ORIGINAL PAPER

In vitro experiment of the modular orthopedic plate based on Nitinol, used for human radius bone fractures

DANIELA TARNIŢĂ[1)], D. N. TARNIŢĂ[2)], L. HACMAN[3)], C. COPILUŞ[1)], C. BERCEANU[1)]

[1)]*Department of Applied Mechanics, Faculty of Mechanics, University of Craiova*

[2)]*Department of Anatomy, Faculty of Medicine, University of Medicine and Pharmacy of Craiova*

[3)]*S.C. INDA S.R.L., Craiova*

Abstract

Shape memory alloys (SMAs) and in particular Ni–Ti alloys are commonly used in bioengineering applications as they join important qualities as resistance to corrosion, biocompatibility, fatigue resistance, MR compatibility, kink resistance with two unique thermo-mechanical behaviors: the shape memory effect and the pseudoelastic effect. They allow Ni–Ti devices to undergo large mechanically induced deformations and then to recover the original shape by thermal loading or simply by mechanical unloading. Diaphyseal fractures of the radius and ulna present specific problems not encountered in the treatment of fractures of the shafts of other long bones. The adaptive modular implants based on smart materials represent a superior solution in the osteosynthesis of the fractured bones over the conventional implants known so far. To realize the model of the implant module we used SolidWorks software. The small sizes of the modules enable the surgeon to make small incisions, using surgical techniques minimally invasive, having the following advantages: reduction of soft tissues destruction; eliminating intra-operator infections; reduction of blood losses; the reduction of infection risk; the reduction of the healing time. Numerical simulations of the virtual modular implant are realized using Visual Nastran software. The stress diagrams, the displacements diagram and the strain diagram are obtained. An *in vitro* experiment is made, simulating the osteosynthesis of a transverse diaphyseal fracture of human radius bone. The kinematical parameters diagrams of the staple are obtained, using SIMI Motion video capture system. The experimental diagram force–displacement is obtained.

Keywords**:** modular plate, osteosynthesis, human radius, Nitinol.

Introduction

The shape memory alloys exhibit a number of remarkable properties, which open new possibilities in engineering and more specifically in biomedical engineering. Shape memory refers to the ability of certain materials to 'remember' a shape, even after rather severe deformations. Once deformed at low temperatures, in their martensitic phase, these materials will spontaneously return to their original pre-deformation shape when heated. Besides the shape memory effect, this family of alloys exhibits remarkable characteristics such as a pseudo-elastic behavior and a very high damping capacity. The most important alloy used in biomedical applications is Ni–Ti, which is able to fulfill functional requirements related not only to their mechanical reliability but also to its chemical reliability and its biological reliability. Ni–Ti combines the highly superior characteristics of the shape memory effect and super-elasticity with excellent corrosion resistance, wear characteristics, mechanical properties and a good biocompatibility. These properties make it an ideal biological engineering material, especially in orthopedic surgery and orthodontics [1–11].

AO classification of the forearm bones diaphyseal fractures

The groups of radius and ulna diaphyseal fractures bones, in conformity with *Association of Orthopedics* classification [12] are:

A: Simple fractures of one or both bones;

B: Fractures with intermediary fragments;

C: Complex fractures of one or both bones.

The subgroups of A-group of radius and ulna diaphyseal fractures are (Figure 1):

A1. Simple fractures of the ulna, radius intact:
- .1 oblique;
- .2 transverse;
- .3 with dislocation of radial head.

A2. Simple fractures of the radius, ulna intact:
- .1 oblique;
- .2 transverse;
- .3 with dislocation distal radio-ulnar joint.

A3. Simple fractures of both bones:
1) without dislocation;
2) with dislocation of radial head;
3) with dislocation distal radio-ulnar joint:
   - .1 radius, proximal area;
   - .2 radius, middle area;
   - .3 radius, distal area.

A statistical study [12] shows that the A-diaphyseal fractures distribution of radius/ulna or both bones is: 18% simple fractures of the ulna, 21% simple fractures of the radius and 26% simple fractures of both bones. The B-fractures distribution of radius/ulna or both bones is: 7% fractures for ulna, 8% fractures of the radius and 14% fractures of both bones. The C-fractures distribution of radius/ulna or both bones is: 2% fractures for ulna, 2% fractures of the radius and 2% fractures of both bones. Therefore, the A-diaphyseal fractures of radius/ulna or both bones are the most frequent fractures. This is the reason to focus our present study on the analysis of the behavior simulation of the modular implants based on smart materials for diaphyseal radius bone fractures osteosynthesis.

