ORIGINAL PAPER





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Abstract

Purpose Biodegradable interference screws (IFS) can be manufactured from different biomaterials. Magnesium was previously shown to possess osteoinductive properties, making it a promising material to promote graft-bone healing in anterior cruciate ligament reconstruction (ACLR). The purpose of this study was to compare IFS made from magnesium to a contemporary biocomposite IFS.

Methods In a porcine model of ACL reconstruction, deep porcine flexor tendons were trimmed to a diameter of 8 mm, sutured in Krackow technique, and fixed with either 8×30 mm biocomposite IFS (Bc-IFS) or 8×30 mm magnesium IFS (Mg-IFS) in an 8 mm diameter bone tunnel in porcine tibiae. Cyclic loading for 1000 cycles from 0 to 250 N was applied, followed by load to failure testing. Elongation, load to failure and stiffness of the tested constructs was determined.

Results After 1000 cycles at 250 N, elongation was 4.8 mm ± 1.5 in the Bc-IFS group, and 4.9 mm ± 1.5 in the Mg-IFS group. Load to failure was 649.5 N ± 174.3 in the Bc-IFS group, and 683.8 N ± 116.5 in the Mg-IFS group. Stiffness was 125.3 N/mm ± 21.9 in the Bc-IFS group, and 122.5 N/mm ± 20.3 in the Mg-IFS group. No significant differences regarding elongation, load to failure and stiffness between Bc-IFS and Mg-IFS were observed.

Conclusion Magnesium IFS show comparable biomechanical primary stability in comparison to biocomposite IFS and may therefore be an alternative to contemporary biodegradable IFS.

Keywords Interference screw, Biocomposite, Magnesium, Acl reconstruction, Biomechanics

Introduction

Interference screws (IFS) are the most frequently used implants for tunnel aperture fixation of soft tissue anterior cruciate ligament (ACL) grafts [7]. While originally made from nondegradable materials like titanium alloys, contemporary IFS are mostly made from biodegradable materials. These suggest reliable graft fixation, as well as subsequent resorption, omitting the need for implant removal, especially in case of revision [29]. Different



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biomaterials like biopolymers, or biocomposites are available, each with different biological and mechanical properties [33]. However, for biodegradable IFS, incomplete resorption, or replacement with insufficient bone material are described [5, 32], which may cause inflammatory reactions with possible detrimental effect for the patient.

A possible alternative material for biodegradable IFS may be magnesium (Mg). It closely resembles the stiffness of human bone and was shown to elicit osteoinductive effects, both in vitro and in vivo, which may facilitate a quicker graft healing in ACL reconstruction [8, 40, 42, 47, 49]. Implants made of pure Mg have already been used in trauma surgery, but suffered from certain drawbacks. One of which was the unpredictable speed of degradation, which caused implant failure before adequate healing could be obtained [2, 47]. Furthermore, release of hydrogen gas during degradation may lead to osteolysis and formation of gas caverns [25, 30]. Due to these disadvantages, different solutions, including alloying magnesium with other metals, surface modifications such as coating or ceramization, were introduced to control the degradation process and to better suit these implants for orthopedic and trauma surgery [2, 20, 21, 39]. Even though magnesium IFS (Mg-IFS) are already purchasable, there is limited data on their biomechanical properties [15].

Thus, the purpose of this study was to investigate the biomechanical primary stability of ACL graft fixation with a novel Mg-IFS, and to compare it to a biocomposite IFS (Bc-IFS). We hypothesized that Mg-IFS show equivalent primary stability for ACL graft fixation.

Materials and methods Ethics statement

Frozen (-20 °C) Porcine knees and lower legs were obtained from a local butcher, who confirmed adequate health and comparable age of all used animals. Magnesium IFS were kindly provided by Medical Magnesium GmbH (Aachen, Germany). All other implants and materials were commercially purchased. Ethical approval was waived by the institutional review board of our institute.

Graft fixation strategies

The following implants were used and compared in this study (Fig. 1): For interference screw fixation, 8×30 mm



Fig. 1 Implants utilized for graft fixation. Left: 8 × 30 mm FastThread[™] biocomposite interference screw (Arthrex, Inc); right: 8 × 30 mm magnesium interference screw (Medical Magnesium GmbH)

FastThread[™] biocomposite (30% biphasic calcium phosphate, and 70% poly L-lactide-co-D acid) IFS (Bc-IFS; Arthrex, Inc) and 8×30 mm mm.IF WE43MEO (alloy containing Yttrium, Zirconium, and rare earths) magnesium IFS (Mg-IFS; Medical Magnesium GmbH) were used (each n=10). Porcine knees were defrosted at 7 degrees Celsius for 24 h (no repeated freezing and thawing), muscles and soft tissue were removed, and the tibia embedded into an aluminum mount using synthetic resin (RenCast[®] FC 52/53 A ISO and Ren Cast[®] FC 53 B Polyol, Gößl & Pfaff). In case of visible osteoarthritis, or fracture of the specimen, it was excluded. Deep porcine flexor tendons were prepared from porcine hind feet and trimmed to a diameter of 8 mm and a length of 100 mm, to resemble the thickness of a quadriceps ACL graft typically used in the clinical setting [38]. The diameter of the tendons was measured using a standardized sizing device (±0.5 mm, Karl Storz). The distal 20 mm of the tendon grafts were sutured in Krackow technique with four stiches on each side using high strength polyethylene suture (FiberWire[®] #2, Arthrex, Inc). An 8 mm bone tunnel with a length of 5 cm and an angulation of approximately 50° was drilled through the anatomical insertion site of the native ACL. The graft was then shuttled through the tunnel and fixed with one of the two IFS (Fig. 2). Envelope randomization was used to determine the implant used for each test.

