Shape memory alloy based
Modular Adaptive Orthopedic Implants

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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 doctor 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.

Key-Words: - bionics, modularity, implants, numerical simulation

1 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 roll 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. 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.

1.1. 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.

The nickel titanium alloys, used in the present research, generally refereed to as Nitinol, have compositions of approximately 50 atomic % Ni/ 50 atomic % Ti, with small additions of copper, iron, cobalt or chromium. 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[1].

2. 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 Hospital from Craiova was used.
obtain the tomography of the two bones (tibia and femur) were used two scanning schemes presented in Figure 1.
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.

Figure 1 . Scanning schemes applied to the femur and tibia

In Figure 2, Figure 3 were presented main images of the medial and lower femur, which shown the changes of the shape of the bone.

Figure 2 . Images obtained in the medial area of the femur

Figure 3 . Two images obtained in the lower area of the femur

The obtained images were re-drawn in AutoCad over the real tomography and the drawing were imported in Solid Works (a parametrical CAD software), section by section, in parallel planes. The structure of the femur bone (Figure 4) has the following characteristics: the finite element size is 10 mm, the structure factor is 0.0132. A number of 13399 nods and 7178 finite elements are obtained for femur.

Figure 4 . The mesh structure of the virtual model of the femur

2.2. Numerical models for bones mechanical loads

For the next step we used the ANSYS program for the discretisation with finite elements method of the spatial structure of the tibia bone [12.], [13.], [14.]. The modelation was realised with hexahedral finite elements.

The characteristics of a finite element are, usually, by: the displacements functions, the deformation matrix, the elasticity matrix, the rigidity matrix and the exterior forces matrix.

The element displacement is defined by 12 displacement components of the nodes:

\[
\{\delta\}_j = \begin{bmatrix}
\delta_{i} \\
\delta_{j} \\
\delta_{m} \\
\delta_{p}
\end{bmatrix}
\]  

where:

\[
\{\delta_{i}\}_j = \begin{bmatrix}
\delta_{i} \\
\delta_{j} \\
\delta_{m} \\
\delta_{p}
\end{bmatrix}
\]  

We can explain the displacements of a current point as a function:

\[
\{f\} = \begin{bmatrix}
IN_{p}, \quad IN_{j}, \quad IN_{m}, \quad IN_{p}
\end{bmatrix} \{\delta\}_e
\]

where the scalars N have the following form:

\[
N; = \frac{a_i + b_j + c_j + d_j}{6V}
\]  

and I is a 3 x 3 identity matrix.

We used displacements functions will satisfy the continuity conditions at the level of separation surfaces between the different elements. This thing is a normal corollary of linear nature of displacements variation.

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where \( e_x, e_y, e_z \) are the specific linear deformations and \( g_x, g_y, g_z \) are the specific angular deformations.

For an isotropic material the matrix \([D]\) is done by the relation

\[
[D] = \frac{E(1-V)}{(1+V)(1-2V)}\begin{bmatrix}
1, x_i, y_i, z_i \\
1, x_j, y_j, z_j \\
1, x_m, y_m, z_m \\
1, x_p, y_p, z_p
\end{bmatrix}
\]

where \( E \) is the elastic constant of the material, \( V \) is the volume.

The rigidity matrix can be integrated because the deformation and tension components are constants in the interior of any element.

The nodal forces are:

\[
\{F\}_0 = [-B]^T[D]\{\varepsilon\}_0 V
\]

with: \([B] = [B_i, B_j, B_m, B_p]\)

For every solicitation case for a correct numerical simulation it is necessary to establish the contour conditions.

The last step of the Finite Element Method consists in the equation system solving. In this stage, the ANSYS program assembles the equation system of the analyzed structure using the characteristics of the finite element. For each finite element of the spatial structure, 24 elementary equations exist in the general system. It results a very complex equation system which is solved by the program using the Gauss method.

Solving the equation system leads to the determination of the principal variables which are the nodal displacements on the three directions in every node of all the finite elements.

The ANSYS program uses these results for the determination of the deformations and stresses which appear in the analyzed structure.

We have taken into consideration the real structure of the human bone.

We know that the bone is one of the most important natural composite materials.

The body of the tibia bone is formed by a compact bone tissue cylinder all pierced by a central channel called the medullar channel.

The ends of the bone are formed by a thin layer made outside by a compact bone substance, and inside by a spongy mass.

The work hypothesis are:

a) Even though the material of the bone is anisotropic and not homogeneous, in the modeling, the bone was considered homogeneous and isotropic, for a zone of solicitation that does not exceed certain limits.

b) The bone is made by two kinds of materials, compact and spongy, like a composite material.

c) The average values considered for the longitudinal modulus of elasticity, \( E \), are: 20,000 N/mm\(^2\) for the compact bone, situated in the exterior zone of the bone and 2 N/mm\(^2\) for the spongy bone, situated in the interior zone. The value of the coefficient for the transversal contraction of Poisson was 0.3.

d) The virtual central channel is realized in accordance with the obtained tomographies, so the complex spatial structure is assured.

The geometrical model was supposed at different solicitations for studying the most solicited parts of the bone which will be the possible broken parts [15.], [13.], [14.].

In the first case, the virtual model of tibia bone was supposed to a torsion couple equal with 4.8 Nm on the top surface (Figure 5).

The bone is leaned in his inferior base. The virtual solicitation is realized with the help of two sets of forces placed on the extremities of had bone, in a perpendicular plane on the longitudinal axe of the bone.
We obtained the resultant stress distribution for the torsion solicitation for the entire bone (Figure 6, Figure 7).

