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Comparative Study about Degradation of High-purity Magnesium Screw in Intact Femoral Intracondyle and in Fixation of Femoral Intracondylar Fracture

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Bone screws encounter complex mechanical environment in fracture fixation of weight-bearing bone. In the present study, high-purity magnesium (HP Mg) screws were applied in fixation of rabbit femoral intracondylar fracture with 3 mm gap. In the control group, HP Mg screws of the same design were implanted at corresponding position of contralateral leg. At 4, 8 and 16 weeks after surgery, retrieved femurs went through micro-computed tomography (micro-CT) scanning and hard tissue processing. Under mechanical stress involved in fracture fixation, bending of screw bolt was observed at the portion exposed to facture gap at 4 weeks. Then local corrosion at the same portion was detected 16 weeks after surgery, which indicated the accumulation effect of mechanical stress on Mg corrosion. HP Mg screws in the fracture group had no significant difference with the control group in screw volume, surface area, surface-to-volume ratio (*S*/*V*). And peri-implant bone volume/tissues volume (BV/TV) and bone volume density (BMD) in the fracture group was comparable to that in the control group. Furthermore, histological analysis showed new formed bone tissues in fracture gap and fracture healing 16 weeks after surgery. Under mechanical stress, HP Mg screw suffered bolt bending and local corrosion at the portion exposed to fracture gap. But it had no influence on the integral corrosion behaviors, osseointegration of HP Mg screw and the fracture healing. Therefore, HP Mg screws possessed good potential in fracture fixation of weight-bearing bones.

1. Introduction

Bone screws are routinely used in fracture fixation, bone graft stabilization and osteotomies with fragment fixation[1]. Traditional materials for bone screws are permanent metals, such as titanium and stainless steel, and biodegradable polymers like poly L-lactic acid (PLLA)[2]. Metallic screws encounter stress shielding effect and second removal surgery[3]. And biodegradable screws are biomechanically inferior to their metal counterparts and are limited in load-bearing conditions[4]. Magnesium (Mg)-based materials are biodegradable *in vivo* and are considered to be clinically safe. Mg devices possess desirable biomechanical properties close to natural bone and are suitable for orthopedics application even in weight-bearing bone[5]. Furthermore, the degradation rate of Mg materials depends on its composition and processing techniques[6]. Therefore, Mg is one promising biodegradable material for bone screws.

Mg screws are the focus of biodegradable implant research in recent years[7–10]. Bone screws fabricated from various Mg alloys and pure Mg possess high initial mechanical strength, and several Mg screws perform stable mechanical retention with uniform corrosion behaviors *in vitro*[11,12]. However, the corrosion behaviors and related mechanical retention *in vivo* perform differently from that of *in vitro*. Waizy et al. observed that the maximum pull-out force of MgCa0.8-screws decreased by 30% after 96 h in Hank's solution with a flow rate corresponding to the blood flow in natural bone[11]. In further research, Erdmann et al. confirmed that the pull-out strength of MgCa0.8 screws in the tibial shaft of adult rabbits decreased by 34.4% six weeks after surgery[13]. The differences between

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in vitro corrosion behaviors of HP Mg screws and that of *in vivo* were consistent with previous reports. Martinez Sanchez et al. correlated the average corrosion rates of 19 Mg alloys (MgCa0.8, AZ31, and so on) and pure Mg in bone implantation with those in corrosive solution, and found that the corrosion rate *in vivo* was actually described by a smaller range of values than the *in vitro* corrosion rate[14]. The physico-chemical environments are strong reasons for the differences. Considering the use of Mg as orthopedic screws, there remains a lack of data assessing the effect of mechanical stress involved in fracture fixation on the degradation behaviors of Mg screws.

As orthopedics fixation devices, Mg screws should provide a rigid initial fixation under a functional load and it will be gradually replaced by biological fixation of bone tissues with step-by-step degradation. Taken screws and bone fragments as a mechanical system, the screw in fixation of fracture is subjected to a combination of axial, bending and torsional loads[15]. Furthermore, the magnitude and direction of combined loads are changeable in daily activities. Mechanical loads could accelerate the corrosion rate of biodegradable Mg[16,17], and reversely, the corrosion behaviors of orthopedics screws could affect the mechanical retention and fracture fixation[18,19]. Rigid fixation and anatomic reduction should remain in the fracture healing process[20]. Otherwise, severe complications occurred in the rehabilitation, i.e. joint instability, arthritis deformans or function disorder[21]. Therefore, corrosion behaviors of biodegradable Mg screws under mechanical stress involved in fracture fixation on the degradation behaviors should be evaluated in fractured animal models.

