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"In vitro" Implantation Technique Based on 3D Printed Prosthetic Prototypes

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Abstract. In this paper, Rapid Prototyping ZCorp 310 system, based on high-performance composite powder and on resin-high strength infiltration system and three-dimensional printing as a manufacturing method are used to obtain physical prototypes of orthopaedic implants and prototypes of complex functional prosthetic systems directly from the 3D CAD data. These prototypes are useful for in vitro experimental tests and measurements to optimize and obtain final physical prototypes. Using a new elbow prosthesis model prototype obtained by 3D printing, the surgical technique of implantation is established. Surgical implantation was performed on male corpse elbow joint.

1. Introduction

Rapid Prototyping (RP), a relatively new class of manufacturing technology, is the name for several techniques for reading the data provided by computer-aided design (CAD), three-dimensional (3D) automatic design and for manufacturing of virtual objects layer by layer, depending on the design [1].

It started to develop at the beginning of 1980s and many papers were written in this new research field [1-6].

A prototyping process can be called rapid prototyping [3] if:

- The process is based on using 3D CAD data.
- The prototype part is created automatically.
- The model is ready in a few minutes, few hours or few days.

Current basic application of RP systems consists in reducing the time in which a new product is (almost) finished: right before making large expenditures on creating manufacturing equipment [1]. Testing a completely functional prototype part at this moment offers the opportunity of localizing the design errors and their correction while the costs of change are still small, errors that may have been unnoticed in testing only CAD 3D model [1-3]. The important aspect of RP process is the automatic translation of 3D CAD model to the physical model, given that the technology used does not have too much importance [5, 6].The key idea of this new rapid prototyping technology is based on decomposing 3D model in thin cross sectional layers, followed by a physical form of the layers and their bonding "layer after layer" [3].

The objective of this study is to obtain prototypes for human bones and for different types of elbow prosthesis using 3D Printing in order to apply them in experimental testing and surgical techniques establishing of in vitro implantation, developing methods that increase the process flexibility and reduce production costs.

2. 3D Printing

The three-dimensional printing (3DP) is a RP technology, used to create complex 3D parts directly from a computer model of the part, with no need for tooling. Advances in both process capabilities and RP materials have led to the possibility of rapid manufacture of finished components directly from 3D CAD data [7-10, 12-14]. In recent years 3DP has become a very competitive process in terms of cost and speed, creating high accuracy filler structures for the fabrication of complex 3D prototypes from powdered materials. A large number of models can be produced during the product development phase, taking into account the comparatively high speed and low operational cost of 3D printers [7-19].

The general scheme of the 3D printer fabrication principle is shown in Figure 1 [9]. A multichannel head deposition is moved in xy coordinates on the surface of the platform. The prototypes are highly accurate in the XY plane, but they have a scale effect, step by step in z direction. If the model is disposed with very thin layers having only some microns in size, the model looks like the original [2, 13-20].

Instead of printer ink, this head of deposit leaves drops of adhesive in the tank, which will strengthen in contact with particles of material deposited in a thin layer on the working platform [7, 9]. The cavity 1 with moving piston1 contains the initial quantity of powder Figure 1 (a). The process begins by spreading of a thin layer of powder taken from cavity 1 over a build platform 2 Figure 1 (b). Parts are created inside the cavity that contains a powder bed supported by the moving piston 2, by a layered printing process. Computer software splits the 3-D CAD data into a series of thin horizontal cross-sections. Each new layer is fabricated through lowering of the piston by a layer thickness and filling the resulting gap with a thin distribution of powder [7, 9]. An inkjet printing head prints a binder solution onto this layer of powder to form a slice of the 3-D CAD file Figure 1 (c). The layering process is repeated until the part is completed Figure 1 (d). Following a heat treatment, which consolidates the bonded material, the unbound powder is removed, leaving the fabricated part behind [7, 9].

