

Biomechanical properties of a novel biodegradable magnesium-based interference screw

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Abstract

Magnesium-based interference screws may be an alternative in anterior/posterior cruciate ligament reconstruction. The well-known osteoconductive effects of biodegradable magnesium alloys may be useful. It was the purpose of this study to evaluate the biomechanical properties of a magnesium based interference screw and compare it to a standard implant. A MgYREZr-alloy interference screw and a standard implant (Milagro®; De Puy Mitek, Raynham, MA, USA) were used for graft fixation. Specimens were placed into a tensile loading fixation of a servohydraulic testing machine. Biomechanical analysis included pretensioning of the constructs at 20 N for 1 min following cyclic pretensioning of 20 cycles between 20 and 60 N. Biomechanical elongation was evaluated with cyclic loading of 1000 cycles between 50 and 200 N at 0.5 Hz. Maximum load to failure was 511.3±66.5 N for the Milagro® screw and 529.0±63.3 N for magnesium-based screw (ns, P=0.57). Elongations after preload, during cyclical loading and during failure load were not different between the groups (ns, P>0.05). Stiffness was 121.1±13.8 N/mm for the magnesium-based screw and 144.1±18.4 for the Milagro® screw (ns, P=0.32). MgYREZr alloy interference screws show comparable results in biomechanical testing to standard implants and may be an alternative for anterior cruciate reconstruction in the future.

Introduction

The use of interference screws for anterior cruciate (ACL) or posterior cruciate (PCL) reconstruction is widely spread.¹ Degradable screws (DS) manufactured from various poly-

mers such as polylactic acid (PLLA), polylactide carbonate (PLC), and polylactic-co-glycolic acid (PLGA) are the most commonly used DS. Compared to metallic screws (MS) DS show a higher incidence of complications such as implant breakage,^{2,3} tunnel widening due to foreign body reaction,⁴ adverse immune reactions⁵ and prolonged joint effusion.¹ Despite the potential advantages, the use of MS is compromised by artifacts in postoperative magnetic resonance imaging and the necessity of implant removal in case of revision surgery.⁶

Magnesium (Mg) alloys are of high interest for future orthopedic implants. The related modules of magnesium are comparable to natural bone and lead to less *stress-shielding* when Mg is basis of an orthopedic implant.^{7,8} Besides that, Mg has an osteoinductive effect and stimulates the creation of extracellular matrix.⁹⁻¹¹ Promising animal studies have shown no negative effect, such as cartilage toxicity or synovitis, using Mg or Mg-alloys.¹²⁻¹⁴ The MgYREZr alloy is similar to the WE43-alloy, which has shown a good biological response in both, animal studies and clinical applications.^{12,15} A MgYREZr interference screw has been analyzed before.¹⁶ In this study different threads in an all-synthetic *in vitro* setup have been tested. The aim of this study was to evaluate the biomechanical properties of the first MgYREZr interference screw in ACL reconstruction and compare it to a standard implant. We hypothesized that both have similar properties and, therefore, the MgYREZr interference screw may be an alternative for ACL reconstruction in the future.

Materials and Methods

The interference screws used in this study are made of MAGNEZIX™ (Syntellix AG, Hannover, Germany), a powder metallurgical processed magnesium alloy. This aluminum-free material is based on the MgYREZr-alloy system and contains more than 90% magnesium. With an average grain size <5 µm, this high-performance alloy exhibits an offset elastic limit Rp0.2>250 MPa, a tensile strength (TS) >275 MPa, and an elongation at break of more than 10%. Compared with steel or titanium implants that are machined under oil or emulsion, these screws are machined from extruded MAGNEZIX™ bar stocks by dry cutting processes.

A total of 18 flexor *digitorum profundus* tendons and femora from skeletally mature 10-month-old female or castrated male pigs were used in this study. Hind limbs were obtained from an industrial slaughterhouse and stored at -20° C. Before use, specimens were thawed at room temperature for 24 hours. Flexor *digitorum profundus* tendons were harvested from

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Contributions: ME, study design, manuscript writing, data interpretation, biomechanical testing; HM, dissection of specimen, biomechanical testing; AL, development screw design, study design; PH, production process of the screw, study design; TC, statistical analyses, manuscript reading; CB, study design, data interpretation; HW, manuscript reading, study support; ME, study design, manuscript writing, data interpretation, statistical analyses, biomechanical testing.

Conflict of interest: Dr. Arne Lucas is employed by the company Syntellix AG, Hannover; he neither influenced the collection of data nor their interpretation. The other authors have no competing interests.

