The Three-Dimensional Printing – a Modern Technology Used for Biomedical Prototypes

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The three-dimensional printing is a rapid prototyping technology, used to create complex three-dimensional parts directly from a computer model of the part, with no need for tooling. This paper investigates the use of a modern RP technology known as 3-D printing. Using the Rapid Prototyping 3D Zcorp 310 Printer system, we manufactured the prototypes for orthopedic adaptive modular plates based on intelligent materials, human bones and an artificial hand necessary for 'in vitro' simulations, experimental tests, experimental measurements. The material used is a High performance composite powder Zp131. After printing, we used Z-Max Resin - High Strength Epoxy Infiltrant System to provide strength and impart specific properties. Using Rapid Prototyping as a fabrication method one can finally obtain functional assemblies. Experimental studies of the staple made of the shape memory alloy named Nitinol are presented. The complexity of the shapes and dimensions of the fabricated parts recommends Rapid Prototyping method as a future fabrication method in different applications and scientific fields of research.

Keywords: CAD-CAM, rapid prototyping, 3D-printing, Nitinol, composite powder, epoxy resin, orthopedic applications

The concept of rapid prototype (RP) manufacturing technology is an innovation meant to fulfill this demand. Since the advent of the first commercial rapid prototyping in 1987, this technology has developed over forty machines of different technical types [1, 2]. RP technology has been diversified into several fields of application, such as aerospace, automobile, medical therapy, and architectural engineering. Current RP methods have several shortcomings; the accuracy and repeatability of the machines do not consistently match the claims of the manufacturer, and replacement parts are often difficult to procure. Finally, there is a strong demand to further decrease the rapid prototyping building time [3-7].

Rapid prototyping (RP), a relatively new class of manufacturing technology, has the potential to create different prosthesis, bones, or artificial hand assembly, directly from the 3D CAD data. The process begins with the digital acquisition of three-dimensional (3-D) geometric data. The digital model is stored on a computer.

Experimental part

3D Printing rapid prototyping technology

The three-dimensional printing (3DP) is a rapid prototyping technology, used to create complex three-dimensional 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, the manufacture of finished components directly from 3D CAD data.

3-D printing creates components from powdered materials. Although a number of different RP technologies exist, they are all based on the common principal of building parts layer by layer. In recent years three-dimensional printing has become a very competitive process in terms of cost and speed. The comparatively high speed and low operational cost of 3D printers mean that a large number of models can be produced during the product development phase. It is known from the literature that the accuracy of the 3D-printer is affected by different factors, like: material used, parts orientation within the 3D printer, nominal dimensions, wall thickness, binding agent, post treatment procedures [3, 6].

The process begins by the spreading of a thin layer of powder over a build platform. Parts are created inside a cavity that contains a powder bed supported by the moving piston, by a layered printing process where the information for each layer is obtained by applying a slicing algorithm to the computer model of the part. Computer software splits the 3-D CAD data into a series of thin horizontal cross-sections (slices). 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. An inkjet printing head then selectively prints a binder solution onto this layer of powder to form a slice of the 3-D CAD file. The layering process is repeated until the part is completed. Following a heat treatment, which consolidates the bonded material, the unbound powder is removed, leaving the fabricated part behind (fig.1). The use of the 3DP process is beneficial in the fabrication of prototypes. This method can produce high accuracy filler structures for the fabrication of complex 3D prototypes.

3DP lacks the accuracy and mechanical properties of such higher-end rapid prototyping systems. The process does not require special facilities for its operation. These qualities have led to 3DP being chosen predominantly as a concept modeling system and to its producing multiple iterations of a design both quickly and economically. The 3DP components have poor mechanical properties and generally could not be used for handling. This is the reason, after production, the components must be infiltrated with resins to improve their strength. If the resin is careful selected, the mechanical strength of a 3DP component increases to an extent that would make it suitable for use in prosthetic devices. We used Z-Max Resin - High Strength Epoxy Infiltration System.