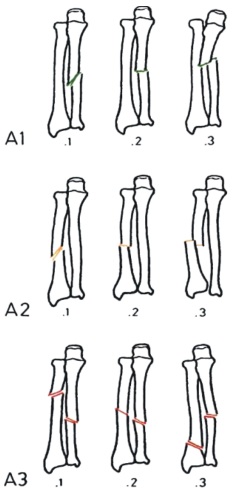

Figure 1 – ***The subgroups of A-group of diaphyseal fractures of forearm bones (AO classification).***

Diaphyseal fractures of the radius and ulna present specific problems not encountered in the treatment of fractures of the shafts of other long bones. In addition to restoration of length, apposition, and normal axial alignment, correct rotational alignment must also be achieved if a good range of pronation and supination is to be restored. Furthermore, there is a high incidence of malunion and nonunion because it is difficult to reduce and maintain the reduction of two mobile parallel bones in the presence of the pronating and supinating muscles which exert angulatory as well as rotational forces.

The results of treatment of forearm displaced diaphyseal fractures reported in different studies are difficult to analyze and compare because of the many variables, such as the proportions of acute fractures, delayed unions and non-unions, the locations and types of fractures, the numbers of open and closed injuries, and the extent of associated soft-tissue and other injuries. The poor functional results were related to rotational and angular malalignment after closed or unsuccessful open reduction, to delayed union or non-union with prolonged immobilization, and to such postoperative complications as radio-ulnar synostosis. The appliances used for internal fixation have included standard and special plates, Egger's slotted plates, primary onlay bone grafts, and intramedullary fixation.

Virtual model of the module implant

For modeling the optimum implant shape according to the type of fracture, it is taken into consideration the simulation of the areas where the implants are to be placed in order to determine the resistance of interweaving between fractured bone elements concurrent with determining the principles of optimum positioning of implants based on virtual modelling. It was taken into consideration the relative position and minimum force necessary for maintaining the interweaving contact. The optimum model has to take into consideration the implant insertion technique as well. To realize the model of the implant module we used SolidWorks, a CAD-software that permits to define parametrical three-dimensional virtual models [13].

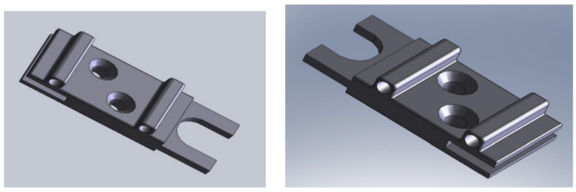

Figure 2 – ***The virtual model of the module.***

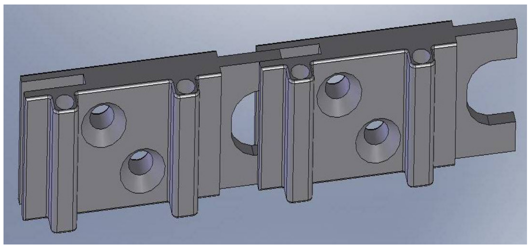

Figure 3 – ***The virtual bone plate assembly made from two modules.***

Numerical simulation of the two modules assembly

The virtual bone plate assembly made from two Titanium modules and a Nitinol staple is meshing in finite elements for the numerical simulations with Visual Nastran software [14, 15]. One of the modules is considered fixed and the other is considered mobile.

The shape memory staple is, initially, in their opened shape. Through heating, this staple tends to the original shape, the closed shape, developing a constant compressing force of 60 N at the 37^0C body temperature. The transformation schema of the staple shapes is presented in Figure 4.

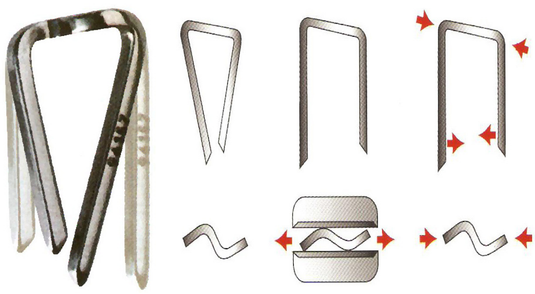

Figure 4 – ***The two memory shapes of Nitinol staple.***

A compression force of 60 N is applied on the Nitinol staple, like in Figure 4. The simulation movie is obtained. In Figures 5–7, the von Misses stress, the displacements and the strains obtained for two different moments of the simulation are presented.