Biomechanical testing

For biomechanical testing, a servo-hydraulic uniaxial testing machine (Model 8874, Instron), equipped with a 0 to 20 kN sensor, was used. The mount containing the embedded porcine tibia was fixed to the base of the machine with two clamps. The proximal end of the graft was fixed 20 mm above the tibial joint line to the testing machine using a cryoclamp, simulating the intra-articular part of the graft. Before starting the experiment, the graft was manually pretensioned to 20 N [19]. All constructs were first exposed to cyclic loading, followed by a load to failure test. For testing of the tibial graft-IFS-construct, the following protocol was used: Preconditioning was performed using 10 cycles at 50 N and cyclic loading was performed at a frequency of 0.5 Hz. Then, 1000 cycles with a load from 30 to 250 N per cycle were performed, as previously described [17]. Subsequently, load to failure testing was performed at a speed of 25 mm/min. Elongation and load were recorded continuously during the entire test. Stiffness was calculated by the slope of the linear portion of the load-displacement curve during load to failure testing. The mode of failure was macroscopically documented, and the tested IFS was visually inspected for damage to the implant.

Data analysis

An a priori power analysis was performed using G*Power 3.1 (university of Düsseldorf, Germany) to calculate the sample size needed for this study [16]. To detect a difference of 100 N between group means at a standard deviation of 60 N, a sample size of n = 10 per group was calculated, to obtain a power of at least 90%. The assumed standard deviation (SD) was based on previously reported studies on graft fixation strategies in porcine knee models [15]. Extraction of biomechanical parameters from test data was performed using Matlab (R2020a, MathWorks). Statistical analysis was performed using PRISM (version 8, GraphPad Software). The results are presented as mean values and corresponding standard deviations (SD). The Distribution of the data for each variable was assessed utilizing histograms, as well as the Shapiro-Wilk test. Since not all groups fulfilled the criteria for normal distribution, statistical comparison was performed using the Mann-Whitney test. A *p*-value ≤ 0.05 was defined as a significant difference.

Results

Both IFS were able to withstand the torques during insertion without breakage. None of the IFS were damaged during insertion into the bone tunnel.

After 1000 cycles at 250 N, elongation was 4.8 ± 1.5 mm in the Bc-IFS group, and 4.9 ± 1.5 mm in the Mg-IFS group (Table 1). No significant differences between Bc-IFS and Mg-IFS were observed. Load to failure was 649.5 ± 174.3 N in the Bc-IFS group, and 683.8 ± 116.5 N in the Mg-IFS group. Stiffness was 125.3 ± 21.9 N/mm in the Bc-IFS group, and 122.5 ± 20.3 N/mm in the Mg-IFS group. No significant differences regarding elongation, load to failure and stiffness between Bc-IFS and Mg-IFS were observed.

Mode of failure was tendon pullout in 8 specimens of the Bc-IFS group, and in 7 of the Mg-IFS group. In the rest of the cases, the constructs failed by elongation of the graft, followed by a rupture at the proximal tunnel aperture. However, elongation and load to failure between the different failure modes did not differ. There was no visual slippage at the cryoclamp and no damage to the cortex, or fracture of the bone in any specimen, after load to failure testing (Fig. 3).

Discussion

The most important finding of this study was that IFS made from magnesium have similar biomechanical primary stability, compared to a contemporary IFS made from a biocomposite material. The loads acting on the ACL during a gait cycle and other everyday activities like sitting and squatting were reported to range from 0 to



Fig. 2 Graft fixation. Deep porcine flexor tendons with a diameter of 8 mm were sutured in Krackow technique and fixed with an 8 mm interference screw in an 8 mm bone tunnel in porcine tibial bone

Table 1 Summa	ry of elongation,	load to failure, stiffness
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	Elongation [mm]		Load to failure [N]		Stiffness [N/mm]	
	Mean	SD	Mean	Mean	Mean	SD
Bc-IFS	4.8	±1.5	649.5	±174.3	125.5	±21.9
Mg-IFS	4.9	±1.5	683.8	±116.5	122.5	±20.3

Bc-IFS Biocomposite interference screw, Mg-IFS Magnesium interference screw



Fig. 3 Biomechanical primary (time-zero) stability. Elongation after 1000 cycles at 250 N (A), load to failure (B), and stiffness (C), as boxplots presenting mean, standard deviation and spread; Bc-IFS = biocomposite interference screw, Mg-IFS = magnesium interference screw

454 N [26, 27, 37]. During early rehabilitation with limited weight bearing, these loads are likely to be further reduced. Both tested IFS were shown to withstand these reported loads.

