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TESTING OF PROTOTYPE INTERFERENCE SCREW FOR ACL RECONSTRUCTION IN PORCINE FEMURS

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Abstract

Multiple techniques for the reconstruction of anterior cruciate ligament (ACL) are available, most of which use implant made from metallic or bioabsorbable materials. Currently one of the most widely used fixation methods for anterior cruciate ligament reconstruction with bone tendon-bone graft is the interference screw.

The aim of our work was to test custom design screw geometry, whether it is appropriate for ACL reconstruction. New screw was designed geometry for the work, so that screws with the same geometry could be produced for later work, from different materials. In this study injection molded biodegradable interference screws were tested on porcine femurs, with bone-patellar tendon-bone (BPTB) graft fixation. The average failure load and the stiffness (772 ± 225 N and 109 ± 33.9 N/mm respectively) of the fixation was higher than literature average, although within standard deviation. Test results showed that the designed screw geometry is adequate for BPTB graft fixation.

Keywords: anterior cruciate ligament, BPTB, interference screw

Introduction

Anterior cruciate ligament (ACL) reconstruction is one of the most common knee surgery since the ACL is torn most frequently in this joint. It causes in instability of the knee joint and requires surgical treatment in the active population. The success of ACL reconstruction is influenced by several factors. These include timing of the surgery, graft choice, tunnel placement, graft tensioning, graft fixation methods, and the postoperative rehabilitation program^{1,2}. One of the most important factors is the security of the graft fixation^{3,4,5}, especially in the early postoperative period, because the advantages of early motion during an accelerated rehabilitation have been shown in different studies. Although it was also shown that during active full extension of the knee, the resultant forces produced in the graft can

attain 200 N^{6,7}, most researchers calculated with a maximum of 500 N daily load, and 450 N in an intensive rehabilitation program^{6,8}.

In the past two decades many different fixation method were developed, such as metal and biodegradable interference screws, post fixations by screws, staples, buttons, sutures and others^{9,10,11,12,13}, and several new fixation methods are under development^{14,15,16,17}. Most of these techniques use implants from metallic or absorbable materials^{18,19}, which are later surgically removed or are absorbed by the body. Exception is the press-fit fixation, during which the BPTB graft is impacted into the bone without the help of foreign bodies^{20,21,22}. These methods for ACL reconstruction must ensure the ultimate tensile strength and stiffness that allows the application of the current accelerated rehabilitation protocols^{7,23,24}.

Nowadays, the interference screw fixation is one the most popular method in ACL reconstruction, and there are several biomechanical studies proving its efficiency and good mechanical properties^{25,26,27,28,29,30,31}.

During interference screw fixation of the BPTB (bone-patellar tendon-bone) graft there is an interlock between the screw threads and the bone (the bone block attached to the graft and the bone of the tunnel). This is due to the triangular cross sectional dimensions of the screw thread in the direction parallel with the screw axis. When loaded under tension a large shearing force is therefore required to break either the bone that engages with the thread, or the thread of the interference screw and cause pull-out. Since the cancellous bone is weaker most times than the metallic or bioabsorbable screw, it is the bone that will brake.

Fixation strength is mainly affected by the interlocking area of the screw, bone block and bone. The interlocking area is affected by the gap size, bone block cross-sectional shape, screw dimensions, etc. (Figure 1). Since both metallic and biomaterial used in orthopedic implants are stronger than cancellous bone the pull-out strength for identically shaped screws

inserted with the same anatomical attributes (gap size, bone block cross-sectional shape, screw dimensions), should be similar³². The majority of original and review works show that bioabsorbable and metallic screws have similar failure loads^{33,34,35}. Only a smaller number of works indicate that one screw is better than the other. In work reporting about comparative tests, most times only screw diameter and maybe length match between the two screws, thread depths and profile, head size, tine differ^{32,33}.

The aim of our work was to produce a bio-degradable interference screw with adequate screw geometry for ACL reconstruction with BPTB graft. Further research will include change of screw material and screw geometry (tine, thread depth, tapering length etc.)

