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Research Paper

# Do biodegradable magnesium alloy intramedullary interlocking nails prematurely lose fixation stability in the treatment of tibial fracture? A numerical simulation

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ABSTRACT

Intramedullary interlocking nailing is an effective technique used to treat long bone fractures. Recently, biodegradable metals have drawn increased attention as an intramedullary interlocking nailing material. In this study, numerical simulations were implemented to determine whether the degradation rate of magnesium alloy makes it a suitable material for manufacturing biodegradable intramedullary interlocking nails. Mechano-regulatory and bone-remodeling models were used to simulate the fracture healing process, and a surface corrosion model was used to simulate intramedullary rod degradation. The results showed that magnesium alloy intramedullary rods exhibited a satisfactory degradation rate; the fracture healed and callus enhancement was observed before complete dissolution of the intramedullary rod. Delayed magnesium degradation (using surface coating techniques) did not confer a significant advantage over the non-delayed degradation process; immediate degradation also achieved satisfactory healing outcomes. However, delayed degradation had no negative effect on callus enhancement, as it did not cause signs of stress shielding. To avoid risks of individual differences such as delayed union, delayed degradation is recommended. Although the magnesium intramedullary rod did not demonstrate rapid degradation, its ability to provide high fixation stiffness to achieve earlier load bearing was inferior to that of the conventional titanium alloy and stainless steel rods. Therefore, light physiological loads should be ensured during the early stages of healing to achieve bony healing; otherwise, with increased loading and degraded intramedullary rods, the fracture may ultimately fail to heal.



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## 1. Introduction

Intramedullary interlocking nailing (IMN) is a modern technique used for long bone fracture treatment, providing satisfactory axial stability and rotational stability (Eveleigh, 1995). IMN causes only minor surgical damage and allows for early load bearing; thus, its use is becoming increasingly popular. The disadvantage of using an IMN device is that a secondary operation may be needed to remove the rod and screws, during which complications could occur such as locking screw breakage, difficulty retrieving the intramedullary rod, or bone refracture (Ieong and Nathwani, 2014; Boerger et al., 1999). Moreover, cases have been reported in which the IMN may have induced excessive stability and caused nonunion or delayed union owing to insufficient mechanical stimulation. "Dynamization" is sometimes performed, during which all or some of the locking screws are removed to introduce increased axial and rotational movements. This approach allows for more mechanical stimulation such that eventual fracture union is expected (Wu et al., 2013; Wu, 1997). Using a degradable IMN device can have obvious advantages: it does not require explantation surgery, and a progressive dynamization occurs naturally as the device degrades.

Many biodegradable materials are currently available, such as biodegradable polymers, biodegradable ceramics, and biodegradable metals (Bakhsheshi-Rad et al., 2014; Zhu et al., 2016). These materials are used in different scenarios, such as fabricating porous coatings on joint prostheses, manufacturing fixation devices, and functioning as drug delivery vehicles. Magnesium and Mg-based alloys are classified as biodegradable metals. Magnesium itself is an essential nutrient in the human body and is abundant in bone tissue. It exhibits favorable biocompatibility and osteoconductivity and is deemed a promising material for degradable fixation devices (Witte et al., 2005). Rössig et al. (2015) reported an IMN system composed of biodegradable magnesium alloy, LAE442, and tested it *in vivo* in a sheep model. Windhagen et al. (2013) used MAGNEZIX® (MgYREZr) screws in human patients to treat hallux valgus and reported satisfactory outcomes. Although new magnesium IMN devices are currently being developed and tested (Krämer et al., 2016), biodegradable IMN devices are not yet clinically available. Concerns exist that magnesium alloy may degrade too rapidly, and that the device may lose its mechanical strength and integrity prior to fracture union. In addition, the relatively low Young's modulus of magnesium may result in insufficient fixation stability compared to conventional orthopedic materials, *e.g.*, titanium alloy and stainless steel.

To further explore these concerns, we employed numerical simulations in addition to clinical and experimental investigations. A mechano-regulatory model was introduced to simulate the primary healing process (Isaksson et al., 2008). In this model, mesenchymal stem cell differentiation is determined by a "mechanical stimulus", which is represented by the solid matrix shear strain and interstitial fluid flow velocity. Using this model, predictions on healing patterns using different fixations and under different loadings could be made. After primary ossification, bone tissue further adapts itself to suit the local mechanical environment, and its apparent Young's modulus can increase from 100 MPa (newly formed woven bone) to over 15 GPa (cortical bone). Thus a bone-remodeling model was used to calculate the changes in bone density and Young's modulus to supplement the healing model (Liu and Niebur, 2008). Furthermore, models representing magnesium degradation were also introduced (Gastaldi et al., 2011; Grogan et al., 2011), and corrosive degradation and mechanical destruction were considered in these models. Based on models of primary healing, bone remodeling and magnesium degradation, the biomechanical and mechano-biological behaviors of an IMN device for the treatment of tibial fracture can be studied.

In this study, a tibial diaphyseal fracture fixed with an IMN device was modeled. The intramedullary rod degradation, fracture healing, and bone remodeling were simulated. The highest degradation rate derived from previous studies was used to clarify whether magnesium alloy intramedullary rods degrade too rapidly. Various degradation-initiating cases were assumed to represent the protective effect of surface coating techniques. Moreover, conventional orthopedic materials, *i.e.*, titanium alloy and stainless steel, were used as controls for evaluating the biomechanical performance of the Mg IMN device.

## 2. Materials and methods

### 2.1. *Fracture healing algorithm and result assessment*

To simulate fracture healing over one year, a numerical model composed of two components was used. The first component was a fracture-healing algorithm that calculated the primary healing process. The second component was a bone-remodeling algorithm that calculated bone enhancement/degradation after primary ossification. In the fracture-healing algorithm, a mechanical stimulus was assumed to regulate mesenchymal stem cell differentiation which subsequently determined the somatic cell and tissue phenotypes. The mechanical stimulus was calculated as $S = \gamma/a + v/b$, where $\gamma$ is the solid matrix shear strain, $v$ is the interstitial fluid flow velocity, and a and b are empirical constants (Isaksson et al., 2008; Lacroix and Prendergast, 2002). The magnitude of S determines the cellular differentiation phenotypes, and its thresholds are shown in Fig. 1A. Basic cellular activities, such as migration, proliferation and apoptosis, were calculated. The equations and parameters used were based on previous studies (Isaksson et al., 2008).

After primary ossification, newly formed bone tissue will adapt its structure to suit local mechanical conditions. Strain was used to regulate the remodeling process (Turner et al., 2005; McNamara and Prendergast, 2007), as shown in Fig. 1B. A "lazy zone" ($1500\mu\varepsilon \pm 3\%$) (McNamara and Prendergast, 2007) of strain was established first. When the local bone strain is within this zone, bone deposition and resorption are dynamically balanced; thus, no apparent property change will be present in the bone. When the bone strain exceeds the "lazy zone", bone deposition will outperform resorption, and the bone tissue will become stronger and stiffer, and *vice versa*. The remodeling rate is determined by $d\rho/dt = C_{re} \cdot S_{re}$, where