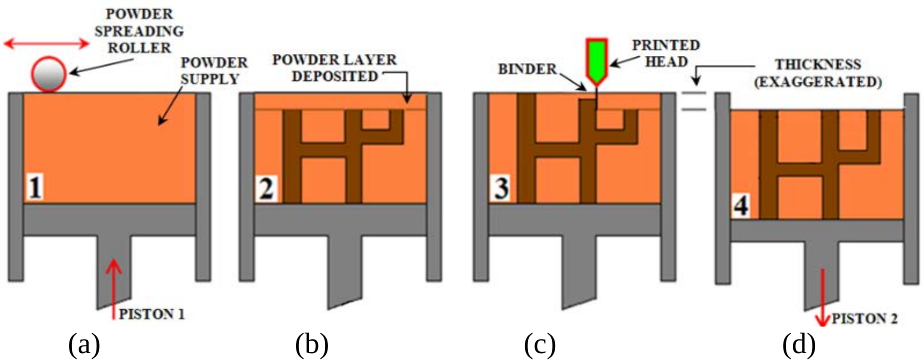

Figure 1. A schematic representation of the 3D printer fabrication principle [9].

3. Material and method

Using the Rapid Prototyping 3D Zcorp 310 Printer system Figure 2, from the Faculty of Mechanics, Craiova, we manufactured prototypes of human bones, orthopaedic implants, endoprosthesis, all of this being necessary for research, for in vitro simulations, experimental tests, experimental measurements etc. Printing System Z 310 Plus creates physical models directly from digital data with a construction volume of 203 mm x 254 mm x 203 mm and a thickness of 0.076 mm to 0.254 mm [7, 9, 11].

3.1. Stages of 3D printing

In rapid prototyping process of 3D printing type, the following stages are passed through:

- 3D geometric modeling.
- Transfer of CAD model to the sectioning processor.
- Prototyping proper.

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- Extraction of prototypes from the powder tank.
- Keeping the prototype in the tank for a period of time imposed by the machine in order to dry the bonding liquid and to harden the prototype.
- Cleaning and finishing.
- Infiltration with epoxy resin.

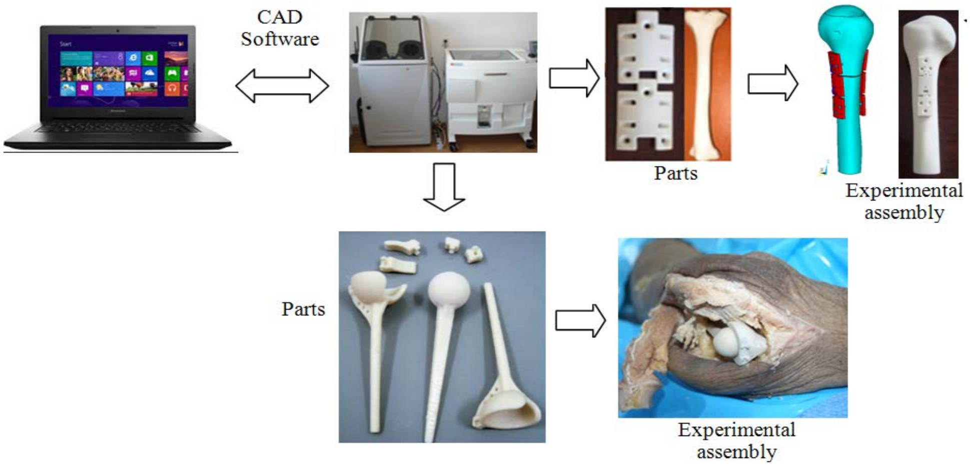
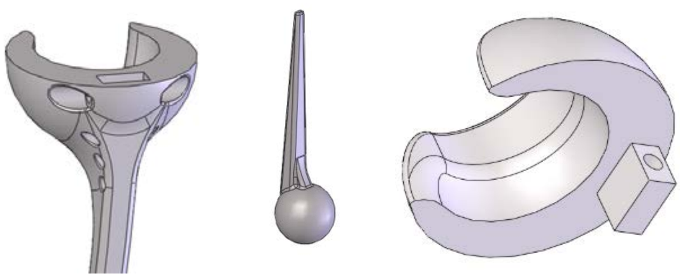


Figure 2. The Zcorp 3D printer and the methodology in order to obtain an experimental assembly using RP.

