIALS

1. Implants

A. FMRP System

The screws and the coupling system with the screwdriver were developed at the Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo - FMRP-USP. They were produced by the company Trautec® - Equipamentos Cirúrgicos Ltda (Ribeirão Preto, São Paulo, Brazil).
The FMRP titanium screw exhibits features similar to those of the interference screws existing in the market, except for its head, which was redesigned to be subjected in a supportive manner to the insertion screwdriver. It is a cannulated screw, conical in its distal portion, with rhomboid proximal edges, and external thread to the right. Its head consists of an external hexagon with internal thread to the left. This internal thread of the screw is what allows supportive coupling to the screwdriver as shown below. As regards the raw material, the screw is made of Titanium Alloy (Ti-6Al-4V) of Classification ASTMS 136. (Figure 1) The corresponding screwdriver is T-shaped with internal distal hexagon, controlled total length, and cannulated route along which the interfixation element passes. (Figure 2) It consists of a straight, smooth and cannulated rod, with an external thread to the left and having a hexagonal fixed manipulator at its proximal end. (Figure 3) The three form the FMRP system of integrated fixation. The distal end of the T-shaped screwdriver, that is, its tip, is composed of austenitic stainless steel hardened by thermal shock of Classification AISI 455. The rest of the screwdriver, as well as the interfixation element, are composed of martensitic stainless steel hardened by tempering (wire drawing) of Classification AISI 304. The mechanism of subjection of the screw to the introduction device is executed as follows: the internal hexagon of the T-shaped screwdriver is coupled to the external hexagon of the screw, and the "inter-fixation element" is introduced, screwing it in completely, and making sure there is no gap between the screwdriver and the screw. This entire device described here is cannulated for the passage of the guide pin. The model is supportive, fixable temporarily to the introduction screwdriver, but preserves the possibility of continuing to use the traditional guide pin. (Figure 4)

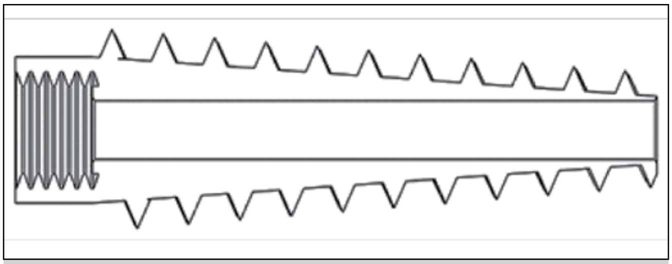
Figure 1. *Detail of the interference screw with an external hexagon shaped head and that contains an internal thread in the anticlockwise direction.*

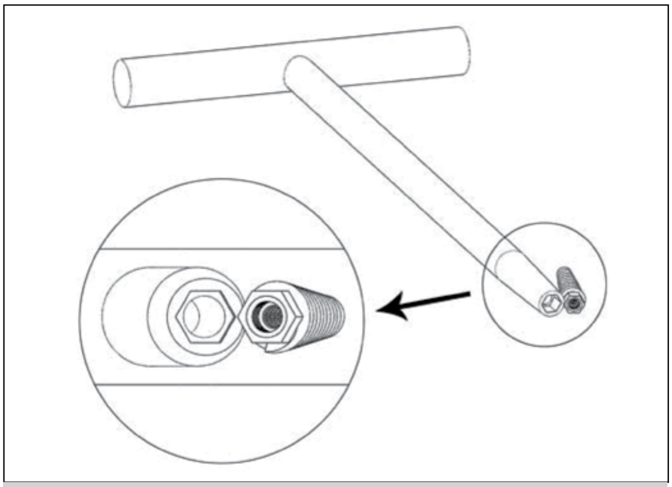
Figure 2. *Details of the fit between insertion screwdriver and interference screw.*

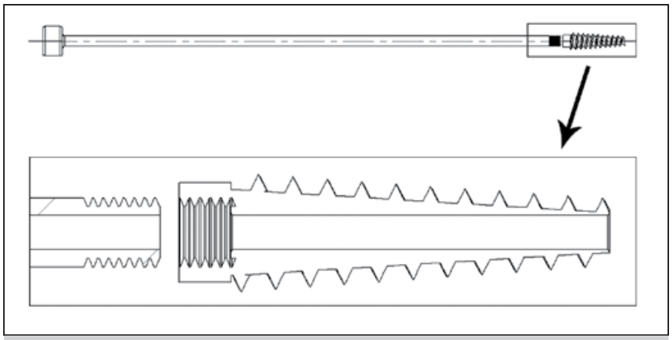
Figure 3. *Coupling between inter-fixation element and interference screw, occurring in the anticlockwise direction.*

