Analysis of dimensional accuracy of two models of customized hip prostheses made of Polyamide powder by Selective Laser Melting Technology

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The Rapid Prototyping (RP) technology allows fabrication of patient customized implants using data derived from Computer Tomography (CT). The CT data was used to replicate bone structures and finally create exact CAD models of the customized prostheses. These CAD models were then used by the (RP) machine to build the model components. The purpose of this study was to design two models of customized hip prostheses based on detailed computed tomography data, fabricate these models by Selective Laser Melting (SLM) technology and validate the obtained models based on dimensional accuracy analysis. The prototyped models were made of Fine Polyamide PA 2200 powder.

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1. Introduction

Advanced researches in computer-aided technology, Information Technology and Biomedicine developed many new and important biomedical applications. New CAD facilities combined with biology, engineering and information science have evolved a new field of Computer-aided tissue engineering. This emerging field encompasses computer-aided design, image processing and manufacturing, enabling modelling of anatomical tissue, 3D anatomy visualization, identification and 3D reconstruction, tissue classification, tissue implantation, prototyping and assisted surgical planning [1-5].

Customized medical devices (implants, prostheses) are currently present in the biomedical applications. The general objective of the developed study was to create customized hip prostheses following the main steps presented in Fig. 1.

The 3D geometrical models of the anatomical areas of interest can be obtained in common medical file format DICOM by medical imaging techniques, usually by Computer Tomography (CT) or Magnetic Resonance Imaging **(**MRI**)**. These models are further refined and processed to create a realistic 3D model. Based on this model of the anatomical structure, a customized implant can be designed, analyzed, fabricated, and finally used, assuring an ideal fit to the patient [6].

The Finite Element Method (FEM) is generally used to understand and predict the biomechanical behaviour of implants/prostheses and anatomical structures. Validation of the Finite Element (FE) model is an important and difficult process. The results of Finite Element Analysis (FEA) must be compared with the results of experimental studies.

One of the primary uses of rapid prototyping is to quickly produce prototypes for model validation and testing purposes. The validated model is then implanted and the patient is subject to clinical monitoring.

Biomedical applications present unique challenges that both draw on the strengths of current fabrication technologies and push innovation in future fabrication technologies. These challenges include the following aspects [7]:
- complex shapes matching human anatomy;
- complex, porous microstructures from biocompatible materials;
- multiple, biocompatible materials together or separately on the same platform;
- resolutions lower than 10 microns over structures greater than 1cm in size.

Some of these challenges were already solved, but a number of research issues still remain to be studied and resolved.

The Rapid Prototyping (RP) technologies play an important role in customization of the medical devices. The main advantages of the (RP) techniques consist in: fabrication flexibility, infinite diversity of the shapes, considerably reducing the "CAD to metal" time, and a low rate of material waste [6].

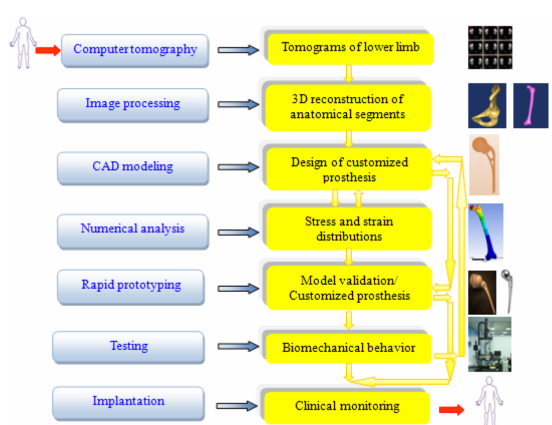


Fig. 1. Aspects of prosthesis customization.

(RP) research and development is an ongoing activity, with new technologies and applications continually evolving. (RP) is increasingly more used to enhance medical applications and healthcare delivery. Thus, (RP) technologies are currently applied in design and fabrication of various medical devices, including customized implants and prostheses.

(RP) machines are highly productive systems for fabrication of objects with complex geometries directly from CAD data and within a relatively short time. Especially for individualized products such as customized implants, the (RP) machine unleashes its full potential [8].

The quality of the prototype must be correlated with the fabrication costs. Whatever prototyping technology or equipment are used, the cornerstones of (RP) are the dimensional accuracy and surface finishing.

Dimensional accuracy varies depending on the prototyping process parameters, equipment, material, and skill level of the operator [9-13]. Dimensional accuracy specified by the vendor must be considered as the best deliverable accuracy.

Generally, additive manufacturing using laser sintering and stereolithography yields tolerances that are +/- 0.3 % overall, with a minimum of +/- 0.005" on features and parts less than 1.75" in size [10]. Practically, some of the dimensions fall within this range, while others significantly deviate [12].