Materials and methods

14 fresh porcine knees were used, from animals between 1–1.5 years and 100–130 kg. The harvesting of the distal femurs, patellae and the patellar tendons and the measurements took place within 24 hours after death. The specimens were kept in plastic bags to prevent

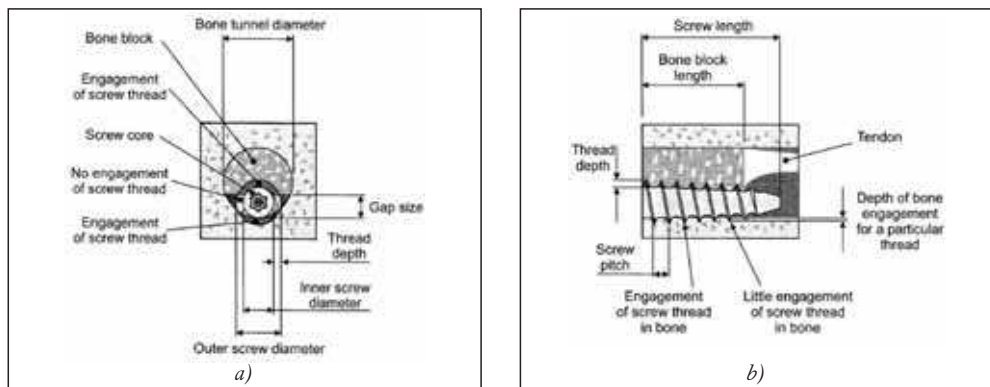


Figure 1. Characteristics of the interference screw when used to fix a bone block of the BPTB graft to the tunnel wall³²

(a) End view (b) Side sectional view through bone tunnel and block

dehydration, and the prepared specimens were tested right after preparation.

The specimens were prepared by removing all the soft tissue from the distal femur. The femoral tunnel was placed at the previous attachment of the anterior cruciate ligament. The cortex was removed at that site with a conventional drill, exposing the cancellous bone. The femoral tunnel was created with a conventional 10 mm drill. 8 mm wide central patellar bone-tendon-bone graft was harvested from the patellar tendon. The patellar end of the bone-tendon-bone graft was placed into the femoral socket with the tendon positioned posteriorly. The patellar semicircular bone plug measured 8 mm in diameter and 25 mm in length. The tibial end bone-tendon-bone graft was used for securing the graft in the testing machine.

The screws were injection moulded into a rapid prototyped mould from non medical grade PLA (NatureWoks 3051D) on an Arburg ALLROUNDER 320C injection molding machine. Medical grade materials was not necessary for the tests, as one of the main objective of this study was to test whether screw geometry and manufacturing technology are adequate for further research. Effect of screw geometry and manufacturing technology will be discussed in a later paper.

Screw design was determined after consulting with practitioner surgeons, performing ACL reconstruction³⁶. The length of tapering of the screw end was chosen to be 1/3 of the total screw length. The screw is fully cannulated, the screwdriver socket is hexagonal, and 17 mm deep. The pitch of the screw thread was chosen 7°. The respective dimensions of the interference screw are illustrated in (Figure 2).

A computer-controlled testing device (Zwick Z020) was used for the pull-out tests. A spe-

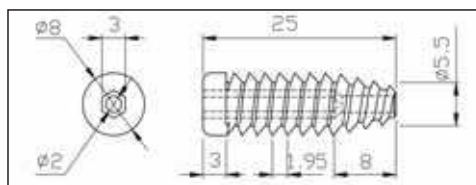


Figure 2. Main dimensions of the interference screws in mm

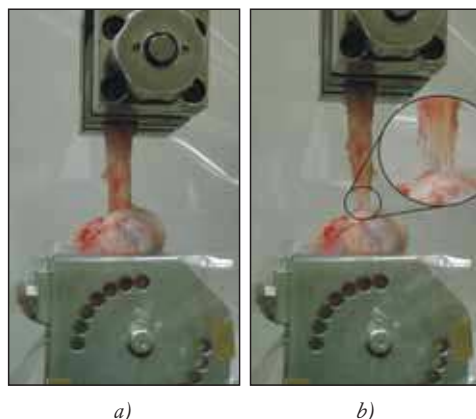


Figure 3. Specimen preparation in Zwick testing machine (a) after pretension (b) during failure

cially designed holder was fixed on the base of the testing machine, and the crosswise (medial to lateral) drilled femur was joined to it with a metallic bolt. The tibial bone end of the BPTB graft was secured to the crosshead of the testing device (Figure 3). A pretension of 10 N was applied to the bone-patellar tendon complex and tensile-strength test was performed with a constant 200 mm/min speed along the longitudinal axis of the tendinous part of the graft. Testing speed was chosen according to previous researches in this field at our department²⁰.