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the hinder limbs. The graft diameter was measured with an ACL graft sizer tube. Only tendons passing through the 8 mm sizer were included.

Porcine tendons were randomly assigned to one of the following groups: i) Interference screw fixation with a standard Implant (Milagro® 8×23 mm) or ii) custom made magnesium-based (MgYREZr-alloy 8×23 mm interference screw) (Figure 1). The potted femurs were rigidly fixed in a base platform at 50°, with the bone tunnel force direction angle at 0°. There was a distance of 30 mm between the graft and the clamp. Photo optical markers were placed on the tendons in order to measure the relative construct elongation within the tendons and from the fixation. During the entire procedure, tendons were kept moist with saline spray. For biomechanical evaluation, specimens were placed into a tensile loading fixation of a servohydraulic testing

machine (Mini Bionix 858; MTS Systems Co, Minneapolis, MN, USA). The tendons were rigidly fixed in a clamp holding 2 cm of the distal end of the tendon.

Biomechanical analysis included pre-tensioning of the constructs at 20 N for 1 min following cyclic pre-tensioning of 20 cycles between 20 and 60 N. Biomechanical elongation was evaluated with cyclic loading of 1000 cycles between 50 and 200 N at 0.5 Hz. The increase in construct length was recorded at a frequency of 20 Hz and a measurement accuracy of 0.1 mm. Ultimate failure load test was performed with a ramp speed of 20 mm/min. The maximum failure load and failure mode of the constructs were analyzed. A video analysis was performed in order to exclude a fixation bias. Elongation was measured evaluated after

preloading, after cycles 200, 400, 600, 800 and 1000 as well as after failure. Stiffness (N/mm) was analyzed during failure testing.

Statistical analysis

Sample size determination was performed using an online tool (www.clinical-trials.de). The sample size calculation advised 9 specimens per group for a power of 0.8 at a significance level of alpha 0.05. All statistical analyses were performed using Graph Pad Prism (GraphPad Software Inc., La Jolla, CA, USA). Normal distribution was analyzed by the D'Agostino & Pearson omnibus normality test. All values are presented in the form of mean \pm standard deviation (SD). Analysis of variance was used for parametric data and Kruskal-Wallis test for nonparametric data. A P value less than 0.05 was considered to be statistically significant.



Figure 1. Interference screws: 1) Milagro® 8×23 mm, DePuy Mitek, Raynham, MA, USA and 2) custom made magnesium-based (MgYREZr-alloy) 8×23 mm interference screw.

Results

Maximum load to failure was 511.3 ± 66.5 N for the Milagro® screw and 529.0 ± 63.3 N for magnesium-based screw (ns, $P=0.57$; Figure 2). Elongations after preload, during cyclical loading and during failure load were not different between the groups (ns, $P>0.05$; Figure 3). Total elongation after preload averaged from 5.1 ± 0.5 mm in the Milagro group and 5.1 ± 0.4 in the Mg group ($P=0.92$). Stiffness was 121.1 ± 13.8 N/mm for the magnesium-based screw and 144.1 ± 18.4 for the Milagro® screw (ns, $P=0.32$). In the Mg group fixations failed by a tendon rupture in 2/10 cases and by

a tendon pull out of the bony tunnel in 8/10 cases. In the Milagro® group fixations failed by a tendon rupture in 3/10 cases and by a tendon pull out of the bony tunnel in 7/10 cases. In both group the video analysis indicated no significant elongation between tendon and clamp.

Discussion

The most important finding of this study is that the MgYREZr alloy interference screw showed similar biomechanical properties compared to a standard implant. Consequently, our null hypothesis is to accept.

Several study limitations have to be addressed: i) we only applied one force-angle of 0° . This gives no conclusion about the biomechanical properties in flexion-extension motion. ii) This is a time zero scenario. No conclusion concerning the characteristics of the degradation process as well as the changing biomechanical properties is possible. The use of degradable magnesium interference screws may be controversial. Kuhlmann and colleagues described how hydrogen gas is produced and gas cavities are seen during the degradation process of magnesium-based implants. The source of the gas cavities remains an issue of debate.¹⁷ The MgYREZr alloy showed no bone erosion resulting from gas formation after 1 year of follow up in a recently published animal study.¹⁸ iii) We used a whole porcine model for our investigation. Compared to human hamstring tendons, porcine flexor *digitorum profundus* tendons have a lower maximum load to failure, but