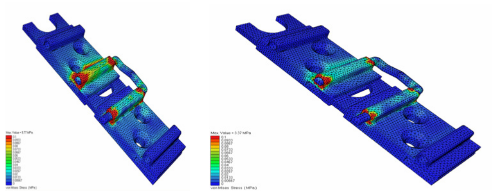

Figure 5 – ***The von Misses stress (MPa) in two different moments of the simulation.***

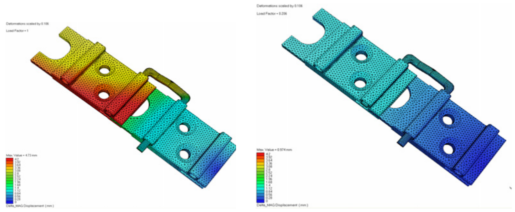

Figure 6 – ***The displacements [mm] in two different moments of the simulation.***

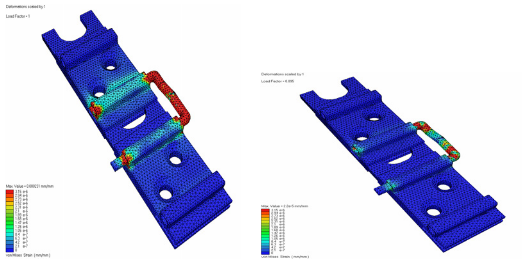

Figure 7 – ***The strains [mm/mm] in two different moments of the simulation.***

Material and Methods

Material

- human bones collected from cadaver from the Anatomy Department of the University of Medicine and Pharmacy of Craiova (Figure 8);
- osteosynthesis prototypes implants, obtained by the research team using virtual simulation in 3D, and fabricated from titanium biocompatible material (Figure 9);
- staples made from Nitinol, fabricated by Lepine Group, France (Figure 9);
- screws: 1.5 mm diameter and 25 mm in length;
- spiral: 1.5 mm diameter; saw;
- Akku–Bohrschrauber 18v drill.

Working principle

Treatment of the radius fractures depends on the stability of the fracture configuration. A stable fracture can be adequately managed with cast immobilization. An unstable fracture may require surgical fixation. In selecting the optimum technique, the surgical complexity, mechanical performance, and biological response should be considered. Technically, the method should be simple and inexpensive. Mechanically, the fixation should provide sufficient stability. Biologically, the treatment should be minimally invasive, the implants well tolerated, and the resulting bone stresses optimal for fracture healing. For this experiment, we use a human radius bone collected from cadaver and a modular plate made from minimum two modules (Titanium) and Nitinol staple (Figure 8).

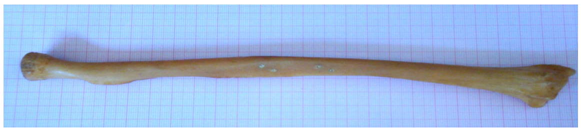

Figure 8 – ***The real human radius bone collected from cadaver.***

Using the saw a section through the radius bone diaphysis has been made in average 1/3 (Figure 10).

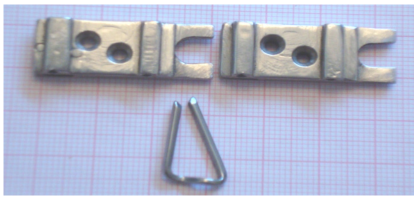

Figure 9 – ***The module prototypes made of biocompatible materials and the Nitinol staple.***

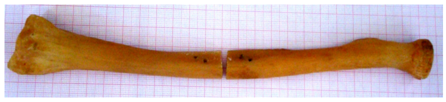

Figure 10 – ***The two fragments of the radius bone, simulating a transverse diaphyseal fracture.***

One of the osteosynthesis implants has been positioned on the proximal fragment and using the drilling machine and the spiral two channels in the bones cortical have been made. Afterwards, two screws have been mounted into the channels, making an assembly through which the implant was fixed to the bone. A similar approach involved the distal fragment on the bone, the second implant has been positioned on the bone so it could be coupled with the first implant and, in the same time, to allow the longitudinal sliding of the two implants and of the two sectioned bones by 2 mm.