3.1.1. 3D geometric modeling. For bones prototypes Solid Works was used to geometrically reconstruct them based on a large number of electronic cross sections obtained using CT imaging device. Newly designed components, implants or prosthesis were designed as 3D virtual models using Solidworks or ANSYS software through original design or based on existing models on the medical market and continuing to optimize them [14-19]. In order to generate and design the new virtual geometric model of elbow prosthesis with ball coupling, the conditions imposed by elbow joint anatomy, by surgical prosthetic techniques and by the analysis of the cinematic parameters of unaffected elbow biomechanics were analyzed. It was also intended to obtain prosthesis with fewer components, with simpler technologic process, after athorough analysis of the constructive or functional advantages, disadvantages, shortcomingsand deficienciesof the elbow prostheses currently used elbow prostheses currently used for elbow joint reconstruction [20].Solid Works program was used for the parametric modeling of ball coupling prosthesis, the model being designed to allow the modification of dimensions [20] for its adjustment to groups of patients using the complete geometric parameterization property.



(a) (b) (c)

Figure 3. Virtual models of (a) ulnar component; (b) humeral component; (c) closing ulnar component [20].

The model of elbow prosthesis with ball coupling Figure 4 was designed using the assembly module of the program (Assembly) and specific commands that cancel certain degrees of freedom.

Figure 4. Model of elbow prosthesis with ball coupling [20].

3.1.2. Transfer of CAD model to the sectioning processor. In many cases, sectioning can be made by the CAD program used for modeling. The most common method for sectioning and construction is the approximation of the model with plane triangular elements Figure 5 and Figure 6.

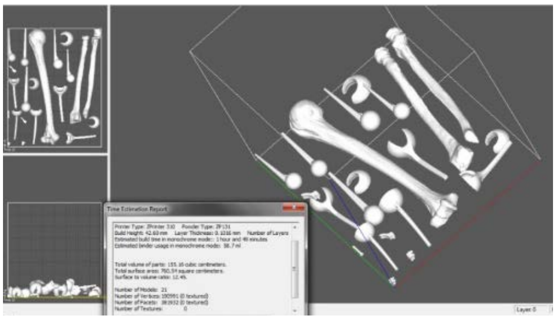


Figure 5. Transfer of CAD models in Zcorp processor.

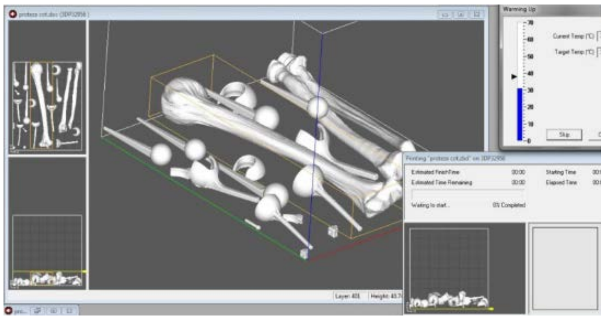


Figure 6. Verification of temperature increase stage to the value imposed for starting prototyping process.

3.1.3. Prototyping process

Figure 7. Printing process.

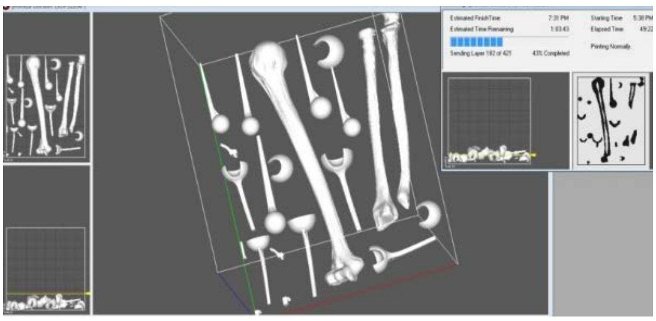


Figure 8. Verification of prototyping stage.

