Modular adaptive implant based on smart materials

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Abstract
Applications of biological methods and systems found in nature to the study and design of engineering systems and modern technology are defined as Bionics. The present paper describes a bionics application of shape memory alloy in construction of orthopedic implant. The main idea of this paper is related to design modular adaptive implants for fractured bones. In order to target the efficiency of medical treatment, the implant has to protect the fractured bone, for the healing period, undertaking much as is possible from the daily usual load of the healthy bones. After a particular stage of healing period is passed, using implant modularity, the load is gradually transferred to bone, assuring in this manner a gradually recover of bone function. The adaptability of this design is related to medical possibility of the physician to made the implant to correspond to patient specifically anatomy. Using a CT realistic numerical bone models, the mechanical simulation of different types of loading of the fractured bones treated with conventional method are presented. The results are commented and conclusions are formulated.

Keywords: bionics, modularity, implants, numerical simulation.

Introduction
Bionics or Biomechatronics is a fusion science, which implies medicine, mechanics, electronics, control and computers. The results of this science are implants and prosthesis for human and animals. The role of the implants and prosthesis is to interact with muscle, skeleton, and nervous systems to assist or enhance motor control lost by trauma, disease, or defect [1]. Prostheses/implants are typically used to replace parts lost by injury (traumatic) or missing from birth (congenital) or to supplement defective body parts. In addition to the standard artificial limb for every day use, many amputees have special limbs and devices to aid in the participation of sports and recreational activities.

Shape memory alloy
The shape memory effect was first noted over 50 years ago; it was not until 1962, however, with the discovery of a nickel titanium shape memory alloy but Buehler, that serious investigations were undertaken to understand the mechanism of the shape memory effect. The shape memory alloys possess the ability to undergo shape change at low temperature and retain this deformation until they are heated, at which point they return to their original shape [2–18].

The nickel titanium alloys, used in the present research, generally referred to as Nitinol, have compositions of approximately 50 at.% Ni/50 at.% Ti, with small additions of copper, iron, cobalt or chromium [19–25]. The alloys are four times the cost of Cu–Zn–Al alloys, but it possesses several advantages as greater ductility, more recoverable motion, excellent corrosion resistance, stable transformation temperatures, high biocompatibility and the ability to be electrically heated for shape recovery (Figure 1) [26–28].

Material and Methods
The parametric 3D model of the bones
To obtain the bone cross sections of the bones, a PHILIPS AURA CT-tomograph installed in the Emergency County Hospital of Craiova was used (Figure 2). To obtain the tomographies of the two bones (tibia and femur) were used two scanning schemes presented in Figure 3. For the ends of the bones, the scanning operation was made at the distances of 1 mm and for the medial areas at the distances of 3 mm.

Results
Sixteen images folders were obtained and, after a strict selection, were used only six, three for each bone component including the upper and lower areas (scanned at 1 mm) and the medial areas (scanned at 3 mm).

In Figure 4, two important images of the upper femur in the area of the femoral head were presented. In Figures 5 and 6 main images of the medial and lower femur, which shown the changes of the shape of the
bone were presented. In the Figures 7–9 important images of the upper tibia, the medial tibia and the lower tibia, which show the shape changes of the bone were presented.

The obtained images were re-drawn in AutoCad over the real tomographies and the drawing were imported in SolidWorks (a parametrical CAD software), section by section, in parallel planes. The sketches made in the upper and lower areas for femur and tibia are presented in Figures 10 and 11.

SolidWorks permits to obtain a solid by “unifying” the sections drawn in parallel planes. The shape which solidifying these sections was the Loft Shape and it define the solid starting with the sections and a Guide Curve defined automatically by the software.

In Figure 12 are presented the definition scheme for the femur bone and for the tibia bone. For defining the virtual models of the bones, the software SolidWorks are used. The virtual models can be transferred into kinematic simulation programs or into finite element analysis programs.

The structure of the femur bone (Figure 13) has the following characteristics: the finite element size is 10 mm, and the structure factor is 0.0132. A number of 13399 nods and 7178 finite elements are obtained for femur.