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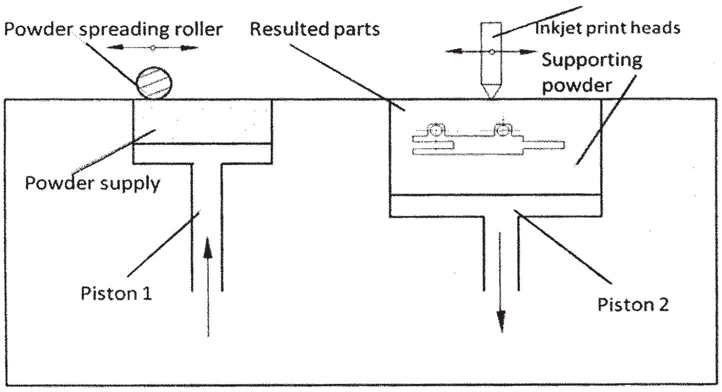

3 D Zcorp printer-Work principle

Fig.1. A schematic representation of the 3D printer and the fabrication principle

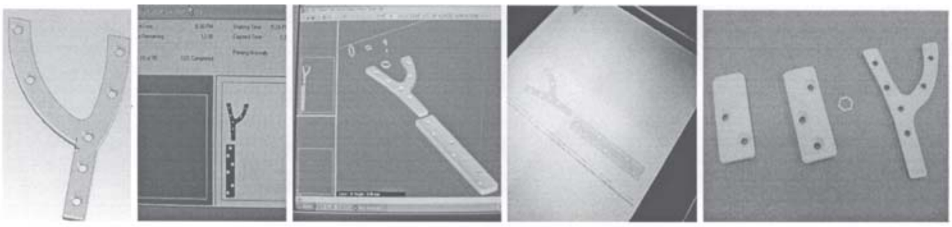

Fig..2. The main stages of the 3DP method (from virtual model to real prototype)

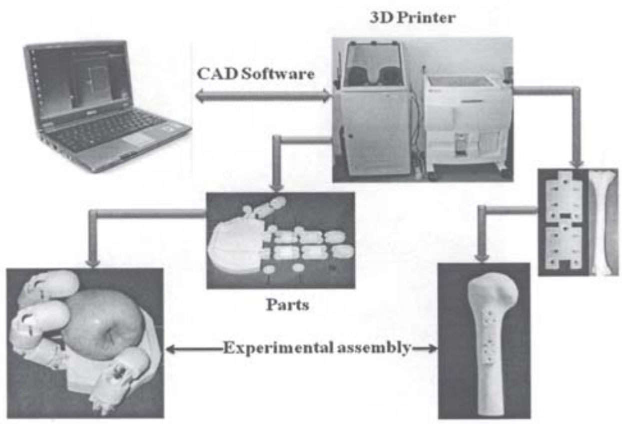

Fig. 3. The Zcorp 3D printer and the methodology used to obtain an experimental assembly using RP

Material and method

Using the Rapid Prototyping 3D Zcorp 310 Printer system (fig. 3), from the Faculty of Mechanics, Craiova, we manufactured the prototypes for original orthopedic modular plates, human bones and the artificial hand necessary for ‘in vitro’ simulations, experimental tests, experimental measurements etc.

The Z Printer 310 Plus System creates physical models directly from digital data with a build volume of 203 mm x 254 mm x 203 mm and a layer thickness of 0.076 mm to 0.254 mm. The equipment dimensions are 740 mm x 810 mm x 1090 mm, and it weights 113 kg.

The material used is a High performance composite powder Zp131 whose ingredients are: Plaster which contains Crystalline Sillica at <1%, Vinyl Polymer, Carbohydrate, and Sulfate Salt. The binder Zb 60 clear is a mixture formula to be used to fuse powder for making rapid-prototyping 3D models. The binder components are as in table 1.

Infiltration is the process of applying a liquid resin to a printed part to provide strength and impart specific properties. Our infiltration systems have been selected for their ability to fill porosities, for the exceptional mechanical and thermal properties they confer models and for their ease of use.

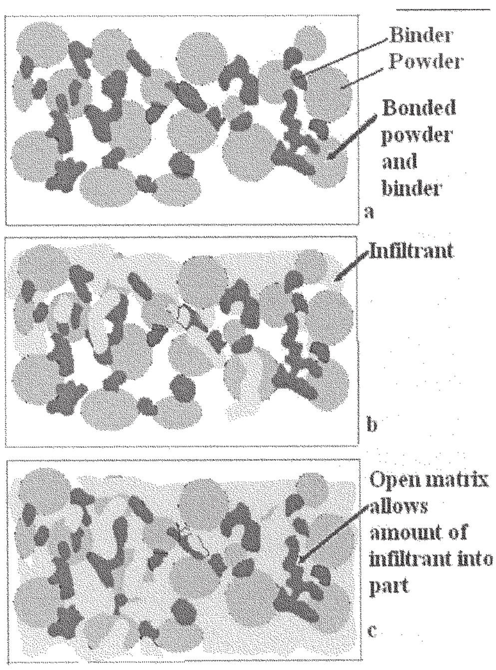

Fig.4. The infiltration stages

Table 1

Components	Approximate % by weight
1. Homectant 1	<10%
2. Homectant 2	<8.0%
3. Polymer	<4.0%
4. Water	85-95%

Table 2

Properties	Z-Max™
Tensile Strength, MPa	26.4
Elongation at Break, %	0.21
Modulus of Elasticity, MPa	12,560
Flexural Strength, MPa	44.1
Flexural Modulus, MPa	10,680

Table 3

Product	Description	Application Method	Mix Ratio	Penetration Depth (mm)	Working time	Cure Time 70°F/ 21°C	Cure Time 160°F/ 71°C
Z-Max™ High Strength	Maximum Strength Heat resistant	Brush Spray	100: 37 by weight	5-10	35 min	24 h	2 h

The figure 4 a. illustrates the open matrix of just-printed parts. The powder particles are bonded to each other by the binder. In the figure 4 b infiltrant has been applied to the surface of the matrix, and is starting to penetrate, displacing air from the interior of the matrix. The figure 4 c illustrates how the infiltrant is drawn into the part, sealing the surface area and improving the appearance and strength of the part. The properties and the description of Z-Max™ Infiltrant are presented in table 2, respectively, in table 3.

Z-Max™ is a functional high strength infiltrant great for more demanding applications such as fit testing, functional testing, tooling or molding. It is very useful for the user that needs prototyping functionality from their parts. A part infiltrated with Z-Max™ allows the interdisciplinary research team to quickly test design iterations without the cost and time associated with waiting for molded plastic parts. Z-Max™ is a low viscosity formulation, 120 cP, which means deeper, quicker penetration. The result is 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 do not deform under load. Z-Max™ also has good temperature resistance, with a Heat Deflection Temperature (HDT 66 psi) of 115°C.

Z-Max is a two-part system: Z-Max™ Infiltration Resin and Z-Max™ Infiltrant Hardener. Both parts of the infiltrant are requiring mixture before use. The composition of Z-Max™ Infiltration Resin is: Neopentyl glycol diglycidyl ether, 10-25 %, Butyl glycidyl ether, 1-10 %, Phenol, polymer with formaldehyde, glycidyl ether, 70-90%. The composition of Z-Max Infiltrant Hardener is: Tetraethylenepentamine <1 %, 4-Aminopropylmorpholine 10-25%, Aminoethyl-piperazine 40-60%, 2,4,6-Tris (Dimethylaminomethyl) phenol 1-10 %, Epoxy curing agent 1% Amido-amine * 20-40%.

After infiltration, Z-Max™ infiltrated parts cure at room temperature in 12-24 h. The use of an oven for the cure cycle reduces the cure time to just 2 hours, producing consistently strong parts quickly. Once infiltrated, parts can easily be machined, tapped, sanded, drilled, machined and painted. Z-Max™ gives a very hard, very rigid, and very strong part.

Interesting theoretical and experimental research studies concerning different composite materials reinforced with fibers and resins are presented in [8-10]

Results and discussions

An example of a novel fabrication process (using Rapid Prototyping) of a mechanical articulated hand is showed further on [11,12]. We began the development of the new artificial hand with the virtual models of the phalanxes and palm. For this purpose we have used specialized CAD software – SolidWorks 2008. After the virtual models of the parts have been completed we were able to construct the hand assembly (fig. 5). From the mechanical structure point of view, the new hand possesses three fingers (a fixed thumb with two phalanxes and two identical fingers with three phalanxes) and a palm.

In order to construct the hand assembly we have used another aftermarket parts: 8 plastic pulleys (25 mm in diameter) and 8 steel bolts (25mm in length and 3 mm in diameter) (fig. 6). In the case of presented artificial hand the movement is transmitted from the three DC servomotors (one per finger) to the tip of the finger (distal phalanx) via two cable transmission, one for the flexion and the other for the extension of the finger. The cables are routed through three holes in the palm and afterwards on the pulleys corresponding to each joint of the finger (two pulleys for the thumb and three pulleys for the other fingers). The actuators are commanded by an electronic control board equipped with Atmel Atmega 328 microcontroller based on various control algorithms written in "C/C++" programming language.

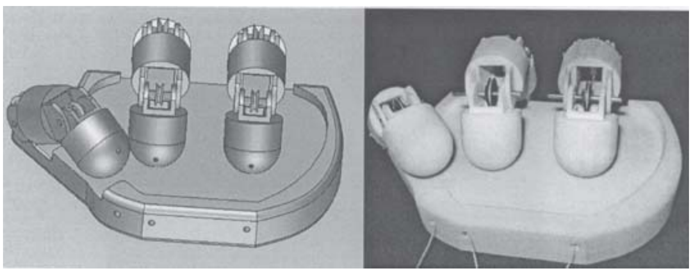

Fig. 5. The virtual model and the resulted prototype hand

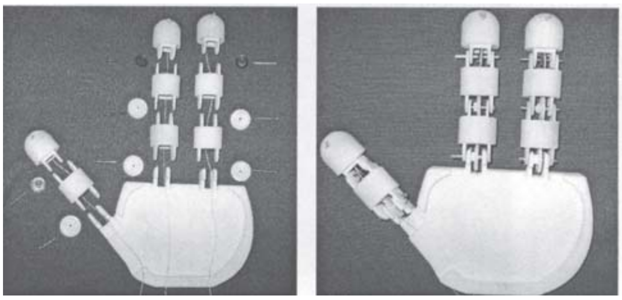

Fig.6. Two pictures with the parts before and after completing the artificial hand assembly

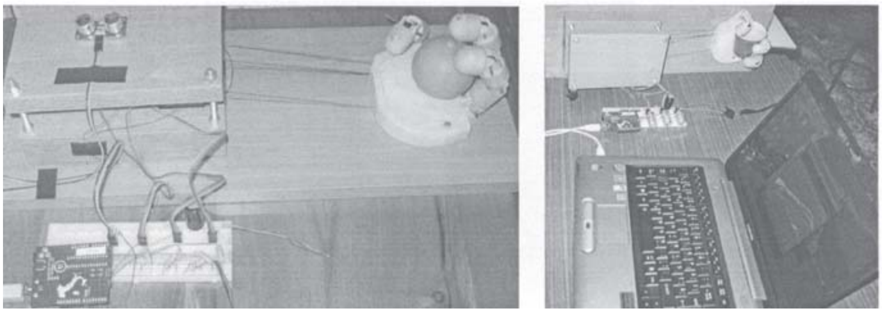

Fig. 7. Two pictures with the complete grasping system (mechanical hand, actuators, sensors, electronic control board etc.)