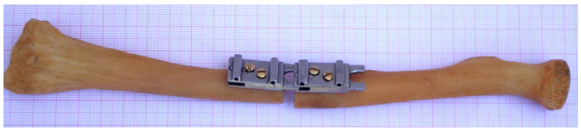

Figure 11 – ***The assembly made from bone and modular plate.***

After the second implant has been mounted by means of the two screws, the implants have been coupled by means of the Nitinol staple, which was before cooled to -20^{0}C in a NaCl liquid solution kept in a refrigerator. By cooling, the staple is opened and driven into each of both mounted modules. A warm air jet was directed over the assembly until a 37^{0}C was obtained. As the staple warms (possibly just upon heating to body temperature) the pins return to their original shape, pulling the fracture together, determining the translation of the modules and the separated parts of bone are compressed, reducing the risks of wrong orientation or additional bones callus. The compression staple made from Nitinol provides an adequate source of fracture fixation. The force generated by this process accelerates healing and reduces the time of bone recovery. The adaptability is related to medical possibility of physician to made the implant to correspond to patient specifically anatomy. The final assembly made from radius bone, two modules and Nitinol staple is presented in Figure 12.

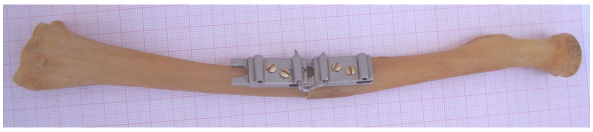

Figure 12 – ***The assembly made from bone, two modules and Nitinol staple.***

The experimental system used for measuring the staple force and the modules displacements is made from human radius bone, two markers, a comparison watch Reicherter, (one division = 0.01 mm), Probat-Werke balance, (0–200 N). In the same time, a SIMI Motion acquisition data system is used to obtain the kinematical parameters of the staple.

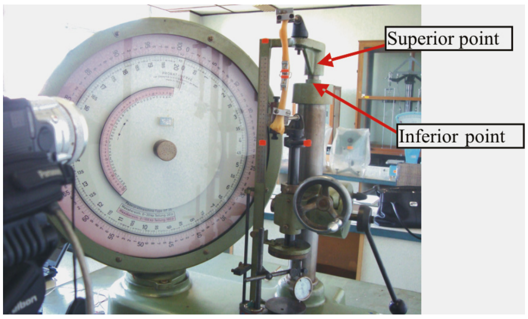

Figure 13 – ***The experimental system.***

The acquisition data system is made from:
- a laptop Lenovo;
- two video cameras Sony (60 frames/sec);
- the specialized software;
- markers.

The main stages of video capture analysis using SIMI Motion software are [16, 17]:

1. Camera calibration.
2. Definition of the studied points.
3. Definition of the connections between the points.
4. Tracking the points (which could be done automatically by computer or manually by indicating each point in each frame).
5. Extraction of the results.

The schema block of SIMI workflow is presented in Figure 14.

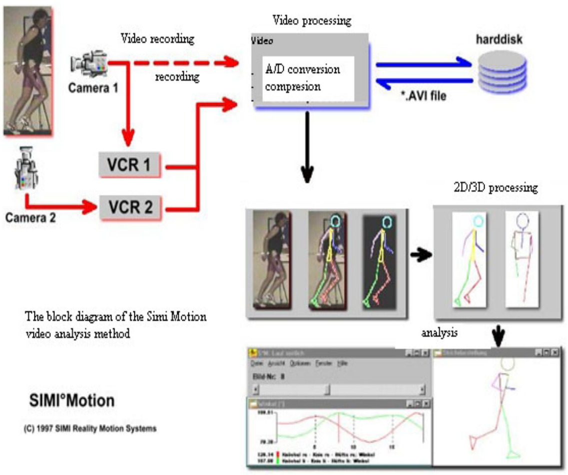

Figure 14 – ***The block schema of the SIMI Motion video analysis method.***

The diagram force–displacement was obtained, and we can observe that the maximum value of the compression force developed by the staple is 60 N (Figure 15).

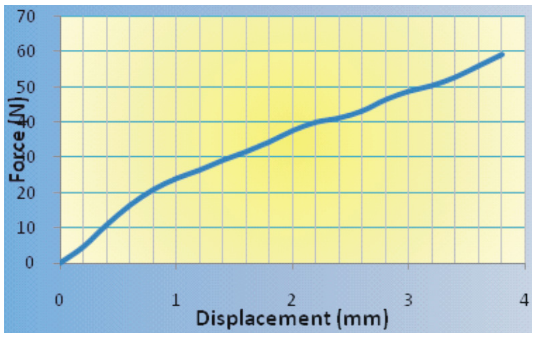

Figure 15 – ***The diagram force–displacement.***

Using the SIMI Motion software, the kinematical parameters of the both extremities of the staple were obtained. In Figures 16–18, the displacement diagram [mm], the speed diagram [mm/sec] and the acceleration diagram [mm/sec^2], as functions of time, for the inferior point are presented. Similarly, the diagrams for the superior point are obtained.