The measured data were recorded on load-displacement diagrams of the testing device (Figure 4). Failure mode was also recorded even it was pull-out from the tunnel, intra substance ligament rupture or femoral bone breakage. Stiffness was calculated as the slope of the

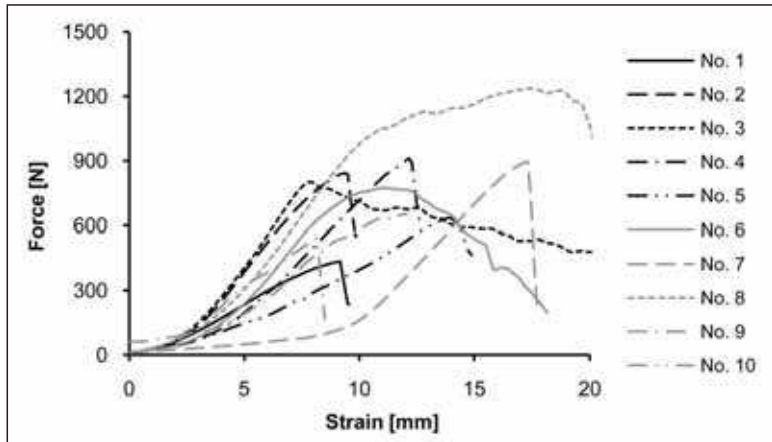


Figure 4. Force vs. displacement graphs of the valid tests

most linear part of the force-versus-displacement graph. Measured ultimate tensile strength and stiffness were compared to literature data.

Results

The results obtained from the pull-out test are summarized in *Table 1*. The mean failure load and stiffness was 772 ± 225 N, 109 ± 33.9 N/mm respectively. Four types of failure modes were recorded. In four cases the pull-out force was smaller than 100 N, these measurements were

not evaluated as the specimen inspection indicated a damaged tendon. In three cases the tendon tearing occurred after the stretching at the bone plug, leaving the bone plug and the screw behind. In four cases the tendon tore away from the bone plug, and in three cases the graft with the bone plug attached pulled out.

Discussion

The fundamental purpose of this work was to test a custom designed interference screw for ACL reconstruction with BPTB graft. Custom design was necessary since further goal was to compare effect of material, screw geometry etc. Such work can not be done with commercially available screws, since these differ in size, thread type, tine etc.^{12,37,38}. In comparative works the bioabsorbable and the metallic screw sometimes come from different manufacturer, thus ensuring different geometry^{32,33,34,35}. Most times only screw diameter and maybe the length match between the two screws, thread depths and profile, head size, tine differ^{32,33}. Currently there are only standards for metallic bone screw threads for medical application (*Figure 5*)^{37,39}. Most manufacturers use these thread for both their metallic and bioabsorbable screws^{37,38}. Our novel screw design resembles

No.	F_{\max} [N]	Stiffness [N/mm]	Failure mode
No. 1	435	63.5	Tendon broke at bone plug
No. 2	841	138.5	Tendon broke
No. 3	801	146.0	Tendon broke
No. 4	911	111.5	Graft pull out
No. 5	633	55.7	Tendon broke
No. 6	773	133.5	Graft pull out
No. 7	895	115.3	Graft pull out
No. 8	1237	147.5	Tendon broke
No. 9	654	104.2	Tendon broke at bone plug
No. 10	543	77.6	Tendon broke at bone plug
Mean	772	109	
S.D.	225	33.9	

Table 1. Results obtained from pull-out tests

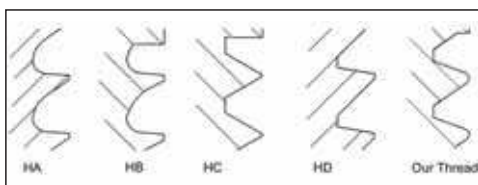


Figure 5. Standard metal bone screw threads for medical application compared to our own design^{37,39}

mostly the HC and HD thread type. The steepness of both upper and lower side of the thread is in between of those from the standard thread types. This thread type was chosen considering the manufacturability with injection molding, and was finalized after consulting with practitioner surgeons⁴⁰. The thread type used in this study can be seen on Figure 7 compared to standard medical threads.