Several studies reported the dimensional accuracy of different technologies and equipments but it was not yet proposed a systematic analysis to assess the dimensional accuracy of the (RP) process [9].

There are some publications dealing with accuracy of particular prototyping technologies [10-12], [14-16], and some reports focused on case studies [9], [13]. Also, some reports deal with overall dimensional accuracy [13], while others investigate the accuracy of the (RP) process in X, Y and Z directions [9]. However, studies on the dimensional accuracy for Selective Laser Melting (SLM) technology using EOS Formiga P 100 machine and Polyamide PA 2200 material were not found in literature.

The study presented in this paper represents a part of the developed research in design, fabrication, and theoretical and experimental analysis of customized prostheses. The objective of the presented study was to determine de dimensional accuracy of two models of customized hip prostheses made of Fine Polyamide PA 2200 by Selective Laser Melting (SLM) technology using EOS Formiga P 100 machine. This RP machine was acquired by the Politehnica University of Timisoara and it is intended to be used in Laboratory of Rapid Fabrication to prototype different parts for medical applications. The studied prototypes mainly have an educational purpose, being used as teaching aids for students in the classroom as well as for future researches. Even the results are applicable only to prototypes of similar material, size, and geometry, this study is important to establish the expected dimensional accuracy of the manufactured models.

2. Modelling of the hip prostheses

Generally, 3D modelling can be performed by classical design-parametric features, using any CAD software. Improved anatomical models are usually generated by 3D image-based reconstruction, through high resolution non-invasive imaging techniques, such as CT or MRI technology and 3D reconstruction techniques. Many commercial types of software are available for 3D reconstruction and surface/solid generation [17], [18].

The paper proposes two distinct models of hip prosthesis: short stem prosthesis and long stem prosthesis. Both models are based on 3D joint reconstruction of the patient's CT images [19].

In order to achieve a customized prosthesis, the modelling process starts with CT scanning of the interest area, left hip joint in our case. Having a resolution of 1 mm, the sequential scanning mode of the CT generated 821 slice images. The CT used for scanning was Siemens SOMATOM Plus 4 Power from Medical Imaging Laboratory of CMPICSU Research Centre in Politehnica University of Timisoara. The image processing was performed in Mimics software package (figure 2), developed by Materialise NV.

From the reconstructed hip bone and femur, the geometry and sizes of acetabular socket and femoral head were assumed and used in conventional CAD modelling of the prosthetic components, in Solid Edge software [19].

The design aspects were focused on obtaining of: suitable shapes, radial dimensional clearance between the femoral head and socket, surface grooves for the stem, fabrication material and manufacturability.

The short hip stem prosthesis (SHP) was sketched on the medial plane of the femur, in order to fill the whole bone marrow canal. Also, the direct sketching of the femur has the advantage of obtaining the optimum orientation angles of the prosthesis (accurate orientation of both the acetabular and femoral parts), minimizing the risk of dislocations caused by mal-position and mal-orientation, micro movements and limbs inequality when implanted.

A series of angled grooves were designed on the side surfaces of the stem, increasing the available surface for bone growing and minimizing the prosthesis migration predilection [19].

The acetabular cup in our design concept consists of two components: a shell (Ti6AL4V) and a liner component (UHMWP) fixed into the shell, which acts as a load-bearing surface due to its low friction coefficient. Also, the liner component has the property of shock absorption.

The external shape and dimensions of the shell were built accordingly to the reconstructed acetabular socket. In addition, circular grooves were designed for osteointegration purposes.

The long hip stem prosthesis (LHP) was designed in the same way, having particular ports on the stem, for bone growing and optimal fastening. The curvature of the stem determines the prosthesis final angle so it will match the geometry of the joint. The components of the acetabular cup are designed in the same concept.

Supplementary, the shell was designed with a peripheral lip that helps to prevent movement inside the shell [19].

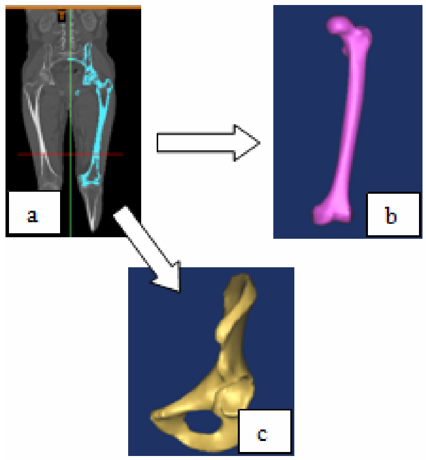


Fig. 2. Stages of 3D hip joint reconstruction: a) Selection of the hip joint bones; b) Reconstructed femur; c) Reconstructed hip bone.

3. Rapid prototyping of hip prostheses by SLM technology

There are several rapid prototyping technologies, such as: Stereolithography (SLA), Selective Laser Sintering (SLS), Selective Laser Melting (SLM), Fused Deposition Modelling (FDM), Electron Beam Melting (EBM), Laminated Object Manufacturing (LOM), Inkjet-based systems and Three Dimensional Printing (3DP). (RP) technologies can use a wide range of materials (paper, plastic, metal and nowadays biomaterials) which allow their application in different fields [8].

Taking into account the laboratory capabilities, all the components of the proposed models of customized hip prostheses were fabricated using EOS Formiga P 100 machine in Laboratory of Rapid Fabrication of Politehnica University of Timisoara. The building principle of this machine is based on SLM technology.

Selective Laser Melting is a layer additive production process that creates three dimensional objects using a CO_2 laser to selective melt or fuse powder molecules based on geometrical and technological information provided by the *job* file content. In the building process, the material is applied in thin layers of very fine powder and, using a laser beam, melted onto those areas where the implant component will be developed. Depending on the surface quality, mechanical properties and production speed requirements, the powder is automatically applied with layer thicknesses ranging from 0.1 up to 0.4 mm. In the following step, a fine laser spot selectively melts the designated areas [20].

Formiga P100 is an EOS Company (EOS GmbH Electro Optical Systems) machine, designed for working with plastic materials in direct manufacturing of small series and prototyping of functional spare parts [21].

The EOS laser system uses a high speed rotating mirror for changing the direction of the laser beam in order to reach the scanning head (Fig. 3). The characteristics of the laser and optic system are [21]:

- nominal power: 30 W;
- laser wavelength: 10.2 to 10.8 μm;
- diameter of the focused beam: approx 0.40 mm;
- F-theta lens, focal length: 440 mm.
- high speed rotating mirror; deflection system with precision galvanometer scanner (with temperature compensation); integrated servo electronics and interface electronics; digital data transmission from controller; digital signal processor;
- beam deflection speed: max. 5 m/s.

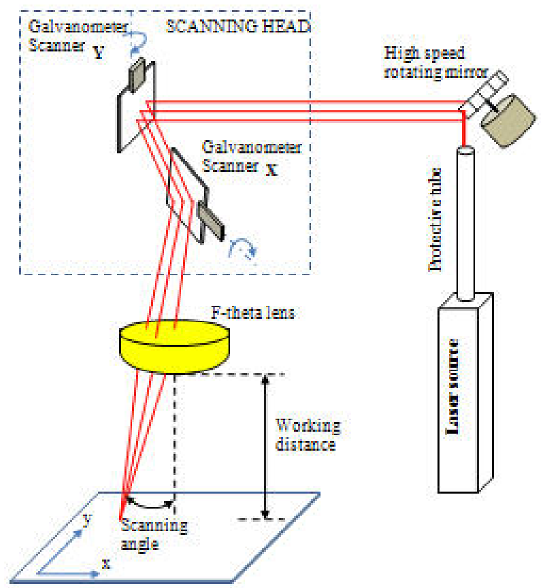


Fig. 3. Laser scanning optics of FORMIGA P100 RP machine.

The material used in the job was Fine Polyamide powder PA 2200 provided by the machine vendor.

Taking into account that the manufacturing of the hip prosthetic components had geometrical validation purpose only (the prototype being not involved in clinical use or mechanical testing), the Polyamide PA 2200 was considered as suitable for our experiment.

Polyamide is resistant to most chemicals, having excellent long-term constant behaviour, high selectivity and detail resolution, various finishing possibilities, and good biocompatible characteristics. The Polyamide material allows production of fully functional prototypes with good mechanical and thermal resistance [21].

Polyamide PA 2200 is a thermoplastic semi-crystalline polymer widely used in rapid manufacturing in a recyclable powder form. Generally, semi-crystalline polymers are used to produce parts with less dimensional accuracy, feature resolution, and surface finish than amorphous polymers. During solidification, the shrinkage of these semi-crystalline polymers influences the part accuracy, depending on the job parameters. Still, Fine Polyamide PA 2200 yields a suitable resolution and surface roughness [22].

The dimensional accuracy of a prototype is influenced by many factors [9], [12], [14], [24]:

- process temperature: sometimes excess material fuses to the top layer of the part, resulting a less Z accuracy;
- layer thickness: is material dependent (depends on the powder chemical composition and grain size); thinner layer thickness contributes to improved accuracy;
- size of the part: larger prototypes have greater dimensional variance;
- placement of the part in the building envelope: errors have greater values for parts positioned in the centre comparing to the parts positioned close to the envelope borders due to the higher radiant heat from the envelope walls;
- scanning strategy: should be selected accordingly to the mechanical and dimensional demands of the building part;
- exposure parameters: are different for contours, edges, and hatching area of the building part;
- cooling and airflow within the building envelope: machine must cool down slowly for several hours in order to allow optimal shrinkage;
- laser scanning system – laser power, laser beam scanning speed, diameter of the laser beam, and galvanometer resolution: must be set properly to obtain the expected quality of the prototype;
- scaling factors in X, Y, and Z directions (shrinkage compensation): the model geometry is modified applying scaling factors to compensate the pattern shrinkage which depends on the part geometry and orientation.

Most of the errors which can occur during the prototyping process are systematic and therefore could be compensated. However, there are some random errors which cannot be easily compensated [9]. When is required a high accuracy of the built part, the process must be repeated on the same machine using the same processing parameters but applying correction scaling factors to improve the dimensional accuracy. This procedure takes time and involves additional costs.

Taking into account the mentioned factors that affect the dimensional accuracy, the following steps were accomplished for rapid prototyping:

- CAD file construction and conversion into *stl* format.
- Model preparation in Magics: part positioning in the building area, keeping a 5 mm clearance between parts, in order to avoid the thermal influences between neighbouring parts; all the parts were positioned at the same height in the building chamber, the two components of the acetabular cup of the long stem prosthesis being placed in the middle and the rest of the parts being placed at periphery; surface mesh checking for errors; merging all the parts and saving in *stl* format (Fig. 4).
- File preparation in EOS RP-Tools: setting the layer thickness to 0.1 mm (for PA 2200, the recommended layer thickness is ranging from 0.1 up to 0.2 mm [21]); file slicing according to the layer thickness; verifying and repairing the layers when needed (Fig. 5);
- File preparation in PSW: model scaling with the factors: 2.6 % in X-Y plane, 1.6 % in Z direction; setting the material type and exposure parameters (Fig. 6 and table 1); verifying the job file and exporting to the machine via LAN;
- Machine and process preparation: setting up the temperature of the building chamber at 169 °C; applying the powder base, inlet the nitrogen into the building chamber; pre-heat the building chamber up to 169 °C; power on the laser system and the automatic job start when the pre-heat temperature was reached;
- Layer by layer building for 5 hours;
- Parts extraction and post-processing: after the building process, the machine has cooled down for 5 hours minimum; extracting the parts from the building envelope, air cleaning and washing.

The rational positioning of the parts within the building area is based on uniform distribution of the melting areas during the fabrication (Fig. 4). A part agglomeration in a certain area having the same Z positions could lead to a local temperature enhancement, influencing the stability of the job.

The slicing tool transforms the 3D file in many 2D images, accordingly to the desired layer thickness. In Fig. 5, a representative layer can be observed, where the black edges represent the contours while the green fields represent the future hatching areas.

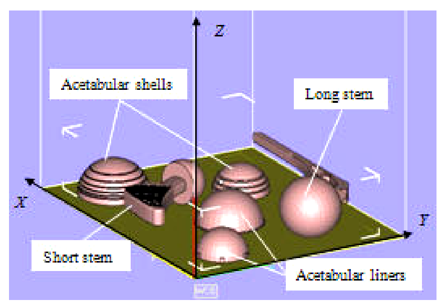


Fig. 4. Merged parts positioning on the building platform.

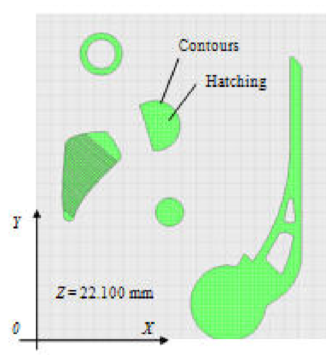


Fig. 5. Representative layer with no errors.

In Fig. 6, the laser trajectories in two consecutive layers can be observed. In order to avoid the anisotropic properties of the built part, the hatching directions in consecutive layers are crossing. This will create a better bounding of the melted material.

There are several strategies for exposing the layers: mechanical, box, contour, core-mesh, skin-core, skin, sorted, unsorted, up-down-skin [23]. Each strategy has advantages and disadvantages and it should be selected accordingly to the building part geometry, required mechanical properties and roughness. The *Sorted* strategy searches the shortest exposure way across the part, whereas the *Unsorted* strategy moves across the part in the easiest way [23]. Sorted strategy can be adopted for faster building process, where the mechanical and dimensional demands between the first and second exposure phase are not so important.