We observe that the most solicited areas of the bone are situated in the 1/3 inferior diaphysis of the bone, where the value of section area is minim. On diagram, the maxim values are indicated by the color red, and the minim values are indicated by the color blue. The values increase from blue to red.

In second case the bone was supposed to a compression force equal with 800 N distributed on the both superiors condils (Figure 8), having the direction of the longitudinal axe of the bone. Finally, we obtained the resultant stress distribution for the compression solicitation (Figure 9, Figure 10).

In both of the analyzed cases (torsion and compression) the results were obtained using the Von Mises theory and the values are presented in N/mm2 or MPa (Mega pascals). On the value scale, the higher values of stresses are indicated by red color and the lower values are indicated by blue color. The values increase from blue to red.
It can be observed that even the solicitations are uniform, the repartitions of stresses along the bone are not uniform. This thing is the result of the complex form of the tibia. The lower values are found at the extremities of the bone and the highest values are found in a limited area on the anterior zone.

It can be also observed that the maximal values are recorded in the 1/3 inferior diaphisis of the bone, where the value of section area is minim. In figure 14 it can be observed the bone structure.

2.2. Studies of normal regime bones mechanical loads

In order to identify the target shape of modular implants, a studies for walking regime was developed [7]. The studies identify the tension maps developed by tibia and femur for different moments. In the following Figure 11, Figure 12, Figure 13 are exemplified only few simulation results, important for identifying tension distribution:

![Figure 11. Tension map for t=0.12 sec., angle tibia-femur ρ=30°](image)

![Figure 12. Tension map for t=0.2 sec](image)

![Figure 13. Tension map for t=0.8 sec](image)

3. Modular adaptive implant

The design idea of modular adaptive implants results from the following observations:
- the doctors have a limited degree of freedom in selecting the proper dimensional apparatus for bones fractures
- the actual mechanical apparatus used in orthopedics, suffer depreciation of mechanical characteristics after some time, (especially elasticity, which assure a constant tension OBLIGATORY for correct anatomically healing of the fractured bones) [8];
- healing fracture process has a particular dynamics, which impose the necessity of particular progressive tension or discharge for improving the recovering time, targeting the normal bones structure and function [3].
- for improving the healing process the fractured parts has to be in permanent contact in order to assure the condition of developing bones callus [2].

The actual external fixator – Ilizarov apparatus – Figure 14 and Taylor Spatial Frame Fixator – Figure 15, has to be manual adjusted respecting the bones main direction. Unfortunate the degrees of freedom of the actual apparatus are limited to 3 or 4 vertical screws

![Figure 14. Iliazev external apparatus](image)
- a minimal invasive chirurgical intervention assures protection of sanguine edema, which improves the bones recover and the vascularisation of the region. The solution of these problems is the **Modular Adaptive Implant - MAI**.

The proper shape of MAI is related to the bones microscopic structure and with the numerical simulation presented in the previous chapter. As can one observe comparing the normal bones (Figure 16) structure with an osteoporosis affected bone structure (Figure 17), the internal architecture has a regular modulus structure [4].

Osteoporosis, affect the bones net and conduct to additional load. These problems, increase bones fracture risks or limit the relative bones mobility [5]. A modular identical structure net, local configurable in relation with tension and release, is the biocompatible best design solution.

Using finite element method and identifying the mechanical solicitation of the particular bones structure, conduct to necessity of practical implementation of a feasible device able to undertake the functionally of normal bones. This device will discharge, partially (the fracture parts still need a particular tension in order to allow the formation of callus) the fractured bones improving the recovery time and the healing conditions. The proposed intelligent device has a network structure, with modules from Nitinol, specially designed in order to assure a rapid connection and/or extraction of a single or a group of module MAI.

The connection of the SMA modules assure the same function as other immobilization solution, respecting and the additional condition concerning variable tension and discharge and even little movement for bone lineament, reducing the risks of apparition of the wrong orientation or additional bones callus.

The unitary SMA module structure has the following design, assuring not only the super elasticity network stability and the constant force requirements, but and a rapid coupling/decoupling procedure.

The doctor can use SMA modules with different internal reaction tension, but all the modules will have same shape and dimension (Figure 18).

Using Solid Works package and COSMOS software [6] we proceed to various numerical simulation of SMA module, in order to test the proper mechanical design. First design relives that applying high force - 30N and torques to the MAI terminals, the coupling connectors will conduct to spike mechanical deformation (Figure 19), potential dangerous for the patients.
The following Figures reflect the MAI response to destructive tension and forces, which can appear in accidental cases (Figure 21):

![Figure 21. Response of MAI - optimal design for accidental tension and forces](image)

The new device conducts to a simple technique for post-operative patient training program. The relative advanced movement independence of patient with MAI network apparatus can conduct to possibility of short distance walking. Actual devices (Figure 22) are quite expensive and implies for implementing 3 persons: the patient, the current doctor and a kinetoterapeut.

![Figure 22. KINETEK device for functional reduction type "continuous passive motion"](image)

**Conclusions**

The studies of the proposed solution offer a feasible direction. In future the authors will realize a different type SMA module and will experiment them to real bones. In the same time the studies will

![Figure 19. Response of MAI - first design for accidental tension and forces](image)

Redesign the modules, using the previous conclusions the second shape of the MAI is an improved solution (Figure 20), which respect the protection of the patients for accidental unusual mechanical tension.

![Figure 20. MAI - SMA modul and network - optimised design.](image)
be developed in the direction of numerical simulation of the complex ensemble bones-MAI network for different functional regime, for different weight, temperature and physico-chemical condition and especially different type of bones fracture. A very promising direction is the design and implementation of an independent and permanent functional adaptive MAI network, which can assure a very rapid reintegration of the patient with minimal costs of the treatment.

References
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