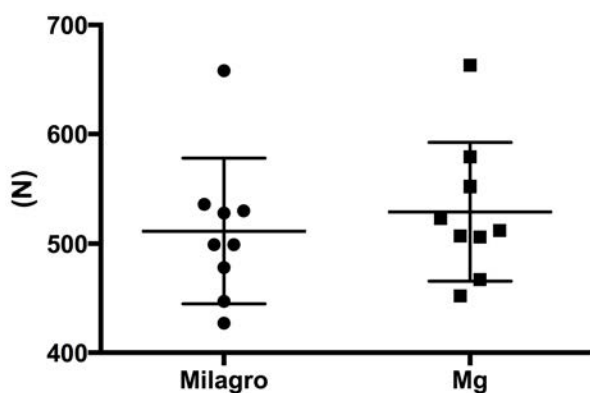


Figure 2. Maximum load to failure was 511.3 ± 66.5 N for the Milagro® screw and 529.0 ± 63.3 N for magnesium-based screw (ns, $P=0.57$).

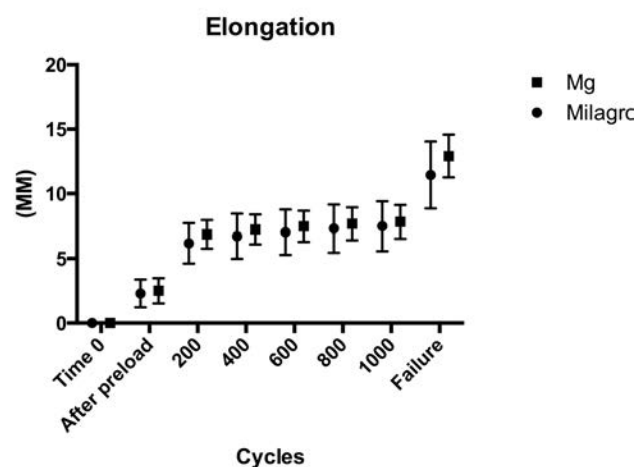


Figure 3. Elongation after preload, during cyclical loading and during failure load were not different between the groups (ns, $P>0.05$).

comparable elongation and lower standard deviations (unpublished data from our study group). Taken this into consideration, porcine flexor *digitorum profundus* tendons can be used as suitable graft substitutes for human hamstring tendons in biomechanical *in vitro* studies. Due to their high availability and constant size they have advantages over human tissue. The uniformity of the porcine tendons may furthermore help to reduce specimen-related bias in comparative studies for ligamentous fixations techniques. To achieve adequate early postoperative rehabilitation after ACL surgery, primary stability of the graft fixation is mandatory. The maximum failure loads observed in our study are comparable to those of other soft tissue interference screw fixations.^{19,20} Our results demonstrate for both screws in this biomechanical setup that maximum load to failure rates are as high as needed for early rehabilitation.^{21,22} It is well known that cyclic displacement has an influence on the long-term graft function. Daniel and colleagues reported that a 3 mm side-to-side laxity after unilateral ACL reconstruction leads to a high rate of ACL failures.^{23,24} Morrison *et al.*²¹ described an estimated force of 350 N achieved in normal walking; however, the peak cyclic loading force in our study was 250 N. We believe that this is not a critical success factor for this study as it was during the initial postoperative period when lower graft forces are expected. The total elongation detected in this study was distinctly higher compared to a screw fixation recently published by Mayr and colleagues¹⁸ (mean: 1.87 mm) but comparable results to Zantop and colleagues²⁵ (mean: 4.81 mm) and Weimann and colleagues²⁶ (mean: 4.1 mm). This might be due to the different test setups (human hamstring graft, porcine bone, calf bone or porcine flexor tendons). The elongation after preload, cyclical loading and the total elongation of the constructs were similar in both of our groups. This reflects the equivalence of the Mg screw.

The overall construct stiffness is a crucial part of ACL reconstruction procedure. It is known that a high stiffness graft construct better restores the anterior and posterior limit to normal compared to a low stiffness graft.²⁷ The stiffness at failure mode evaluated in this study was similar in both groups. Our results are comparable to other studies focusing on the biomechanics of interference screws^{18,25} and to extra cortical fixation techniques.^{28,29}

Conclusions

The present *in vitro* biomechanical examination investigated the biomechanical properties of a novel magnesium alloy (MgYREZr)

screw compared to a control, consisting of a commercial polymer screw. All biomechanical parameters were similar. This study shows the first promising results of a degradable material, which may be a clinical alternative in the future. Further *in vivo* studies, with focus on hydrogen gas production and gas cavities during the degradation process of magnesium, are necessary to validate these biomechanical results.

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