

Chronical Control Degradation of Magnesium Alloy Screws by Hydrophobic Composite Coating: Long-term Animal Study and Clinical Results

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INTRODUCTION:

Magnesium alloys are biodegradable metallic materials that have been applied in orthopedics, such as magnesium alloy bone screws. Their degradable nature eliminates the need for secondary removal surgery, thereby reducing patient trauma [1]. Additionally, the release of magnesium ions can promote bone formation and support fracture healing. However, magnesium alloy screws in clinical use still face the challenge of rapid degradation. Excessive hydrogen gas accumulation may impair bone healing, leading to premature loss of mechanical stability before fracture consolidation. Here we report a composite coating technology using Parylene C. Parylene C (poly-chloro-p-xylylene), a coating material with excellent biocompatibility [2][3], uniform density, and hydrophobic barrier properties, has the potential to effectively regulate the degradation rate of magnesium alloys. This study compared the in vivo degradation behavior of Parylene composite-coated and uncoated magnesium alloy screws in an animal model, aiming to evaluate the ability of the Parylene composite coating to reduce degradation rate and hydrogen gas evolution. We demonstrated that the Parylene composite coating could effectively control the degradation rate of magnesium alloy screws and reduce the rate of hydrogen gas release. Early results of clinical trial were also demonstrated.

METHODS:

Magnesium alloy screws (Mg-Zn-Zr-Mn; diameter 4.8 mm, length 24 mm) were provided by Suzhou InnoTech Medical Technology Co., Ltd. Two types of implants—Parylene composite-coated screws and uncoated magnesium alloy screws—were bilaterally implanted into the proximal tibiae of goats (Fig. 1), with the uncoated screw placed in the left leg and the coated screw in the right leg. Fifteen goats (body weight 45 ± 5 kg) were obtained from Shanghai Mincal Medical Research Co., Ltd, and assigned to five time points (3, 6, 12, 24, and 52 weeks; n=3 per time point). Blood analysis, micro-computed tomography (Micro-CT), and histological evaluation were conducted to assess hematologic changes, in vivo degradation behavior, hydrogen gas evolution, and inflammatory response associated with the Parylene composite coating. Statistical significance was set at p < 0.05.

RESULTS SECTION:

Micro-CT analysis showed that the degradation rate of Parylene composite-coated screws was markedly lower than that of uncoated screws. The remaining volumes of Parylene composite-coated screws at 24 and 52 weeks were 92.28 and 79.68, respectively, whereas uncoated screws had remaining volumes of 85.09 and 50.65 at the same time points (Fig. 2). From 3 to 24 weeks, uncoated screws exhibited visible hydrogen gas accumulation around the implant, while Parylene composite-coated screws maintained their volume and shape with no detectable gas pockets, favoring bone integration (Fig. 2). At 52 weeks, uncoated screws showed fracture and severe degradation, whereas coated screws remained intact. Blood counts, serum biochemistry, and electrolyte levels were within normal ranges at all time points, with no systemic adverse reactions (Fig.3). Histological evaluation revealed that coated screws exhibited minimal degradation within 24 weeks, and no inflammatory cell infiltration was observed in surrounding tissues. Collectively, these findings indicate that Parylene composite coating effectively reduces degradation rate and gas production, and thus the implants can maintain mechanical stability during early bone healing period, and are gradually resorbed afterwards, satisfying the dual requirements of stability and biocompatibility in bone repair. Clinical trial (n = 188; 113 males, 75 females) was also conducted and early results demonstrated the effective control of implant degradation by our composite coating (Fig. 3).

DISCUSSION:

This study demonstrates that Parylene composite coating can effectively regulate the degradation process of magnesium alloy screws, enabling slow magnesium ion release, minimizing hydrogen gas accumulation, and creating a favorable microenvironment for fracture healing. In this animal model, coated screws remained largely intact within 24 weeks, providing stable support for bone healing. These findings suggest that our composite coating using Parylene can effectively control the degradation of magnesium alloy in vivo, and hold great potential for clinical translation. Further studies are undergoing to evaluate their performance in human bone healing and long-term degradation behavior.

SIGNIFICANCE/CLINICAL RELEVANCE:

Parylene composite coating exhibits excellent adhesion to magnesium alloy screws, significantly reducing degradation rate, controlling gas evolution, and maintaining desirable fixation performance. This technology holds promising application potential for orthopedic implants.

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IMAGES AND TABLES:

