Development of an Advanced In Silico Framework for Predicting Bone Regeneration and Biodegradable Implant Degradation Following Reconstructive Surgery

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Abstract

Biodegradable magnesium (Mg) implants offer a promising alternative to permanent metallic implants for fracture fixation, but their degradation rate must be synchronized with the bone regeneration process. To date, these two processes have generally been modeled separately, despite occurring simultaneously and influencing one another.

This study developed an in-silico framework based on the finite element method (FEM) and Python, integrating two models: (1) a mechanoregulation model of callus tissue differentiation and (2) a diffusion-based Mg implant degradation model.

The degradation framework and the integrated framework were successfully developed and tested using a simplified long-bone model. The framework demonstrated its ability to simulate callus maturation, tissue stiffening, implant degradation, and load redistribution. In vivo rabbit femur data were acquired for subsequent model validation.

Keyword: Reconstructive surgery; in silico; post-surgery prediction; bone regeneration; biodegradable implant degradation

Introduction

Long-bone fractures are commonly treated using permanent fixation made of stainless steel or titanium. However, these implants may cause long-term complications and often require a second surgery for removal.

Magnesium (Mg)-based implants offer temporary mechanical support while gradually degrading as bone heals. Their lower elastic modulus may also help reduce stress shielding. However, achieving an appropriate degradation rate remains challenging since excessively rapid degradation compromises fixation stability, whereas excessively slow degradation limits the benefits of biodegradability.

Bone regeneration is a mechanobiological process in which local mechanical conditions regulate callus tissue differentiation into fibrous tissue, cartilage, and eventually mature bone. Meanwhile, implant degradation alters construct stiffness and load distribution, consequently affecting the mechanical environment for bone regeneration. These interconnected processes highlight the need for an integrated computational framework.

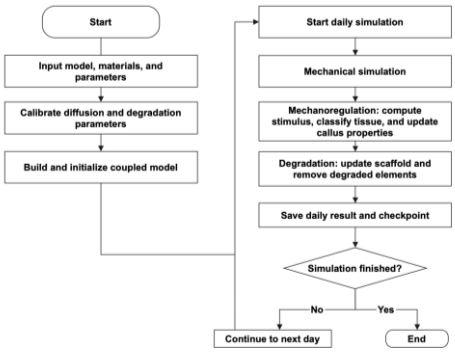
Research Objectives

To develop and validate an integrated in silico predictive model capable of simultaneously predicting biodegradable implant degradation and postoperative bone growth, providing a scientific basis for more precise, safe, and effective implant design and selection in reconstructive surgery, particularly in maxillofacial and orthopedic applications.

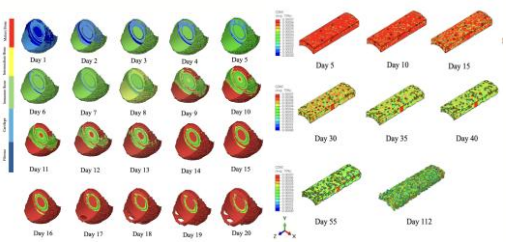
Research Method

The computational framework was developed progressively, from simplified to more complex models, through the following stages.

1. **Mechanoregulation Model**
   Biophysical stimuli were calculated from octahedral shear strain and interstitial fluid velocity. Tissue differentiation was combined with osteoprogenitor cell distribution (diffusion model) to determine element-wise callus phenotypes throughout regeneration.
2. **Implant Degradation Model**
   Mg concentration reduction followed Fick's law, with a Weibull-based surface flux distribution to represent localized corrosion. Elements with Mg concentration ≤40% of the initial value were removed. The degradation rate parameter (β) was calibrated using the bisection method.
3. **Daily Sequential Coupling**
   Callus properties were updated before implant geometry at each simulation day. The resulting configuration was used as the input for the subsequent day, enabling continuous interaction between bone regeneration and implant degradation.
4. **Computational Model and In Vivo Data**
   The computational model comprised cortical bone, bone marrow, callus, and Mg implant. Callus geometry was estimated through iterative removal of low-strain elements over 10 iterations.
   In vivo experiments involved AZ31 Mg fixation plates implanted in rabbit femurs. CT and micro-CT data were processed to obtain geometric, volumetric, and bone/implant density measurements for model calibration and validation.



Picture 1. Flowchart of the integrated in silico mechanoregulation-implant degradation framework



Picture 2. Evolution of callus tissue phenotypes (days 1-20) and Mg implant degradation (days 5-112) predicted by the integrated framework.

Result and Discussion

An **integrated computational framework coupling magnesium implant degradation with bone regeneration was successfully developed and implemented,** combining a spatially dependent degradation and mechanoregulation models. The framework was implemented in simplified 2D and 3D models and a plate-fixed fractured tibia model. Simulations demonstrated progressive and localized implant degradation, with approximately 60% residual implant at day 112 (degradation rate, $\beta = 1.264 \times 10^{-11}$), progressive callus tissue differentiation, and evolving mechanical load transfer.

In parallel, in vivo micro-CT data of AZ31 Mg fixation plates and rabbit fractured femurs have been acquired at multiple time points. These experimental data will serve as a reference for subsequent validation of the developed computational framework, which is currently ongoing.

Conclusion

An **integrated Python-based in silico framework** coupling mechanoregulation-based bone tissue differentiation with magnesium implant degradation **was successfully developed**. The framework was progressively implemented and evaluated, from predefined callus models to an estimated callus model of a fractured femur. The simulation results demonstrated its capability to evaluate callus maturation, changes in tissue stiffness, implant degradation, and mechanical load redistribution within a unified computational framework.

Achieved outcomes:

1. Development of an in-silico framework for magnesium implant degradation.
2. Development and implementation of an integrated in silico framework coupling bone regeneration and implant degradation.
3. Presentation of preliminary findings at the 7th International Symposium on Advances and Innovation in Mechanical Engineering (ISAIME), titled "Preliminary study: coupled degradation and mechanoregulation in bone healing with biodegradable implant using finite element analysis".
4. Manuscript titled "Biomechanical Behavior and Implications for Bone Regeneration of Patient-specific Biodegradable Scaffold Designs for Mandibular Reconstructions" submitted to the *International Journal of Biomaterials* and currently under review.

Ongoing and future work:

1. Development of a 3D rabbit femur model based on the in vivo specimens.
2. Implementation of progressive loading and simultaneous coupling of degradation and bone regeneration.
3. Validation against experimental in vivo data.