**Studies of normal regime bones mechanical loads**

In order to identify the target shape of modular implants, a studies for walking regime was developed [29]. The studies identify the tension maps developed by tibia and femur for different moments. In the Figures 14–16 are exemplified only few simulation results, important for identifying tension distribution.
Figure 6 – Two images obtained in the lower area of the femur

Figure 7 – Four main images of the upper tibia

Figure 8 – Four main images made in the medial tibia area

Figure 9 – Four main images scanned in the lower tibia area

Figure 10 – Sections for the femur bone

Figure 11 – Sections for the tibia bone

Figure 12 – The definition scheme of the virtual femur and tibia
Discussion

Modular adaptive implant

The design idea of modular adaptive implants results from the following observations:

- physicians have limited degrees of freedom in selecting the proper dimensional apparatus for bone fractures;
- the current mechanical devices used in orthopedics lose some of their mechanical characteristics after some time (especially elasticity, which should ensure a constant tension that is mandatory for the correct anatomical healing of the fractured bones);
- the process of fracture healing has a particular dynamic, which imposes the necessity of particular progressive tension or discharge to improve the recovery time, depending on the normal structure and function of the bone;
- to improve the healing process, the fractured parts have to be in permanent contact in order to ensure the proper conditions to develop bone calluses. The actual or external fixator has to be manually adjusted with respect to the main axis of the bone. Unfortunately, the degrees of freedom of current devices are limited to three or four vertical screws;
- a minimally invasive surgery ensures protection from blood edema and improves bone recovery and vascularization of the region.

The solution to these problems is the Modular Adaptive Implant – MAI. The proper shape of MAI is related to the microscopic structure of the bone and to the numerical simulation presented in the previous chapter. As one can observe, comparing the structure of a healthy bone (Figure 17) with that of an osteoporotic bone, the internal architecture of the healthy bone has a regular modular structure.

A modular net, identical in structure with the bone and locally configurable in terms of tension and release, is best design solution in terms of biocompatibility [30]. The identification of the mechanical solicitation of the
particular bone structure leads to the concept of the practical implementation of a feasible device able to undertake the functionality of normal bones. This device will partially discharge the tensions in the fractured bones (the fractured parts still need to be tensioned to allow the formation of the callus) improving the recovery time and the healing conditions.

The proposed intelligent device has a network structure, with modules made out of Nitinol, especially designed in order to ensure a rapid connection and/or extraction of one or more MAI modules. The binding of the SMA modules ensures the same function as other immobilization devices, but also respects additional conditions concerning variable tension and its discharge. Moreover, these modules allow little movement in the alignment of the fractured parts, reducing the risks of wrong orientation or additional bones callus.

We suggest the design shown in Figure 18 for the unitary SMA module structure, a design which ensures not only the stability of the super-elastic network and constant force requirements, but also a rapid coupling/decoupling procedure.

Physicians can use SMA modules with different internal reaction tension, but all the modules will have same shape and dimension (Figure 19).

The connection with affected bones and the support for this net are similar to those of a classic external fixator, but allowing for the advantages of minimal invasive techniques. The new device leads to a simple post-operatory training program of the patient (Figure 20) [31].

The study of this technique offers a feasible direction. In the future, we want to realize different types of SMA modules and to experiment with them on real bones. At the same time, the studies will be developed in the direction of numerical simulation of the complex ensemble made up of the bone and the MAI network for different functional regimes, for different weight, temperature and physico-chemical condition and especially for different types of bone fractures.

A very promising direction is the design and implementation of an independent and permanent functional adaptive MAI network, which can ensure a very rapid reintegration of the patient with minimal costs of the treatment.

Acknowledgements

This research was supported by Romanian Ministry of Education, Research and Youth, Programs CEEX no. 259/11.09.2006, CNCSIS no. 620 and Ideas no. 92 – PNCDI II.
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Received: September 17th, 2008
Accepted: October 25th, 2008