DEGRADATION PROCESS ANALYSIS OF BIORESORBABLE CAGE APPLIED TO LUMBAR INTERBODY FUSION

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Abstract. *Bioresorbable materials have a function of great interest in biomedical and bioengineering studies, which is the bioresorption process, i.e., the breaking of polymer by hydrolysis into lactic acid and glycolic acid. These monomers are eliminated through body natural cycle called Krebs cycle. Degradation process is directly related to the mass loss, which depending on the polymer composition, has a predetermined time to degrade. This loss of mass over time, promotes a lower mechanical strength. In surgical procedures, these implants must withstand the loads imposed until the healing and osteosynthesis process. In this case, the design of these devices has a great importance in the patient's recovery process. Mathematical models of the degradation process of these materials evaluate molecular weight loss over time and are validated by "in vitro" and "in vivo" tests. Here we show a methodology to evaluate the mechanical behavior of bioresorbable cage applied in lumbar spine during the degradation process by finite element analysis..*

Keywords*: Bioresorbable materials, cage, spine, finite element analysis*

1. INTRODUCTION

The spinal deformities treatment, such as, degenerative disorders, lesions and tumors usually require some internal fixation system. The spine degenerative instability has been effectively treated with implants of type "Cage", that can be stabilized or not by plates attached with pedicle screws.

The first Cages emerged in 1980s and were made with stainless steel. Initially, these devices were primarily used as scaffolds for spinal fusion in order to treat degenerative diseases of the lumbar spine (KURTZ; EDIDIN, 2006).

Several works have been performed applying the finite element method (FEM) in order to compare different geometries of these devices to be better adapted to the backbone with good mechanical behavior (ZHONG et al., 2006; FANTIGROSSI et al., 2007; SOUZA et al., 2011).

However, much of this work has been done in analyzing Cages made of stainless steel, titanium and carbon fiber reinforced and polymer composite with cylinder's form with vertical and horizontal rings, where it is placed the bone graft to promote fusion named arthrodesis (NABHAN et al. 2009).

In recent years implants made of bioresorbable polymers started gaining special attention in this context once these materials are absorbed by tissues and eliminated from the body via natural pathways. Made by combination of Polylactic acid (PLA), these materials have been used in surgeries such as cranio-maxillofacial surgery, knee and shoulder ligament reconstruction, mini-plates and screws forms for fixation, stents for angioplasty surgery, as well as the application pins and interference screws (LUNT et al., 1998; VACCARO et al., 2003; BELL; KINDSFATER, 2006; SABIR; XU, 2009; HAN; PAN, 2009).

Van Dijk et al. (2002), are among the first authors to investigate the degradation in vitro and in vivo bioresorbable cages made with (PLLA) to spinal fusion. Although this work has been developed with bioresorbable Cages and the growing interest in them, there are few types of this implant on the market (VACCARO et al., 2003).

Currently, the development of these materials and their behavior in vivo is widespread in several areas, from biological tissue analysis, cell adhesion, cell growth, to mathematical models to describe the kinetics of the degradation process.

Several authors (WANG et al., 2008; HAN et al., 2009; HAN et al., 2010; HAN et al., 2011), who recently studied mathematical and numerical modeling of the kinetics biodegradation process of bioresorbable polymers, especially PLLA, have obtained numerical models that describe the degradation process with good approximation when compared in vitro and in vivo tests. Knowing better these materials in vivo degradation process, it becomes possible to develop implants with optimized geometries able to withstand the initial loads until the beginning of bone healing, and during the degradation the bone graft can receive gradual charging, promoting bone cells stimulation and consequently the osteointegration process to complete spinal fusion.

Therefore, this work proposes to develop an implant design methodology using degradation curve of bioresorbable materials and the involved charging in vivo function.

The methodology was applied to evaluated numerically the mechanical behavior of a spinal implant (Cage) made of bioresorbable materials (PLLA) simulating the degradation process and bone healing at the same time. To obtain the degradation curve, we used the mathematical model proposed by Han and Pan (2009).

2. MATERIALS AND METHODS

A tridimensional finite element model for vertebrae were developed in ANSYS workbench simulation software and the implant (cage), Fig.1a, was adapted to the lumbar spine set (L3-L4), Fig.1b and Fig.1c.