3.1.4. Extraction of prototypes from the powder tank

Figure 9. Extraction of prototypes from the powder tank.

Figure 10. Infiltration with epoxy resin.

3.1.5. Keeping the prototype in the tank for a period of time imposed by the machine in order to dry the bonding liquid and to harden the prototype.
3.1.6. Cleaning and finishing. These are operations in which the supports used in construction and the excess material are eliminated or other processing operations (including mechanical) aimed to improve the dimensional precision and the quality of surfaces.
3.1.7. Infiltration with epoxy resin. 3 DP components have low mechanical properties, and they must be infiltrated with resin to improve their characteristics Figure 10. Infiltration is the process of applying a liquid resin to a printed part to provide strength and impart specific properties. After infiltration with Z-Max ™ which is a two-part system: Z-Max™ Infiltration Resin and Z-Max™ Infiltrant Hardener, the parts are hardened at room temperature, within 12-24 hours [7, 9]. Once infiltrated, the parts can be easily processed, exploited, burnished and processed. The material Zp131 is a high-performance powder with composition containing ingredients such as: Crystalline Silla Plaster containing <1% vinyl polymer, carbohydrate, salt and sulphate produced consumables Technologies Ltd, (www.technologysupplies.co.uk). 60 Zb clear binder mixture is a formula to be used to fuse the powder to achieve 3D models in rapid prototyping [7, 9].The process achieve in a few minutes to several hours, the three-dimensional physical models of the objects starting directly from the electronic format 3D CAD/CAM, the only equipment used being the 3D printer [7, 9].

4. Results

The result consists in very strong models, up to 43 MPa of flexural strength and up to 98 MPa of compression strength. Parts made with Z-Max™ are hard and rigid so they dont deform under load [7, 9]. As results, we present some examples of human bones like humerus and radius Figure 11 and two models of elbow prosthesis: the new spherical model Figure 12, the elaboration of the virtual model being presented in [20] and the Latitude prosthesis Figure 13, a well known actual elbow prosthesis, usually used in elbow orthopedic surgery [9].

The prosthetic system is of the ball head type consisting of three parts: a part implanted in the humerus, a part implanted in the ulna bone and a third part transforms the assembly from an unconstrained prosthesis in a semi-constrained prosthesis. The metallic implant is fixed through cementation in the humerus and ulna bones.

The newly created prosthesis fulfils all the criteria in order to be considered a prosthesis superior to those used so far [20], namely:

- criterion of simplicity – regarding the design and the implantation; the implantation kit is simple and it does not use special tools.
- criterion of conservation – meaning the ability to sacrifice a minimal amount of healthy tissue;
- criterion of manufacturing – the simplicity of the prosthetic components allows them to be made with classical tools with no special equipment;

- criterion of cost – due to the simplicity of the components, the costs are much smaller than in the case of current prostheses;
- criterion of safety –the implantation in a human corpse proved the safe operation of the prosthetic components.

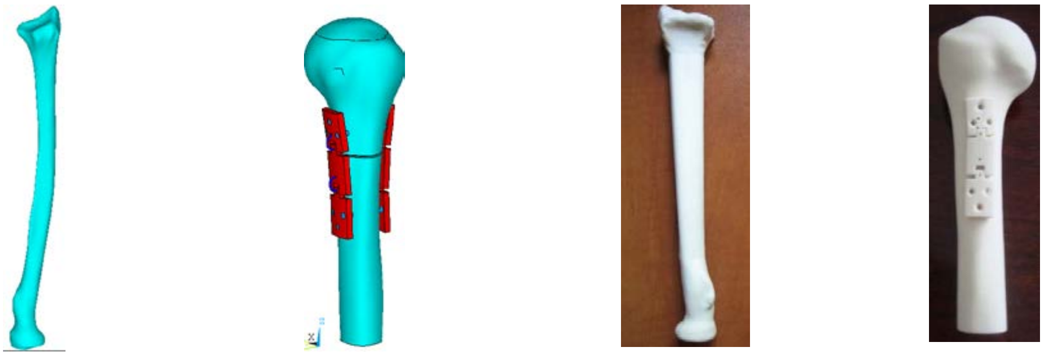


Figure 11. Virtual and prototiped bones: radius, humerus and phalangies [7, 9].