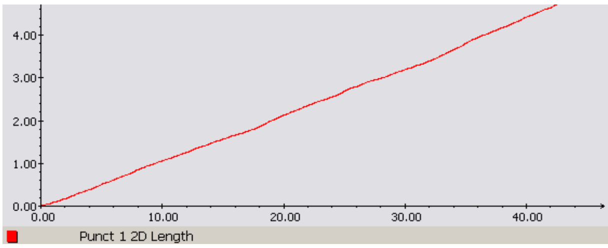

Figure 16 – ***The displacement diagram of the inferior point.***

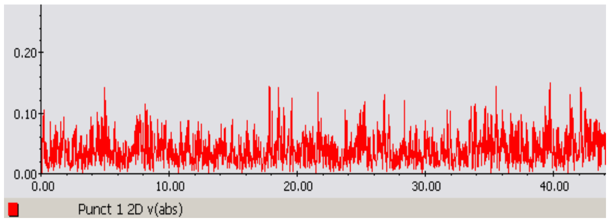

Figure 17 – ***The velocity diagram of the inferior point.***

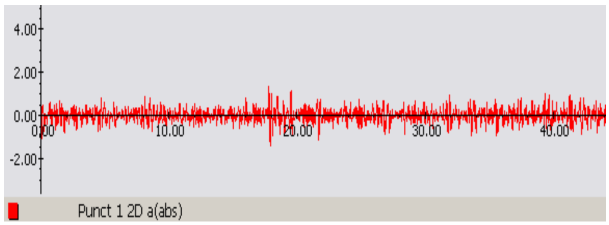

Figure 18 – ***The acceleration diagram of the inferior point.***

Results

We obtained the virtual model of the modular implants, using SolidWorks, a CAD-software that permits to define parametrical three-dimensional virtual models. The simulation movie of the plate implant made from two modules and a Nitinol staple is obtained. In Figures 5–7, the von Misses stress, the displacements and the strains obtained for two different moments of the simulation are presented. For a compression force of 60 N for the staple, one can observe the displacements of the staple extremities are 4.2 mm. We obtained an assembly formed by the two radius bone fragments, and the modular plate, which has enough rigidity and stability to the bending, torsion or traction. The shape memory staple plays an important role in the stability and rigidity of the assembly, allowing the bone fragments to slide one to the other until the good union. By adding other modules to the initial assembly again, we can augment the stability and rigidity of the assembly.

The results obtained using the SIMI Motion acquisition data represent the evolution in time for the position (displacements), velocities and accelerations. Also, the diagram force-displacement for the staple is obtained.

Discussion

The modular adaptive implants conceived by our team of researchers have confirmed, using *in vitro* experiments, cohesion of the diaphyseal transverse fracture bone fragments of the radius. The mounting of the modules to the bone is very easily. The addition of the Nitinol staple is also simple, this piece stabilizing the whole assembly as well as compacting the bone fragments, an essential advantage in the process of healing. A good bone apposition, stabilization and compression of the bone surfaces before staple fixation are very important when using staple fixation to promote an optimal environment for bone healing.

The diagram force-displacement proves the maximum of the compression force obtained in the Nitinol staple used for the proposed modular implant is 60 N.

The video capture analysis is a fast, accurate method of study for kinematical analysis.

The experimental method presented in this paper treats the kinematics of the staple, but is a general method and it can be used to analyze any other movement, especially, human joints movements.

The data acquired through this method can be used to corroborate the experimental kinematical parameters with kinematical parameters obtained using various analytical or computer aided simulations in order to confirm a certain mechanical model.

Conclusions

The adaptive modular implants based on smart materials represent a superior solution in the osteosynthesis of the fractured bones over the conventional implants known so far.