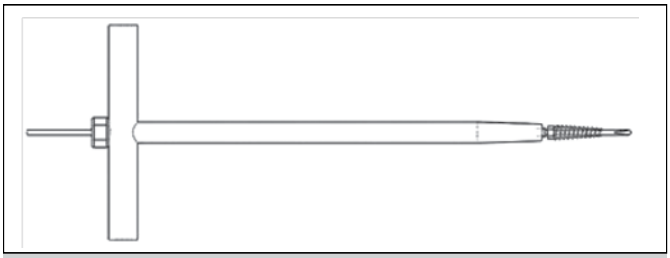
Figure 4. *Complete system: T-shaped screwdriver containing the inter-fixation element already fixed to the screw. The whole system is cannulated and crossed by a guide thread.*

B. Standard System

We used Acufex® (Smith & Nephew, USA) screws and their respective introducer screwdriver as a means of control. (Figure 5)

2. Test Samples

Twenty (20) pieces of left bovine femur in natura (estimated age of the bovines between two and three years at the time of slaughter), which were acquired at Frigorífico Barra Mansa in the city of Ribeirão Preto (SP). The pieces already separated from the tibia were initially dissected, removing the soft parts and cutting the bone with the use of an electric saw in the supracondylar distal third in the metaphyseal region of the femur. Standardized cuts were performed to obtain bone blocks corresponding to the lateral femoral condyle. Drillings were executed to create 10x25mm orifices in each bone block, and 9x25mm bone cylinders were removed to fill these orifices.

METHODS

Twenty (20) torsion assays were performed with the screws in bovine bones. We separated ten (10) new 7x25mm FMRP screws and ten (10) 7x30mm Acufex® control screws. The pieces already broken off from the tibia were initially dissected, removing the soft parts and cutting the bone with the use of an electric saw in the supracondylar distal third in the metaphyseal region of the femur, then taking them to the Endocrinology Laboratory of Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto-USP for densitometric examination. The BMD (bone mineral density) of the bovine femurs was determined by the densitometry exam for dual energy x-ray absorption (DEXA) and QDR system with version 11-2:5 software (Hologic 4500 W, Waltham, MA, USA). We adapted a digital torque meter (MK software, Version 1.0.0.6/2004) to the respective introduction screwdrivers to evaluate the maximum values of the insertion torque of each interference screw. The torque calibrating device and method was developed in the Bioengineering Laboratory of Faculdade de Medicina de Ribeirão Preto[3]. (Figure 6) The insertion torque of each screw represented the moment of angular force for insertion of the implant. The maximum value of the insertion torque was obtained for each screw, when introduced through handle executed by the same evaluator by torsion mechanism in the torque meter adapted to the screwdriver. In this manner, way, the implant was advanced in a standardized fashion at an angle perpendicular to the bone surface and positioned in the interface between the graft and the femoral tunnel. Besides the assays on bovine femurs we also conducted destructive torsion assays, using only the screws. Ten (10) screws were submitted to torsion assays, with five (5) FMRP 7x30mm screws and five Acufex® 7x30mm control screws. In the torsion assay we evaluated the maximum rupture torque (Nm) and the angular deformity (degrees). The assay used standard ASTM F543:2007 (Standard Specification and Test Methods for Determining the Torsional Properties of Metallic Bone Screws) as a basis.

The test equipment consisted of the INSTRON 55MT machine, belonging to the Bioengineering Laboratory of Faculdade de Medicina de Ribeirão Preto. The assay speed was 2 rpm (=720 degrees/min), (room) temperature of 22 degrees centigrade, scale of 21x110 and span (W) of 6.5mm. (Figure 7) For the Acufex screws three threads were exposed, and for the FMRP screws there was one (1) thread exposed. Before the torsion assays, dimensional evaluations were carried out on all the test samples with a Mitutoyo digital caliper, involving external diameter, internal diameter, thread depth, thread length and total length.

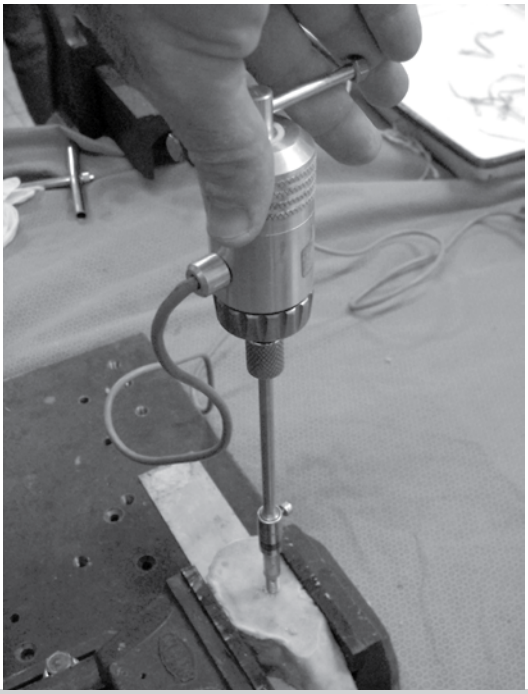

Figure 6. *Manual insertion of the screws in bovine specimen, with screwdriver especially adapted to a digital torque meter.*