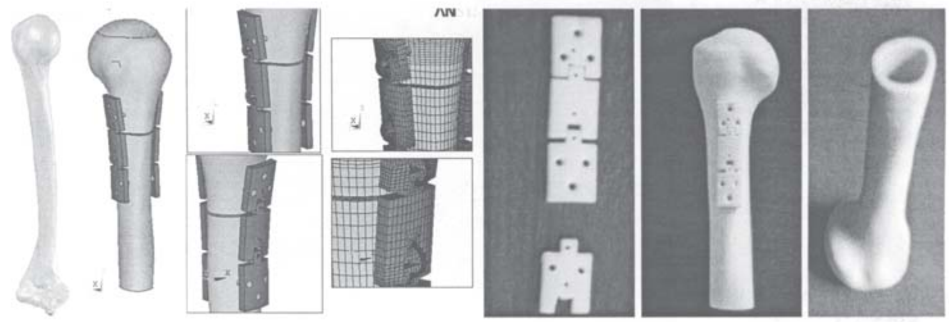

Fig. 8. The virtual humerus – plate assembly vs. prototyped humerus – plate assembly

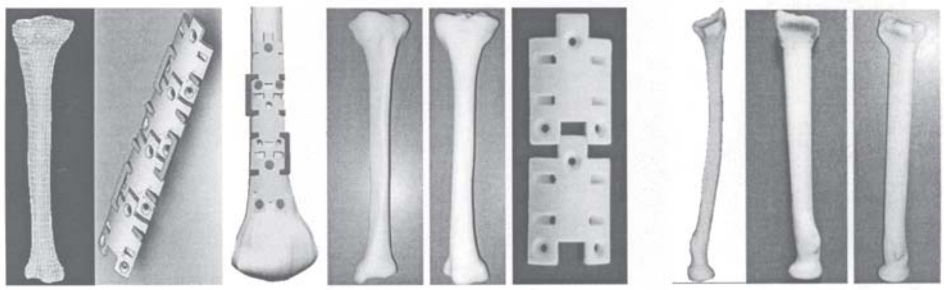

Fig. 9. Tibia and modular plates: virtual and prototiped (left), radius bone: virtual and prototiped (right)

In order to illustrate the potential of the new developed artificial hand and, generally, the functionality of an assembly whose parts have been fabricated with Rapid Prototyping Technology we present in figure 7 two pictures in which various objects are being grasped by the three fingered artificial hand.

Another example of functional assembly whose parts have been fabricated with Rapid Prototyping Technology describes human bones like humerus, tibia or radius and special conceived orthopedic modular implants based on shape memory alloys which are intelligent materials aimed to be used in the case of various fractures of these bones [13-15]

The modules are conceived to work in conjunction with special connection elements used to compress the fractured bone fragments, thus enhancing the healing process of the bone. These elements are staples made of NiTinol – a shape memory alloy. Applications of Shape Memory Alloys to the biomedical field have been successful because of their advantages over conventional implantable alloys, enhancing both the possibility and the execution of less invasive surgeries. Different applications exploit remarkable properties of Nitinol like:

- biocompatibility, superelasticity, force hysteresis, the shape memory effect (one-way or two-way), the steerability, torquability, less sensitivity to magnetic resonance imaging, excellent corrosion resistance [13-22].

The proposed intelligent device is a modular bone plate, with modules made of Titanium or Stainless Steel 316 L, and the staples made of Nitinol.

The shape memory staples, in their opened shape, are placed in the special places build in to the modules. Through heating, this staple tends to the original shape, the closed shape, developing a constant compressing force of 60 N at the 37^{0}C body, compressing the modules and determining the translation of the modules. In this way, the separated parts of the bone are compressed. The force generated by this process accelerates healing, reducing the time of recovery Moreover, these modules allow little movement in the alignment of the fractured parts, reducing the risks of wrong orientation or additional bones callus. The transformation schema of the staple shapes is presented in figure 10.

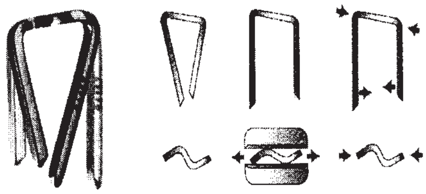

Fig. 10 .The two memory shapes of Nitinol staple

In order to obtain the kinematic laws for the pins of the Nitinol staple we used the motion acquisition and analysis system SIMIMotion [23]. SimiMotion is worldwide known software for motion analysis, having a great number of applications in fields such as: sports [24], medicine [25], biomechanics [26], etc. In [24] a sport race is analyzed using three synchronized cameras, while in [26] SimiMotion is used to study the kinematics of the human upper limb or finger movements.