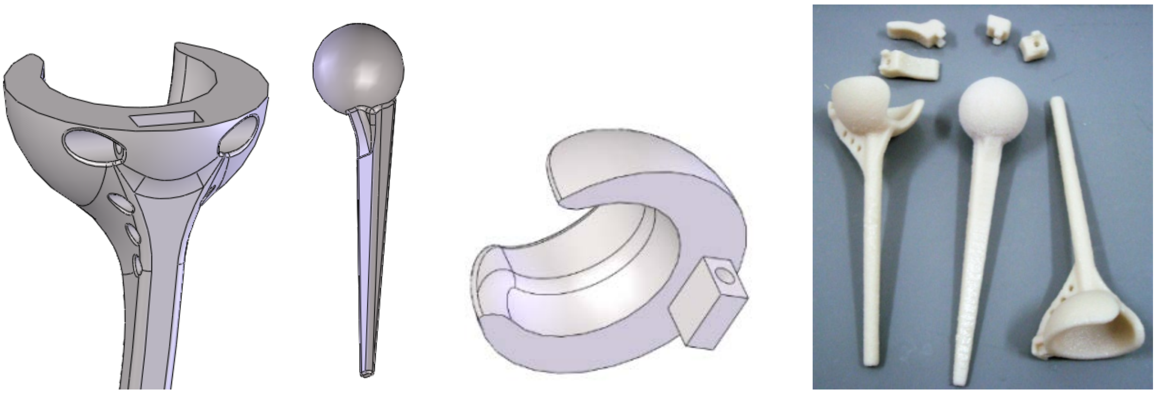


Figure 12. The virtual model and the prototype of the components of the spherical prosthesis.

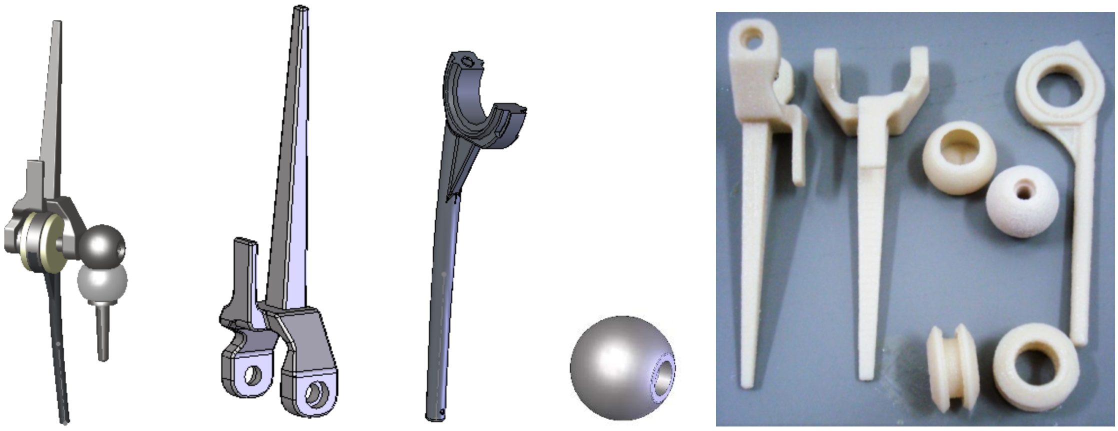


Figure 13. The virtual model of Latitude elbow prostheses, the virtual models of some components and some of the prototyped components [9].

The experimental part of the new model of elbow humero-ulnar prosthesis implantation on the elbow joint was carried out in one of the dissection laboratories belonging to the Department of Human Anatomy of the Faculty of Medicine of Craiova.

