

# MATHEMATICAL MODELING OF STRESS SHIELDING WITH BIORESORBABLE MATERIALS FOR INTERNAL FRACTURE FIXATION

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## INTRODUCTION

Treatments of fractures with stainless steel implants are associated with significant problems including stress shielding, the risk of late infection, allergic or toxic reactions and the necessity for a second surgery to remove some of the implants. A material that is absorbed slowly by hydrolysis or enzymatic degradation is a better alternative. A second operation will not be necessary and risk of osteoporosis caused by stress shielding will not occur. Another advantage is that the risk of tissue reaction caused by metallic corrosion will be eliminated. In 1971, implants for fracture fixation made from biodegradable polymers were first described [1]. Selection of implant materials and geometry is dependent on an improved understanding of the interactions between resorption, stress shielding and fracture healing rates. The goal of this study was to develop a mathematical model of fracture fixation to illustrate the stress shielding phenomenon and the potential advantages of resorbable materials. A polymer and ceramic/polymer composite are compared to a stainless steel implant in a model of axial loading in the femur.

## METHODS

### Model description

In this preliminary model, a mid-diaphysis femur fracture is modeled, and only axial loads are considered. The study is divided into two parts. The first part compares the different materials by showing how the unfractured bone responds to an implant of the specific material. The decrease in bone modulus due to stress shielding and the degradation rate of the bioresorbable materials are considered.

For the second part, a fractured bone is considered. When a bone is fractured, the modulus of the bone is temporarily lower during the healing process. The initial value of the modulus is assumed to be 8 GPa. The modulus is assumed to increase linearly from 8 GPa until it reaches its normal value of 17.4 GPa after 12 weeks. At the same time as the bone modulus decreases due to shielding, the implant material experiences degradation and the number of loading cycles changes with time. As the bone heals, the activity that the bone is being exposed to is assumed to increase. The number of loading cycles

increases until 12 weeks are reached. Once the bone is considered healed, the numbers of cycles are fixed.

### Materials

A literature review shows that among polymers Poly-L-Lactic Acid (PLLA) is more frequently used than other polymers because the degradation rate is lower which results in a lower rate of inflammatory tissue reaction [2]. The ultimate strength of PLLA is almost the same as for cortical bone, i.e. 10-150 MPa, and the elastic modulus is 6.5 GPa. *In vivo* studies of PLLA have shown a considerable decomposition of both chemical and mechanical properties, which has been considered too high for bones carrying large stresses [2].

An ultra high strength composite of hydroxyapatite/Poly-L-Lactide (HA/PLLA) has been developed by Shikunami and Okuno [2]. The material properties for this composite include an initial bending strength of 250 MPa and a modulus of 12.1 GPa, with a rate of degradation of molecular weight that is lower than for pure PLLA. Although the modulus degradation rate has not been reported for the composite, the degradation of molecular weight in the pure PLLA was found to be similar to its modulus degradation rate. Therefore, it is assumed that the modulus degradation rate in the composite is comparable to the degradation rate of its molecular weight.

### Simulation

The theory presented by Beaupré and Carter [3,4] is used to predict bone remodeling. The essence of the bone adaptation theory is that bone needs a certain level of mechanical stimulation to maintain its density. If bone tissue experiences excess stimulation, additional bone will be deposited. If bone tissue experiences insufficient stimulation, it will resorb. The latter can result from stress shielding from traditional implants. The theory has been used to investigate both cortical and trabecular bone. The Voight model for uniform strain is used to find the composite modulus and the stresses in the bone and the implant under axial loads.

The net daily rate of apposition or resorption in a bone is determined by the difference between the appropriate stress level (1), attractor state (without implant) and the actual stress stimulus (with implant).

$$\Psi = \left( \sum_{\text{day}} n_i \cdot \sigma_i^m \right)^{1/m} \quad (1)$$

where  $n_i$  is the number of cycles of load type  $i$ ,  $\sigma_i$  is the bone tissue level stress and the exponent  $m$  is a weighting factor for the relative importance of the stress magnitude to the number of load cycles. The difference between the actual tissue level stress stimulus and the tissue level attractor state stress stimulus represents the driving force for the remodeling and is then converted into the change in density (2).

$$d\rho = c \cdot (\Psi - \Psi_{AS}) \quad (2)$$

Once the change in density is calculated the new density can be calculated and then the new modulus can be obtained (3).