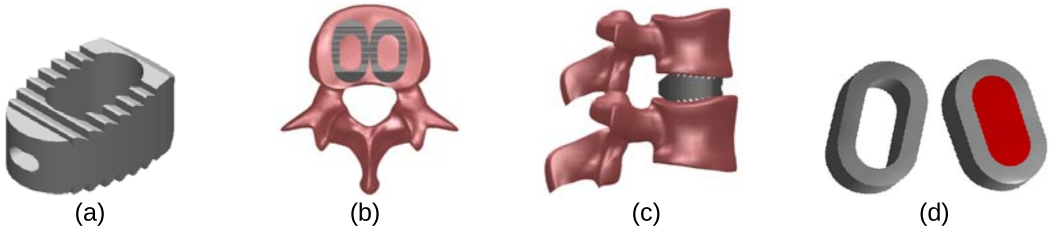
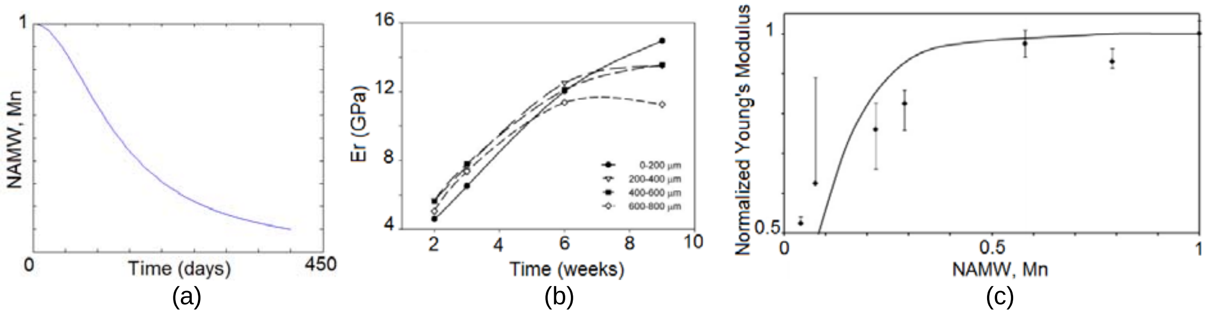

(a) (b) (c) (d)

Figure 1: (a) Implant model (cage), (b, c) the cage adapted to the lumbar spine set (L3-L4), (d) Simplified implant with bone graft.

The bone graft was modeled occupying the entire space inside the implant, red color in Fig.1d. The vertebrae and bone graft were considered like cortical bone.

From the mathematic model [1] we obtained the degradation curve for PLLA during the time, Fig. 2.



(a) (b) (c)

Figure 2: (a) NAMW (Normalized Average Molecular Weight) during the time, (b) In vivo results of bone elastic modulus during the osteosynthesis process, (c) Elastic modulus over NAMW for PLLA.

Curves for bone graft osteointegration based on elastic modulus over the time were obtained from the literature [2], Fig.2b. These curves (Fig.2a, 2b e 2c) associated with mechanical properties of bone and implant, Tab.1, were applied in the finite element model to represent the recovery process of patients. Multi-objective software was used to manage the simulation.

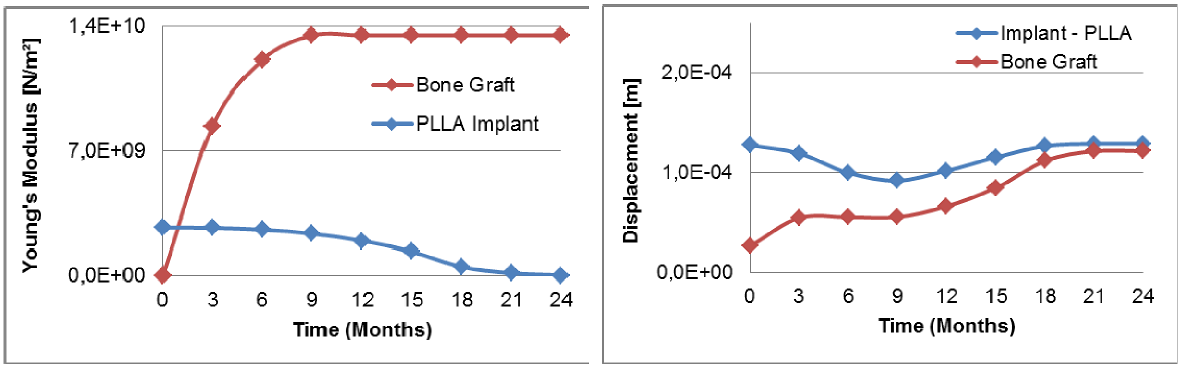
Table 1: Mechanical properties of bone graft and implant. Source: Cowin, 2001.

Mechanical Properties	**Bone graft**	**PLLA**
Average Elastic Modulus [GPa]	13.5	2.7
Poisson's ratio	0.39	0.34
Density [Kg/m3]	1500	1270
Compressive Yield Strength [MPa]	182	70
Tensile Yield Strength [MPa]	115	45
Degradation Time (months)	-	24

The complex implant geometry, Fig.1a, was simplified in order to decrease parameterized variables, consequently the reduction of computational time. The bone graft was obtained varying the Young's modulus proportionally to the loss of implant stiffness due to degradation. The relation between Young's modulus and NAMW for PLLA was obtained from literature [4], Fig.3a. The Young's modulus values for bone graft were assumed from the literature [2], but distributed in months with safety factor of 3 months, totalizing 9 months.

3. RESULTS

Figure 3a shows the relation between Young's modulus and displacement for PLLA with time (months). Through numerical analysis, Fig.3b, observed while the bone graft wasn't consolidated the displacement are practically restricted by the cage structure. On the other hand, when the cage material degrades, the vertebrae fixation is transferred to the bone structure formed by the bone healing in 9 months. Cage lost its structural integrity at about 18 months.



(a) (b)

Figure 3: (a) Young´s modulus variation with time for PLLA implant and bone graft (b) Displacement resulting of simulation.

4. CONCLUSION

The tridimensional finite element model associated with degradation curves process of bioresorbable materials and bone healing proved to be a powerful tool in developing new implants to the human body. These models need to be validated through in vitro tests.

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7. INFORMATION RESPONSIBILITY

The authors are the only responsible for the information included in this work.