In the present study, we aimed to analyze the corrosion behaviors of Mg screws under mechanical stress in fracture fixation and whether Mg screws were suitable for fracture fixation of weight-bearing bone. The primary goal was to evaluate the degradation of HP Mg screw under mechanical stress conditions and to test its influence on osseointegration and fracture fixation. We performed comparative analysis of high-purity (HP) Mg screws in intact femoral intracondyle and in fixation of femoral intracondylar fracture. 4, 8 and 16 weeks after surgery, the femurs were retrieved for further analysis. Volume, surface area and surface-to-volume ratio (*S*/*V*) of HP Mg screws were evaluated by micro-computed tomography (micro-CT) analysis, and the radiological parameters for osseointegration including bone volume/tissues volume (BV/TV) and bone volume density (BMD) were calculated. Furthermore, fracture healing process was evaluated using histological evaluation.

2. Experimental

2.1. Screw preparation

HP Mg (99.99 wt% Mg; 0.002 wt% Si; 0.0015 wt% Fe; 0.0008 wt% Al; 0.0008 wt% Mn; 0.0002 wt% Ni; 0.0003 wt% Cu) screws were supplied by Suzhou Origin Medical Technology Co. Ltd. The materials, processing and designs of Mg screws were in consistent with previous study[12]. In brief, as-casted HP Mg bars were hot extracted with a ratio of 148:1 at 200 °C, rolled from φ8.2 mm to φ7.5 mm at room temperature and heat-treated at 160 °C to relieve the residual stress. Before implantation, HP Mg screws with 2.5 mm in diameter and 10 mm in length were rinsed in acetone, ethanol and distill water successively, and also sterilized with 29 kGy of ^{60}Co radiation.

2.2. Animal studies

12 skeletally matured New Zealand white rabbits were used in the experiment. Animal procedures were approved by the Animal Care and Experiment Committee of Shanghai Jiao Tong University Affiliated Sixth People's Hospital. Both hind legs were used with right side as the fracture group and left side as the control group. After anesthetization and sterilization, a 5 cm longitudinal lateral parapatellar incision exposed the femoral intracondyle. In the fracture group, bone lesion was created on femoral intracondyle using a 3 mm-blade hand hold saw. And HP Mg screw was implanted in fixation of femoral intracondylar fracture. In the control group, a bone screw was implanted into intact femoral intracondyle without lesion. The wound was closed in layers by silk suture (Fig. 1). After anabiosis, the rabbits were confined to individual cages without immobilization. Antibiotic administration was conducted daily within one week after surgery. In addition, general behavior, movement, incision healing, and food and water intake were checked throughout the experimental period.

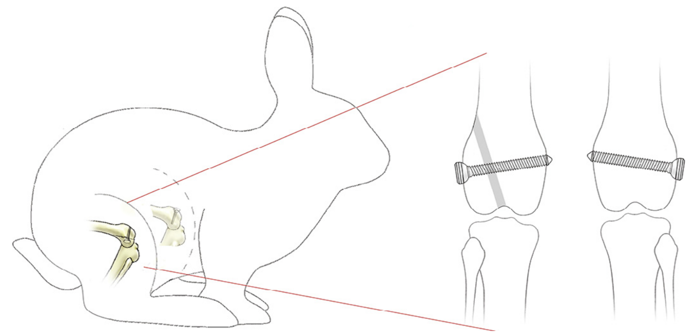

Fig. 1. Diagrammatic drawing showing that HP Mg screws in fixation of femoral intracondylar fracture (right leg) and its implantation in the intact femoral intracondyle (left leg). The gray zone in the right leg marks the 3 mm fracture gap.

2.3. Micro-CT measurements

The intact distal end of rabbit femur was harvested 4, 8 and 16 weeks after surgery. Micro-CT scanning was performed to analyze the *in vivo* corrosion behaviors and osseointegration of HP Mg screws. All samples were scanned with Laboratory Micro-CT Scanner eXplore RS 80 (GE Healthcare, Little Chalfont, UK) setting as follows: 80 kV, 450 μA, 400 ms and a voxel size of 45 μm. Three-dimensional (3D) remodeling of rabbit femoral intracondyle was conducted using the medical image processing software Mimics 15.0 (Materialise NV, Leuven, Belgium). Screw volume (*V*, mm^3), surface area (*S*, mm^2) and surface-to-volume ratio (*S*/*V*, mm^{-1}) were calculated using MicroView 2.2 Advanced Bone Analysis Application software (GE Health Systems, Waukesha, WI, USA)[22]. Volume and surface area were conventional parameters for the integral corrosion behaviors of Mg devices. *S*/*V* was used as a measurement for local corrosion on screw surface, and high *S*/*V* values reflected severe localized corrosion attack and fragmented implant surface topography. For osseointegration parameters, BV/TV and BMD of peri-implant bone tissues were performed according to previous reports[23].

2.4. Histological analysis

After immersion in 4% neutral buffered formalin for 48 h, the bone samples underwent hard tissue process. Briefly, femur samples were dehydrated in 70%, 95%, and 100% ethanol, respectively for 3 days. After immersion in xylene for 3 days, the bone samples were embedded in methyl-methacrylate for about 8 weeks. The embedded samples were cut into sections with a thickness of 200 mm. Then sections were micro-ground to a thickness of 50–70 mm. All thin sections were Van Gieson stained. Under optical microscopy (Leica DM2500, Leica, Germany), the fracture healing process was observed.

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