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Surgical implantation was performed on the elbow joint of a male body preserved by embalming by injection with alcohol and glycerol solution, stored in a refrigerator dedicated to body preservation.

The surgical technique for implanting elbow prosthesis according to the invention involves the following steps:

- an incision is made on the dorsal face of the elbow, long about 10 cm, 5 cm on the cubital edge of the forearm and 5 cm on the dorsal face of the arm, Figure 14.

Figure 14. Incision on the dorsal face of the elbow.

- a longitudinal incision of the cubitus periosteum along the whole length of the tegument incision is made.
- the periosteum of the cubitus proximal epiphysis is removed using a cutting specific instrument.
- the olecranon is transversely cut with an oscillating saw, Figure 15.
- two longitudinal incisions are made using a scalpel at the level of the triceps brachii muscle tendon and the trochlea of the humerus pallet is pointed out, Figure 16.

Figure 15. The olecranon transverse cut.

Figure 16. Longitudinal incisions at the level of the triceps brachii muscle tendon.

- with an oscillating saw, the trochlea of the humeral pallet is cut out by two longitudinal sections at the level of the trochlear ridges and a transverse one above the trochlea. By the trochlea removing, the humeral medullary canal can be seen.
- the cubitus medullary canal is prepared with a calibrated rasp after the stem of the cubital component, Figure 17.
- also the humeral medullary canal is prepared with a rasp calibrated for the dimensions of the stem of the prosthesis humeral component, Figure 18.

Figure 17. The cubitus medullar canal preparation.

Figure 18. The humeral medullar canal preparation.

- the test is made by positioning the two components of the prosthesis in the two bones, Figure 19 and Figure 20.

Figure 19. Positioning of the first component of the prosthesis in the bone.

Figure 20. Positioning of the second component of the prosthesis in the bone.

- the stems of the two prostheses are cemented into the corresponding bones;
- the two components of the prosthesis are coupled in the non-constrained or semi-constrained manner, Figure 21 and Figure 22.

Figure 21. Coupling of the prosthesis components in the non-constrained manner.

Figure 22. Coupling of the prosthesis components in the semi-constrained manner.

- the olecranon is resected.
- the tricipital tendon is armed with special wire threads bind to the special holes of the cubital

component, Figure 23.

- the two longitudinal incisions made in the triceps tendon are sutured with resorbable threads; the suture of the skin wound is performed in anatomic layers, Figure 24.

Figure 23. The tricipital tendon armed with special wire threads.

Figure 24. The suture of the skin wound.

5. Conclusions

Rapid prototyping (RP), a relatively new class of manufacturing technology, has the potential to create different parts or assemblies like human bones, prosthesis, orthosis or other biomedical devices, directly from the 3D CAD data. Rapid Prototyping method exceeds the conventional manufacturing methods in terms of accuracy and fabrication time. Using Rapid Prototyping as a fabrication method one can finally obtain functional assemblies which can be used afterward in various experiments (for example, kinematic or dynamic studies) just as in the case of conventional metal based assemblies.

Rapid Prototyping ZCorp 310 system based on high-performance composite powder and on resin-high strength infiltration system and three-dimensional printing may be also used as a prototypes manufacturing method in industrial field because of the rapidly evolving industry requirements to validate products with low cost using new in vitro methods.

3D Printing is a Rapid Prototyping technology, an easy and versatile process making complex varied geometries by combining a 3D printer, CAD development software and special materials from which the prototype will be created. The complexity of the shapes and dimensions of the fabricated parts recommends Rapid Prototyping method as a future fabrication method in an increasingly number of applications and scientific fields of research.

In medicine, physical prototypes of orthopaedic implants and prototypes of complex functional prosthetic systems obtained directly from the 3D CAD data by Rapid Prototyping allow in vitro experimental tests and measurements in order to optimize and obtain final physical prototypes.

Developing the most suitable mechanical model and its validation in vitro experiments by reproducible testing spurred a significant research interest into biomaterials using because many biomaterials fail after implantation, so comparative biomechanical studies help a lot to improve the knowledge.