The superiority of this design results from the following advantages:

(a) their structure is based on small modules which can be mounted easily on the bone;

(b) the modules can be used for every region of the bone, for the bones extremities, being conceived the corresponding modules;

(c) by combining a certain number of modules we can obtain implants with various lengths depending of type, position or dimension of the fracture;

(d) the possibility of mounting the Nitinol staple to the modules near the fracture hotbed enables the stabilization of the implants and the good union of the bone fractures, a key element in the healing process;

(e) low number and small dimensions of the holes used for implant fixing;

(f) due to constant pressure exerted in one of the two layers for which it was designed, provides the compaction of the fractures fragments.

(g) the small sizes of the modules enable the surgeon to make small incisions, using surgical techniques minimally invasive, having the following advantages:

- reduction of soft tissues destruction;
- eliminating intra-operator infections;
- reduction of blood losses;
- the reduction of infection risk;
- the reduction of the healing time for the plagues;
- reduction of the scar (the aesthetic aspect).

Acknowledgements

This work was supported by CNCSIS–UESFISCSU, "Ideas_92" Grant No. 86/2007.

References

[1] FRIEND CM, MORGAN NB, *Medical applications for Shape-Memory Alloys (SMA)*, Professional Engineering Publishing Ltd., UK, 1999, 1.

[2] FRANK TG, *Medical applications for Shape-Memory Alloys (SMA)*, Professional Engineering Publishing Ltd., UK, 1999, 31.

[3] RYHÄNEN M, KALLIOINEN J, TUUKKANEN J, *Medical applications for Shape-Memory Alloys (SMA)*, Professional Engineering Publishing Ltd., UK, 1999, 53.

[4] PELTON AR, STÖCKEL D, DUERIG TW, *Medical uses of Nitinol*, Mater Sci Forum, 2000, 327–328:63–70.

[5] MANTOVANI D, *Shape memory alloys: properties and biomedical applications*, J Miner Met Mater Soc, 2000, 52(10):36–44.

[6] DUERIG TM, PELTON AR, STÖCKEL D, *The use of superelasticity in medicine*, Metall, 1996, 50(9):569–574.

[7] CHU Y, DAI K, ZHU M, MI X, *Medical application of NiTi shape memory alloy in China*, Mater Sci Forum, 2000, 327–328:55–62.

[8] AIROLDI G, RIVA G, *Innovative materials: the NiTi alloys in orthodontics*, Bio-Med Mater Eng, 1996, 6(4):299–305.

[9] LAGOUDAS DC, REDINIOTIS OK, KHAN MM, *Applications of shape memory alloys to bioengineering and biomedical technology*, Proceedings of the 4th International Workshop on Mathematical Methods in Scattering Theory and Biomedical Technology, Perdika, Greece, October 8–10, 1999.

[10] DUERIG TM, PELTON AR, STÖCKEL D, *An overview of nitinol medical applications*, Mater Sci Eng A, 1999, 273–275:149–160.

[11] SHABALOVSKAYA SA, *Biological aspects of TiNi alloy surfaces*, Journal de Physique IV, 1995, 5/2(8):C8.1199–C8.1204.

[12] MÜLLER ME, NAZARIAN S, KOCH J, SCHATZKER J, *Fractures classification. AO classification of the long bones fractures*, Edition in Romanian language from TOMOAIA GH, Ed. Risoprint, Cluj-Napoca, 2006.

[13] ***, *SolidWorks Software: Manual*, www.soliworks.com.

[14] TARNIȚĂ D, TARNIȚĂ DN, BÎZDOACĂ N, TARNIȚĂ C, BERCEANU C, BOBORELU C, *Modular adaptive bone plate for humerus bone osteosynthesis*, Rom J Morphol Embryol, 2009, 50(3):447–452.

[15] TARNITA D, TARNITA DN, *Modular adaptive bone plate based on intelligent materials*, 11th Essen Symposium on Biomaterials and Biomechanics: Fundamentals and Clinical Applications, Essen, March, 5–7, 2009, 102–103.
[16] ***, *SIMI Reality Motion Systems: Manual*, www.simi.com.
[17] BERCEANU C, TARNITA D, *Experimental method for measuring the kinematics of the human motion*, J Rom Sports Med Soc, 2009, Suppl 2:244–247.

Corresponding author
Daniela Tarniță, Professor, PhD, Department of Applied Mechanics, University of Craiova, 107 Bucharest Avenue, 200478 Craiova, Romania; Phone +40251–419 400, e-mail: dtarnita@yahoo.com

Received: August 10th, 2009

Accepted: April 25th, 2010