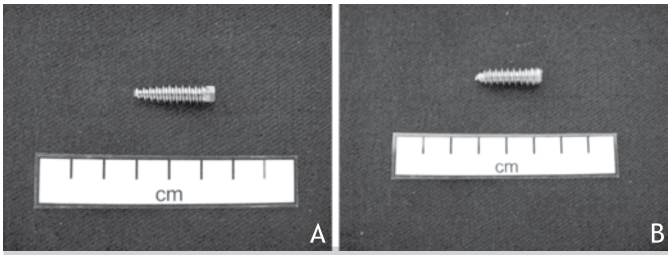

Figure 5. *Screws used in the study. A) FMRP screw - note that the screw head has a hexagonal shape, where the T-shaped screwdriver will be coupled externally; B) Acufex® screw - this screw has a conventional head with hexagonal recess.*

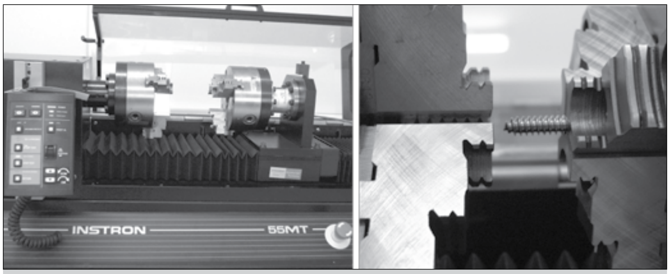

***Figure 7**. Destructive assay of torsion of the screws, in Instrom 55 MT equipment, to gauge the maximum torque resistance in both the systems studied.*

STATISTICAL ANALYSIS

In the statistical analysis of the results of the values of maximum torque of insertion in the bovine bone, we used nonparametric tests in the comparisons between the two brands of screw (Mann-Whitney Test). In the torsion assays we used the Kruskal-Wallis test. The significance level $p \leq 0.05$ was adopted. The statistical tests were conducted in SPSS® version 15.0.

RESULTS

We evaluated the maximum insertion torque (N.m) values of the FMRP 7x25mm and Acufex® 7x30mm screws, with Mean and Standard Deviation. The mean values found were 1.958 Nm for Acufex® and 2.563 Nm for FMRP. Considering $p < 0.05$, there was no significant difference ($p = 0.02$) when using the digital torque meter to quantify the maximum insertion torque value in the two systems studied.

In the torsion assays, considering $p < 0.05$ when evaluating the maximum torque, there was no statistical difference between the Acufex® 7x30mm and FMRP 7x30mm screws. The mean values of maximum torque to deform the screw were 15 N/m for the Acufex® screw and 13 N/m for the FMRP screw. When evaluating angular deformation, there was no significant difference between the groups of screw ($p = 0.15$).

DISCUSSION

In the choice of the specimen to act as experimental model in the study of the screw insertion torque, we opted for the bovine femur, as according to the findings of Brown *et al*,[4] it has a bone density that is more similar to and compatible with the bone of young human adults.

We decided on the insertion torque study since the main difference between the new system and the systems already in use is the adaptation between the screws and their insertion screwdriver. We wished to know whether the new coupling method is safe to the torque, not leading to ruptures caused by fatigue or torsion stress in the screw head during insertion. We used a system already consolidated and widely used in the international market as a reference.

For the insertion of screws, Browner[5] reports that the torque usually applied by orthopedists in surgeries ranges from 2.95 Nm to 5.98 Nm. It is important for the torque in habitual conditions to allow good fixation and not to cause any structural damage to the screw to be implanted. We opted to evaluate the maximum torque of manual insertion of the same surgeon gauged by a digital torque meter. This was motivated by the practicality of the measurement and due to the possibility of a significant variation of torques measured with a conventional torque meter. There was no significant difference between the maximum insertion torque values when we compared the FMRP and Acufex® screws. Our mean values encountered were 1.958 NM for Acufex® and 2.563 NM for FMRP. Brown *et al*.[4] found a moderate positive correlation between the torque of insertion and the pull-out strength for 7 and 9mm screws used in bovine bones. Daftari *et al*. [6] also found the same correlation with the application of certain screws used in surgery on the spinal column in vertebral bodies of sheep. Zdeblick *et al*.[7] made identical findings in favor of the correlation between torque of insertion and pull-out strength using pedicle screws. Other authors did not find correlation between the torque of insertion and the pull-out strength for several types of screw applied in human cadaver bones.[7,8] Due to the possible relationship of the insertion torque of the interference screws with important mechanical properties such as pull-out strength and stiffness, we believe that subsequent biomechanical studies should be planned to gauge the safety of the use of the new system in vitro.

In our study there were no cases of damage to the implant or fracture in the bone block during the insertion of the screws in bovine femurs. The maximum rupture torques of the implants were far higher than the maximum torques necessary for bone insertion in the bovine specimens.

CONCLUSIONS

We presented a new system for coupling between screwdriver and interference screw. Preliminary torsion assays carried out on bovine specimens reveal that the new system has torque resistance comparable with systems already available in the market and approved according to international regulations. New biomechanical studies should confirm the safety of the use of the new system, to enable clinical studies to be designed.

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