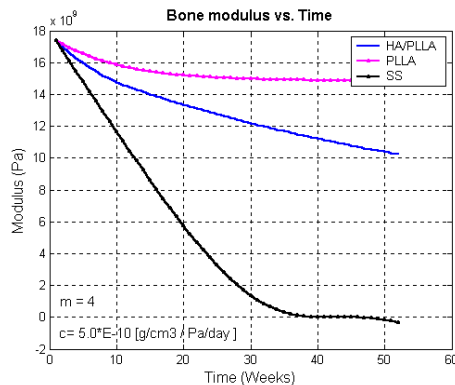
$$E_{NEW} = 1.99 \cdot 10^9 \cdot (\rho_{NEW})^{3.3} \quad (3)$$

The initial density for cortical bone is assumed to be  $1.92 \text{ g/cm}^3$  [3,4]. Once the new modulus is obtained, the new stress levels in the bone can be calculated and the model can be iterated over time. The modulus is plotted against the time.

Several loading conditions and numbers of repeating cycles are intended to simulate the loading conditions during a typical day. The loading conditions used are from a study by J.P. Paul [5]. The time for the simulation to run is 1 year.

## RESULTS

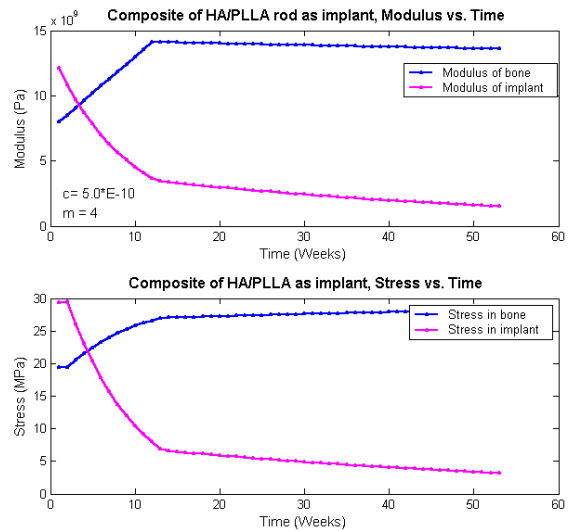
For the first part, only changes in the bone and the degradation rate of the bioresorbable materials are considered. The results in Figure 1 demonstrate how the bone modulus decreases significantly faster for stainless steel implants than for the bioresorbable implants. The difference between PLLA and the composite of HA/PLLA is also significant. The pure PLLA implant affects the bone less than the composite. The initial stress ratio is calculated as the stress in the bone with an implant over the stress in the bone without an implant, the attractor stress. This variable is used to compare the materials to each other. The stress ratio, initially and after 30 weeks, in the bone with a stainless steel implant is much smaller than for the other two implant materials.



**Figure 1. Modulus over time for the pure PLLA, the composite of HA/PLLA and stainless steel**

For the second part, the bone is modeled as fractured. The simulations for the composite of HA/PLLA are presented in Figure 2. In this simulation, both the modulus and the stress are modeled, because it must be made certain that these implants are not exposed to higher stress than their breaking stress. The results show how the composite takes most of the load during the first weeks with increasing stresses in the bone over time. The same graph for the pure PLLA

implant (data not shown) leaves the majority of the loads to the bone in the beginning of the healing process and the curves never cross each other.



**Figure 2. Modulus and stress vs. time for a fractured bone with the HA/PLLA composite as implant**

## CONCLUSIONS

This preliminary model clearly illustrates how material properties and their degradation behavior have the potential to cause changes in bone modulus over time. None of the calculated stresses are above the breaking strength of the materials. Even though some assumptions still are made, the results clearly shows the variation between the materials, but no more quantitative conclusions related to specific materials are made at this point. The existing model and loading conditions did not confirm literature suggestions that PLLA does not possess enough initial strength and that the composite of HA/PLLA does. However, the PLLA implant provided minimal support to the bone at the beginning of the healing process.

The next step is to incorporate more complex loading conditions, including bending loading and additional angles and also to incorporate new information related to the degradation rate of the composite. This modeling approach could provide a powerful tool to design and select materials for use in fracture fixation.

## REFERENCES

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