The process which enabled us to obtain the kinematical parameters of the pins movement by means of video capture and image processing is illustrated in figure 11. The main stages of video capture analysis using SimiMotion software are [16, 17]:

1.Camera calibration. 2.Definition of the studied points. 3.Definition of the connections between the points.

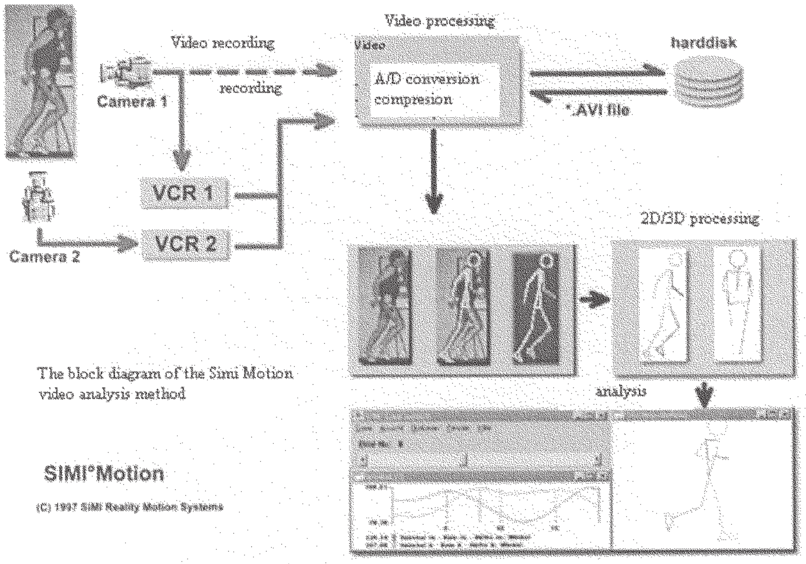

Fig.11. The schema block of SIMI workflow

Fig.12. The SimiMotion acquisition and analysis system

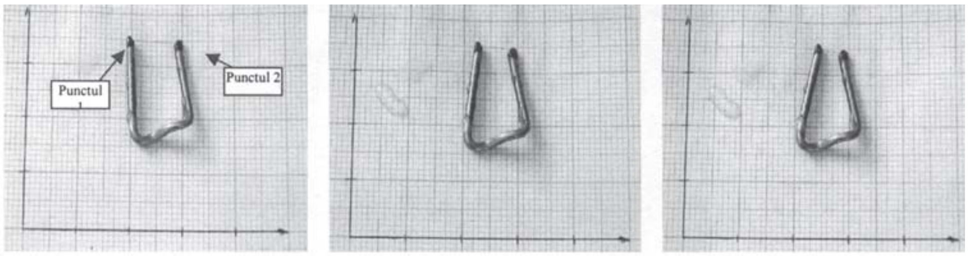

Fig.13. Three successive frames of the Nitinol clip recorded in the heating process

