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Magnesium alloys as a biomaterial for degradable craniofacial screws

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ABSTRACT

Recently, magnesium (Mg) alloys have received significant attention as potential biomaterials for degradable implants, and this study was directed at evaluating the suitability of Mg for craniofacial bone screws. The objective was to implant screws fabricated from commercially available pure Mg and alloy AZ31 in vivo in a rabbit mandible. First, Mg and AZ31 screws were compared to stainless steel screws in an in vitro pull-out test and determined to have a similar holding strength (~40 N). A finite-element model of the screw was created using the pull-out test data, and this model can be used for future Mg alloy screw design. Then, Mg and AZ31 screws were implanted for 4, 8 and 12 weeks, with two controls of an osteotomy site (hole) with no implant and a stainless steel screw implanted for 12 weeks. Microcomputed tomography was used to assess bone remodeling and Mg/AZ31 degradation, both visually and qualitatively through volume fraction measurements for all time points. Histological analysis was also completed for the Mg and AZ31 at 12 weeks. The results showed that craniofacial bone remodeling occurred around both Mg and AZ31 screws. Pure Mg had a different degradation profile than AZ31; however, bone growth occurred around both screw types. The degradation rate of both Mg and AZ31 screws in the bone marrow space and the muscle were faster than in the cortical bone space at 12 weeks. Furthermore, it was shown that by alloying Mg, the degradation profile could be changed. These results indicate the promise of using Mg alloys for craniofacial applications.

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1. Introduction

Magnesium (Mg) alloys have recently been a focus of degradable implant research. Results to date are demonstrating great promise for Mg alloys to regenerate both hard and soft musculoskeletal tissues [1–30], which is valuable for engineering degradable craniofacial implants. Craniofacial implants, e.g. plates and screws, are used in procedures such as osteotomies, bone graft stabilization during reconstructions, and for trauma reconstruction [31]. Previously, craniofacial bone plates and screws have been fabricated from stainless steel, vitallium, chromium–cobalt and other metal alloys [31]. Titanium has become the preferred permanent metal of choice due to its ability to osteointegrate [32]. However, it is estimated that 10–12% of craniofacial implants are removed due to infection, exposure, pain and discomfort [32]. Resorbable polymer plates and screws are becoming more popular for craniofacial implants because they allow for fixation and stabilization but are not permanent [32]. However, biodegradable polymers, such as poly-L-lactide, are biomechanically inferior to their metal counterparts [33]. Two other shortcomings of the polymer implants include the need for a heating device to provide implant malleability and the need to tap the bone prior to screw placement [34]. Thus degradable metals have both the strength and the ability to degrade, unlike their polymer and permanent metal counterparts. In particular, much research has been done on the degradable metal Mg [1–30,35–38].

Many previous studies have looked at the effect of Mg alloys on long bones [1–30], but the effect of Mg alloys on craniofacial bone has not been thoroughly studied. Mg alloy rods and cylinders have been implanted into guinea pig femurs [21,22], rat femurs [26,29], and rabbit femurs [8,11,15–18,20,23–25,27,28,30] and tibias [1,5–7,10,12–14]. Mg alloy screws have been tested in vitro [35–38] and have also been implanted into rabbit femurs [18] and tibias [3,4,9], as well as sheep hip bones [2,19]. Studies of inflammatory and immune response show that degrading Mg scaffolds show good biocompatibility and react in vivo with an appropriate inflammatory host response [1,4,11,20,24–26,29,30]. It has been shown that

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degrading Mg implants promote bone formation [2–6,8,11–14,16,18,19,21–23,26–30] and osteoblastic activity [11,19,21,23,26,29]. In these previous studies several different types of Mg alloy have been implanted: specifically the commercially available alloy AZ31 (2.5–3.5 wt.% Al, 0.6–1.4 wt.% Zn, 0.2–1.0 wt.% Mn) has been previously tested in bone in vivo as rods [21,28] and as screws [2,19]. All four studies revealed new bone formation around the AZ31 implants [2,19,21,28]. One of the studies showed that the corrosion behavior of AZ31 screws differed depending on their location in the original tissue [19]. Bone formation was noted around the Mg rods, but not in the surrounding soft tissue [21]. There was also little change in the blood composition and no inflammation from the degrading implant [28].

Long bones and flat bones, such as the craniofacial bones, form differently during development resulting in differences in the organic and inorganic phases [39]. Long bones and craniofacial bones also undergo different loading. Long bones can undergo extensive loading, as can the mandible, but the skull normally undergoes minimal loading. The blood flow in various regions of the body is also different. All of these factors could affect the degradation rates of the Mg alloys and also the bone regeneration in these areas. An investigation should be conducted to see if there are differences in how Mg behaves in the craniofacial region compared to the long bones.