These 3D printed prototypes made before final prototypes manufactured from expensive materials allow constructive optimization and surgical techniques establishing at low cost.

6. References

[1] Brown R, Lightman A and Wohlers T 1994 Need for Expanding the Development and Refinement of Rapid Prototyping Technologies *Newsletter*ed Society of Manufacturing Engineers (Toronto)

[2] Chua CK and Leong KF 2000 Rapid Prototyping:Principles and Applicationsin Manufacturing, *World Scientific*

[3] Gebhardt A2003 *Rapid Prototyping*ed Hanser Gardner Publications Inc. (Cincinnati)

[4] Pandey P M, Reddy N V and Dhande SG2003 *Rapid Prototyping Journal* **9**(5) 274-88
[5] Pham D T and Dimov S S 2001 Rapid Manufacturinged Springer-Verlag London Limited
[6] Wohlers T T 2005 Wohlers Report 2005, Rapid Prototyping, Tooling and Manufacturing: State ofthe Industry *Annual Worldwide Progress Report* ed Wohlers Associates Inc. (Fort Collins CO USA)
[7] Tarnita D et al. 2010 The Three-Dimensional Printing – a Modern Technology Used for Biomedical Prototypes, *Materiale plastice* **47(**3) 328-34
[8] Herbert N, Phil M, Simpson D, Spence W D and Ion W 2005 A preliminary investigation into the development of 3-D printing of prosthetic sockets *JRRD* **42**(2) 141–6
[9] Tarnita D, Tarnita D N, Boborelu C and Catana M 2013 *Academic Journal of Mechanical Engineering, Academic Journal of Manufacturing Engeneering* **111**/2013 119-24
[10] Tsung-Jung H and Wei-Hsiang L 2010 *Journal of the Chinese Institute of Engineers* **33**(1) 121-30
[11] Tarnita D, Tarnita D N and Bolcu D 2011 Orthopaedic implants based on shape memory alloys Biomedical Engineering – From Theory to Applicationsed InTech Publishing House (Viena)431-68
[12] Thilmany J 2001 Printing in Three Dimensions *Mechanical Engineering* Periodical article, Issue date: May 1.
[13] Dimitrov D, Schreve K and de Beer N 2006 *Rapid Prototyping Journal* **12**(3) 136-47
[14] Tarnita D, Popa D, Tarnita D N and Grecu D 2006 *Romanian Journal of Morphology and Embryology* **47**(2) 181-6
[15] Tarnita D, Boborelu C, Popa D and Rusu L 2010 *Romanian Journal of Morphology and embryology* **51**(3) 489-95
[16] Tarnita D, Tarnita D N, Bizdoaca N, Tarnita C, Berceanu C and Boborelu C 2009 *Romanian Journal of Morphology and embryology* **50**(3) 447-52
[17] Tarnita D, Tarnita D N, Popa D, Grecu D and Niculescu D 2010 Numerical simulations of human tibia osteosynthesis using modular plates based on Nitinol staples, *Romanian Journal of Morphology and embryology,* **51**(1) 145-150
[18] Tarnita D, Tarnita D N, Hacman L, Copilusi C, Berceanu C and Cismaru F 2010 In vitro experiment of the modular orthopedic plate based on Nitinol, used for human radius bone fractures, *Romanian Journal of Morphology and embryology* **51**(2) 315-20
[19] Tarnita D, Tarnita D N, Tarnita R, Berceanu C and Cismaru F 2010 Modular adaptive bone plate connected by Nitinol staple, *Material wissenschaft und Werkstofftechnik, Materials Science and Engineering Technology, Special Edition Biomaterials*, ed Willey-Vch **41**(12) 1070-80
[20] Tarnita D, Boborelu C, Popa D and Tarnita DN 2018 Design and Finite Element Analysis of a New Spherical Prosthesis-Elbow Joint Assembly, *New Advances in Mechanism and Machine Science,* Proceedings of The 12th IFToMM International Symposium on Science of Mechanisms and Machines