One of the most important criteria for successful anterior cruciate ligament reconstruction is the primary stability of the graft^{7,23,24}. As well as the strength of the graft material used for

the replacement, the fixation is also of great concern with regard to the primary stability of the knee^{27,30}. Several studies have found that during maximum tensile strength tests the failure occurs more often at the graft fixation site than within the ligamentous tissue itself^{2,3,4,5}.

During our work four types of failure modes were recorded, one of which resulted in the exclusion of the specimens from being evaluated. In four cases the pull-out force was



Figure 7. Samples of the interference screws used in this study



Figure 6. Sample of bioabsorbable interference fixation devices: Absolute (Mitek), Intrafix (Mitek), Bio-Cortical Distal (Arthrex), Sheathed Femoral (Arthrex), BioRCI HA (Smith & Nephew), Bioscrew (Linvatec), Bioscrew Xtralock (Linvatec), EndoPearl (Linvatec), Wedge (Linvatec), Gentle Threads (Arthrotek), and Bioabsorbable Wedge (Stryker) (left to right)⁴¹



Figure 8. Femur head after pull out tests (a) tendon separated from the bone, (b) tendon broke. In both cases the screw remained behind in the bone tunnel with cancellous bone from the graft

smaller than 100 N. In these cases after closer inspection it was concluded that the tendon was damaged during fixation, which caused the premature failure of the graft. In three cases the tendon tearing occurred at the bone plug, after the stretching leaving the bone plug and the screw behind (Figure 8.a). In four cases the tendon tore further away from the bone plug, leaving the bone plug, the screw and a broken tendon behind (Figure 8.b). In three cases the graft with the bone plug attached pulled out of the bone tunnel. In all cases the screws were recovered from the femurs, after testing. No visible damage could be observed on the recovered screws.

According to Noyes⁴² the maximum failure strength of a human ACL was 1730 N with 182 N/mm stiffness in young cadavers and 734 N with 129 N/mm stiffness in old cadavers. Savio Woo⁴³ measured similar strength and stiffness (1503 N, 220N/mm) on intact ACL in middle-aged specimens at 30 degrees of knee flexion and applied 200 mm/min strain rate. Newer studies indicate the ultimate load of an ACL of a young adult can reach up to 2500 N^{44,45}, and can have a stiffness of 306 N/mm⁴⁶.

The results of this study show, that the custom designed interference screw achieved a mean maximum load of 770 N, which is slightly

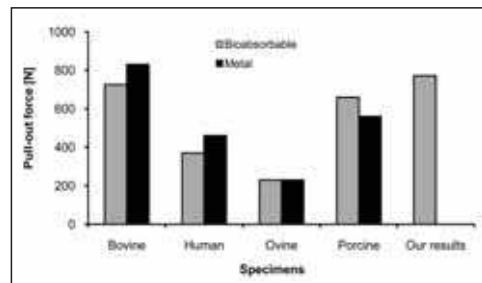


Figure 9. Average pull-out force results compared to literature data³²

higher than literature average (Figure 9). Average stiffness was also well above reference data with 109 N/mm, but this is still far from the stiffness of a knee with an intact ACL.

Since data published in the literature consider ACL reconstruction fixation with maximum load above 450–500 N as adequate^{6,7,8}, it was concluded that our custom designed interference screw is appropriate for further researches. These will include different screw materials, and changes in screw geometry.

Conclusions

The manufacturing technology used for the production of the screws is suitable for the production of small series of medical implants that can be used for biomedical tests in cadav-

ers. The above average pull-out force does not indicate that the examined screw geometry is better than those available on the market, but does show that the custom designed interference screw used in our work is adequate for ACL reconstruction with BPTB grafts. This means that this screw geometry is a good base

for further research, concerning screw material or geometry (tine, thread depth, tapering length etc). The higher average pull-out force could have been caused by several factors, such as animal type, bone tunnel diameter, bone plug size, gap size etc.

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