As a first step towards improving degradable craniofacial plates and screws, this study aimed to evaluate the use of Mg as a degradable biomaterial. The objective of this study was therefore to implant screws fabricated from commercially available pure Mg and Mg alloy AZ31 in vivo in a rabbit mandible. First the pure Mg and AZ31 screws were compared to commercially available stainless steel screws in an in vitro pull-out test to determine the holding strength. A custom finite-element code was then developed to simulate these pull-out tests on a computer. Factors contributing towards the pull-out strength were determined using this computational model. Then, the two types of Mg screws were implanted for three time periods (4, 8 or 12 weeks). Two controls consisted of only osteotomies (holes) with no implant or a stainless steel screw implanted for 12 weeks. Microcomputed tomography (microCT) was used to assess bone remodeling and Mg degradation for all time points, and histological analysis was also performed at 12 weeks.

2. Methods

2.1. Screw fabrication

Bone screws were designed for the rabbit mandible and fabricated from commercially available pure Mg and AZ31 purchased from Goodfellow (Oakdale, PA). The pure Mg was 99.9% pure, and the AZ31 alloy contained 2.5–3.5 wt.% Al, 0.6–1.4 wt.% Zn and 0.2–1.0 wt.% Mn with the remainder being Mg. Similarly sized, commercially available stainless steel screws were purchased from Small Parts (Seattle, WA). The screws were approximately 1 mm in diameter with M0.25 threads and the shaft was approximately 2 mm in length (Fig. 1A).

The Mg and AZ31 screws were fabricated by the University of Pittsburgh Swanson Center for Product Innovation (SCPI) using computerized numerical control machining. After fabrication, the screws were sonicated in isopropanol to remove any residual debris. The screws then underwent a stress-relief heat treatment at 205 °C for 90 min in an argon atmosphere. Next, the screws underwent three cycles of sonication in isopropanol for 3 min each, following which they were allowed to air dry. All of the screws were stored in airtight containers until documentation and use in this study. Documentation included weighing and imaging each individual screw.

2.2. In vitro testing and finite-element modeling

2.2.1. Pull-out test

A mechanical test was designed to compare the holding strength of the pure Mg and AZ31 screws to stainless steel screws. A material testing system was set up for complete axial pull-out tests (Fig. 2A) (MTS Insight, MTS Systems, Eden Prairie, MN). Synthetic bone made of solid rigid polyurethane foam (ASTM F-1839-08) from Sawbones (a division of Pacific Research Laboratories, Inc., Vashon, WA) was used as the control material for the pull-out tests. Screws were placed in the foam after the holes were predrilled and tapped. A testing rate of 5 mm min^{-1} was used according to ASTM standard F543–07. The maximum force needed to release the screw from the foam was recorded for each screw. A one-way ANOVA with Tukey's post hoc test was used to compare the results with a statistical significance set at $P < 0.05$.

2.2.2. Computational techniques

Custom three-dimensional (3-D) finite-element (FE) software was developed to simulate experimental pull-out tests and study the effect of various mechanical properties on the observed pull-out strength. Synthetic bone was modeled as a cylinder with a diameter of 5 mm with the screw inserted along the longitudinal axis (Fig. 2Bi). The screw and the cylindrical bone were discretized with 3731 and 14254 four-noded tetrahedral finite elements, respectively. Details of the finite-element discretization are shown in Fig. 2Bii. The outer surface of the bone was held rigidly in place with fixed boundary conditions. The diameter of the cylinder was chosen such that boundary effects on the stress field were minimal in the vicinity of the screw. All finite-element nodes on the surface of the screw head were given a prescribed displacement Δ of 5 mm min^{-1} to mimic the experimental loading condition. The Young's modulus of the synthetic bone was assumed to be 0.5 GPa while that for the screw was varied to simulate different materials. The interface of the screw and the synthetic bone was

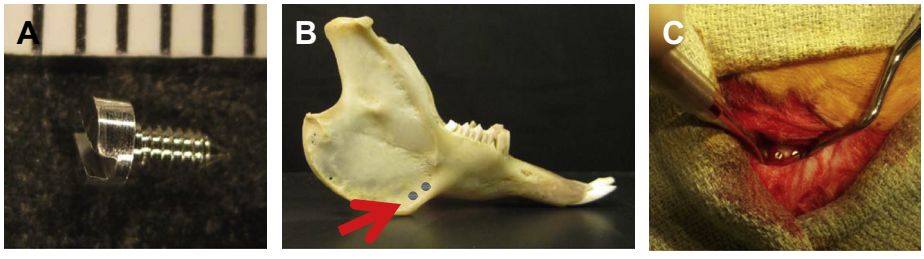

Fig. 1. Mg alloy craniofacial bone screws. (A) Picture of a screw. The screws were machined from commercially available pure Mg and AZ31 stock rods. (B) Screw implantation location in the rabbit mandible. The screws were placed along the lower edge of the mandible just posterior to the molars. (C) View of two Mg alloy screws implanted during surgery.

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