Primary stability of magnesium IFS was previously compared to other materials in few biomechanical studies. In a robotic biomechanical study, utilizing cadaveric knee specimen, IFS made from pure magnesium were compared to polylactic acid IFS for ACL graft fixation, in a human cadaveric knee model of ACL reconstruction [36]. No significant differences in anterior tibial translation in different flexion angles, when ACL reconstructions were fixed with either of the screws, were found. In another biomechanical study, utilizing a porcine model of femoral graft fixation, 8×23 mm IFS made from a MgYREZr (alloy containing yttrium) alloy showed equivalent primary stability in comparison to a 8×23 PEEK screw, with load to failure values of 529.0±63.3 N vs. 511.3 ± 66.5 N, and elongation of 5.1 ± 0.5 mm vs. 5.1 ± 0.4 mm, comparable to the results of the present study [15]. Further studies compared different biodegradable IFS to titanium IFS, with no significant differences between biodegradable and titanium implants, regarding both biomechanical primary stability, as well as clinical outcome [9, 14, 29, 46]. Exemplary, Weiler et al. compared six different biodegradable IFS to a titanium IFS, finding mean load to failure values ranging from 439.2 to 830.2 N for the biodegradable implants, compared to 821.6 ± 129.8 N for the titanium implant [46]. These results, although not directly comparable due to differences in biomechanical testing and experimental setup, are similar to the findings of the present study, which reported load to failure of 683.9±116.5 N for the tested Mg-IFS. This suggests that the tested WE43 Mg-IFS possesses adequate primary stability for ACL reconstruction, comparable to that of other biodegradable IFS.

The integration of a tendon graft into the bone tunnel is known to undergo different phases during which the graft remodels and attaches to the tendon-bone interface [35, 36, 45]. The choice of implant for fixation is known to influence the tendon-bone integration and biomechanical properties during the course of healing [13, 44, 45, 48]. Magnesium IFS were previously shown to improve tendon-bone healing in multiple small animal studies, with favorable results in comparison to both titanium IFS as well as extracortical tendon fixation [8, 11, 42, 43]. Despite these possible advantages, previous generations of magnesium implants suffered from unpredictable speed of degradation [23], as well as intraosseous osteolysis and formation of gas caverns, caused by nitrogen release during corrosion of the implant [25, 30, 41]. Even though degradation speed of newer generations of Mg -IFS has been controlled by alloying magnesium with other metals [22-24], and surface treatment like ceramization, or plasma electrolytic oxidation (PEO) [21, 34], surgeons should still be aware of these possible disadvantages. The Mg-IFS used in this study were made from a WE43MEO alloy, containing Yttrium, Zirconium, and rare earths. WE43 alloys were previously shown to start degradation between the 12th and 16th week in a small animal model, and exhibited favorable degradation kinetics, in comparison to a PLLA implant [19, 20]. PEO coating, as used with the tested Mg-IFS, was shown to decrease the degradation rate and hydrogen gas release in fluid immersion experiments [3, 4]. However, relevant large animal studies and clinical trials are required, to determine in-vivo degradation kinetics, before routinely using the newer generation Mg-IFS for aperture fixation in ACL reconstruction.

This biomechanical study has several limitations to mention. Previous studies showed that the porcine knee anatomy and ligament biomechanics are adequately similar to humans, making it a frequently used model to assess biomechanical primary stability of orthopedic implants [10, 12, 17, 31]. However, bone density in the porcine model is significantly higher in comparison to humans [1]. Since load to failure of IFS fixation was shown to be dependent on the bone mineral density, this could have biased the load to failure towards higher values [6, 28]. Furthermore, freezing and thawing of the porcine knees might have influenced the mechanical properties of the specimens [18]. A Bc-IFS was used as control group in the present study, to compare Mg-IFS to another biodegradable implant. Biodegradable IFS were shown to provide comparable fixation strength, in comparison to titanium IFS [14, 46]. The IFS utilized in this study have different geometries, most prominently different thread shapes and thread pitches, which could have possibly influenced the biomechanical properties of the screws. However, both geometries reflect implants currently available in clinical practice, and thread shape was shown not to influence biomechanical properties of interference screws [17]. The comparisons between the implants are limited to the timepoint zero. Possible influences of the different materials on tendon-bone healing cannot be deduced. Therefore, clinical trials or large animal models are needed to investigate the influence of the material on the course of healing after ACL reconstruction.

Conclusion

Magnesium IFS show comparable biomechanical primary stability in comparison to biocomposite IFS and may therefore be an alternative to contemporary biodegradable IFS.

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Informed consent

Not applicable.

Social media summary

Biomechanical stability of biodegradable magnesium interference screws for anterior cruciate ligament reconstruction was found to be comparable to a biocomposite interference screw, in an investigation performed at @ UK_Muenster.

Authors' contributions

All authors have made substantial contributions to the conception and design of the article, acquisition of data, drafting the article or revising it critically for important intellectual content. All authors read and approved the final manuscript.

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Data will be made available on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was waived by the institutional review board of our institute.

Competing interests

The authors declare that we have no potential confict of interest.

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