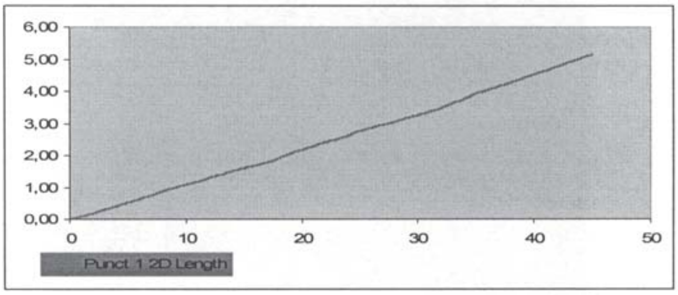

Fig.14. The displacement of point 1 [mm] as a function of time

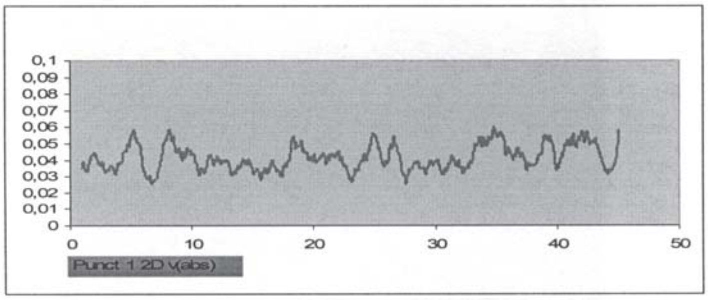

Fig.15.The velocity of point 1 [mm/s]

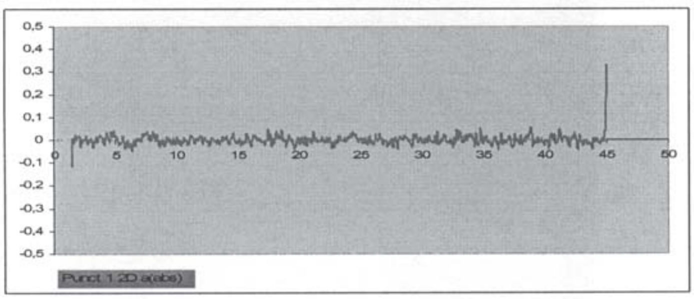

Fig.16. The acceleration of point 1 [mm/s^2]

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 hardware of the SimiMotion acquisition and video analysis system (fig.12) comprises a high-speed Panasonic camera and a LENOVO notebook. The analysis procedure is based on the attachment of two markers which have been applied on the extremities of the two pins of the staple. A plane was chosen to calibrate the camera, plane given by two axes (OX and OY).

A video capture of the staple during the transition between the two shapes memory is realised. The resulted video capture was subjected to a thorough analysis using SimiMotion. The system traces in each frame of the recorded movement the attached markers and finally one can obtain the kinematical parameters (displacements, velocities, acceleration) of the movement. The Nitinol staple was stored for 15 min in NaCl liquid solution, 30% concentration, at -30^0 C. At this temperature the material of the clip enters in martensitic phase and the lateral pins of the staple are parallel. Having this shape, the clip was extracted from the NaCl solution and was put on a paper with millimetric grids. The clip was then left to attain room temperature, 32^{0}C. In figure 13 there are presented 3 consecutive images taken with SONY camera and one can see the change of the staple shapes (period =45s). The diagrams for the displacement, velocity and acceleration of the point 1 of the Nitinol staple as functions of time are shown in figure 14, figure 15 and figure 16. In a similar manner one can obtain the same diagrams for point 2 of the clip.

Conclusions

Rapid Prototyping is a modern method of obtaining in real time almost any desired prototype. This method combines a 3D printer, CAD development software and, of course, special materials from which the prototype will be created.

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 method exceeds the conventional manufacturing methods in terms of accuracy and fabrication time.

The complexity of the shapes and dimensions (here we refer to the capacity of 3D printing system to create very small parts) of the fabricated parts recommends Rapid Prototyping method as a future fabrication method in an increasingly number of applications and scientific fields of research.

Applications of SMA to the biomedical field have been successful due to of their functional qualities, enhancing both the possibility and the execution of less invasive surgeries. The biocompatibility of these alloys is one of their most important features. Different applications exploit the shape memory effect (one-way or two-way) and the pseudoelasticity, so that they can be employed in orthopedic and cardiovascular applications, as well as in the manufacture of new surgical tools.

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:

- their structure is based on small modules which can be mounted easily on the bone;
- the modules can be used for every region of the bone, for the bones extremities, being conceived the corresponding modules;
- by combining a certain number of modules we can obtain implants with various lengths depending of type, position or dimension of the fracture;
- 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;
- low number and small dimensions of the holes used for implant fixing;
- due to constant pressure exerted in one of the two layers for which it was designed, provides the compaction of the fractures fragments.
- 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;
- reduction of infection risk;
- reduction of the healing time for the plagues.

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