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ORIGINAL ARTICLE

Biomechanical comparison of pure magnesium interference screw and polylactic acid polymer interference screw in anterior cruciate ligament reconstruction—A cadaveric experimental study

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Q5 **Summary** Polylactic acid polymer interference screws are commonly used in anterior cruciate ligament (ACL) reconstructions, especially in proximal tibia fixation. However, several concerns have been raised, including the acid products during its degradation *in vivo*. In recent years, biodegradable magnesium (Mg)-based implants have become attractive because of their favourable mechanical properties, which are more similar to those of natural bone when compared with other degradable materials, such as polymers, apart from their alkaline nature during degradation. We developed a pure Mg interference screw for ACL reconstruction. In the present study, 24 fresh cadaver knees were used to compare the mechanical properties of pure Mg interference screws and polylactic acid polymer interference screws for ACL reconstruction via their application on the proximal tibia tested using specific robotics. Results showed that the pure Mg interference screw group showed similar mechanical stability to the polylactic acid polymer interference screw group, implying comparable postoperative fixation effects.

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As there are no commercially available Mg-based interference screws for ACL reconstruction clinically and the *in vivo* degradation of pure Mg promotes bone formation, our cadaveric study supports its clinical tests for ACL reconstruction.
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Introduction

Anterior cruciate ligament (ACL) rupture is one of the most common injuries, which may result in many secondary injuries around knee joints. ACL reconstruction, with a success rate >90% [1], has been the most effective way to treat ACL rupture. The optimal initial graft fixation and the properties of materials are very important in ACL reconstruction. Several years ago, permanent metal interference screws, which provided strong initial fixation, were used in ACL reconstruction [2]. However, the rigid metal interference screws showed several disadvantages, such as the risk of graft damage and accordingly fragility in reconstructions [3], interference with imaging modalities (e.g., magnetic resonance imaging), and requiring an undesirable second operation for implant removal [1]. The interference screws made of permanent metal(s) also increased difficulty in ACL revision [4].

To overcome these limitations of metal screws, biocompatible and biodegradable polylactic acid polymer interference screws were developed for popular ACL reconstruction that provided strong initial fixation and minimal graft damage [5]. A meta-analysis also indicated that there were no clinical difference between the metal interference screws and the polylactic acid polymer interference screws [6]. For regeneration of the soft tissue–bone interface in ACL reconstruction, biodegradable polymer interference screws have become a popular choice as they can be engineered to possess multiphasic properties. However, polymer materials may also have limitations. When poly-L-lactic acid interference screws were used for graft fixation during ACL reconstruction, the devices were reported to be mechanically weaker than metallic devices and often fractured during implantation [7]. Furthermore, according to Johnston et al's [8] study, the interference screws were slowly absorbed over time; 4 years after ACL reconstruction, only 80–90% of screws were completely absorbed. At 5 years follow-up, 29% of patients showed complete ossification of the screw tract in the femur versus 34% in the tibia [8]. Another study also showed poor result that even no bony replacement has taken place up to 24 months postoperatively, and at the same time, after degradation, the bone did not regenerate and the tunnel left was not filled [9]. A long-term follow-up clinical study showed that as the polymer mass reduced, it was replaced by a relatively avascular fibrous tissue containing macrophages, and having an occasional multinucleated giant cell on the implant surface as polymer degradation created an acid local environment [10]. Despite being satisfactory clinically, it would not be an ideal implant material for ACL reconstruction.

In recent years, degradable metals, such as magnesium (Mg) and its alloys, have been intensively investigated preclinically [11,12], and clinical trials were also conducted to study their potential orthopaedic applications [1,13,14], as they possess desirable mechanical properties, good biocompatibility, and biodegradability [15,16]. The lower moduli compared with permanent metals such as titanium-based materials make the mechanical properties of pure Mg or its alloys closer to those of the cortical bone, which could reduce the level of stress shielding effects during fracture fixation [17]. At the same time, the Mg-based implants developed good mechanical properties; the ultimate loads of the graft were comparable to those when using titanium interference screws on a goat model and supported the use of Mg-based interference screws for fixation of the replacement graft in ACL reconstruction [18].

The history of biodegradable Mg-based implants in orthopaedics goes back to the first half of the 20th century. It was Payr who first introduced the use of Mg for joint arthroplasty, fracture fixation with Mg wire, and intramedullary rods [19]. Recently, investigators have reached a consensus that the degradation of Mg *in vivo* promoted soft tissue repair and new bone formation while being gradually and completely absorbed over time [20].

Magnesium is biodegradable and its degradation products include Mg ions, alkaline environment, and hydrogen [20]. In recent years, biodegradable Mg-based implants developed for orthopaedic applications have become increasingly attractive as magnesium's initial mechanical properties (e.g., Young's elastic modulus) are similar to those of natural bone, with higher stability and Young's modulus compared to other degradable materials such as polymers [21]. There are extensive clinical studies to support its *in vivo* applications [22,23]. To date, there have been three clinical trial studies reported in Germany for its indications [1], in Korea for its applications [13], and most recently in China for its application in fixing bony flap in femoral head osteonecrosis [14] based on relevant preclinical experimental models. ACL reconstruction is a clinical routine and has considerable potential for indication of Mg-based interference screws [24,25]. Accordingly, a few preclinical studies have been conducted on Mg-based interference screws to test their *in vivo* potential using animal models such as rabbits [26,27]. We have developed pure Mg interference screw for human application. However, even prior to clinical applications, cadaveric study is essential to confirm its mechanical properties after ACL reconstruction surgery. Accordingly, the aim of the study was to compare the mechanical properties of our pure Mg interference screws and