Taking into account that the prosthesis is a laboratory model only, no special requirements were associated with it. So, *Sorted scanning strategy* was chosen.

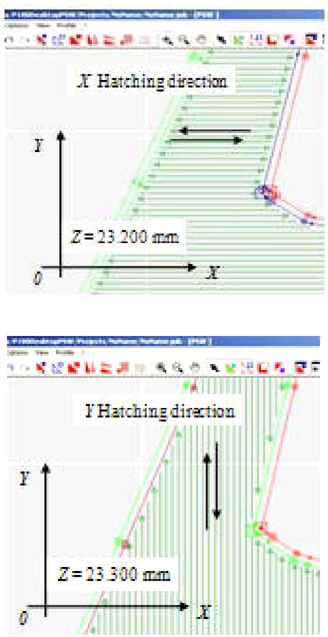


Fig. 6. Contour and hatching directions in two consecutive layers.

The exposure data refers to the process parameters used during the laser exposure of each layer. The variation of these parameters corresponds to the areas to be exposed and the scanning strategy. The chosen process parameters for sorted exposure strategy are presented in Table 1. These parameters are distinctive for contours, edges and hatching area of the building object.

Table 1. Building exposure parameters.

Exposure type - sorted	Parameter	Value
Contour	Speed [mm/s]	1500
	Power [W]	16.0
Edges	Edge factor	1.8
	Threshold	3.0
	Speed [mm/s]	1500
	Power [W]	16
Hatching	Distance [mm]	0.25
	Speed [mm/s]	2500
	Power [W]	21
	Beam offset [mm]	0.15
	Direction	X and Y

The parts resulted from the building process are presented in Fig. 7. Before assembling or evaluating of the geometry and dimensions, the parts were cleaned with compressed air, washed and dried. The fabricated parts typically have a grainy surface but all kinds of (very) fine finishing are possible. In order to protect the rough surfaces of the parts, they can be painted, covered or coated. The components were directly subjected to dimensional verifications and therefore they were not involved in any additional post processing.

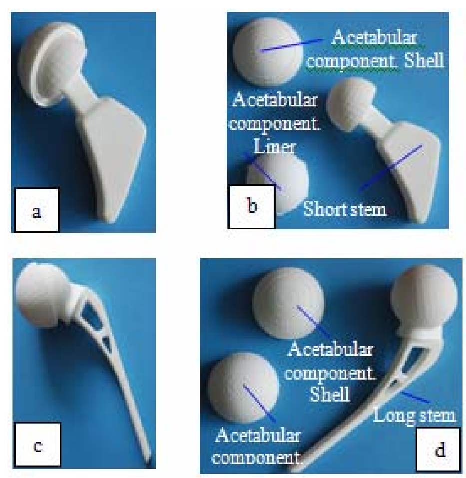


Fig. 7. Hip prosthesis prototypes after the post-processing: a) Short hip stem prosthesis (SHP) - assembly; b) SHP - components; c) Long hip stem prosthesis (LHP) - assembly; d) LHP – components.

4. Results and discussion

Taking into account that the prototypes have an educational purpose, the obtained RP models will be used as teaching aids for students in the classroom as well as for future researches. For the same reason, the model validation was performed by simple dimensional verifications.

The accuracy of SLM parts was determined by measuring certain dimensions and comparing the results with the corresponding nominal values. The measurements were performed with a digital calliper (resolution 0.01 mm). Each dimension was measured 15 times.

The absolute difference in mm and percent (relative) difference in % were computed for each measured dimension. Also, the mean value for each set of measurements was calculated. The dimensions taken into consideration were:

- femoral head diameter;
- internal and external diameters of the acetabular shell and liner components of both short hip stem prosthesis SHP and long hip stem prosthesis LHP;
- thickness of the SHP stem.

The diameters of the femoral head, shell and liner components have to conjugate each other. Therefore, the nominal clearance of 0.2 mm between conjugated parts has to be accomplished, meaning that either positive or negative dimensional variations can occur for both assembled parts. An acceptable dimensional variation of each diameter is 0.1 mm.

The diameters were measured in 15 pairs of diametric points.

Other dimension taken into consideration was the thickness of the SHP stem, which has a nominal value of 16 ± 0.15 mm. Fifteen measurements were performed along the stem length.

Using the recorded values, the absolute and relative differences were computed. The results are graphically illustrated in Figs. 8 and 9 for SHP and Fig. 10 for LHP prototypes. Here, the symbols have the following meanings:

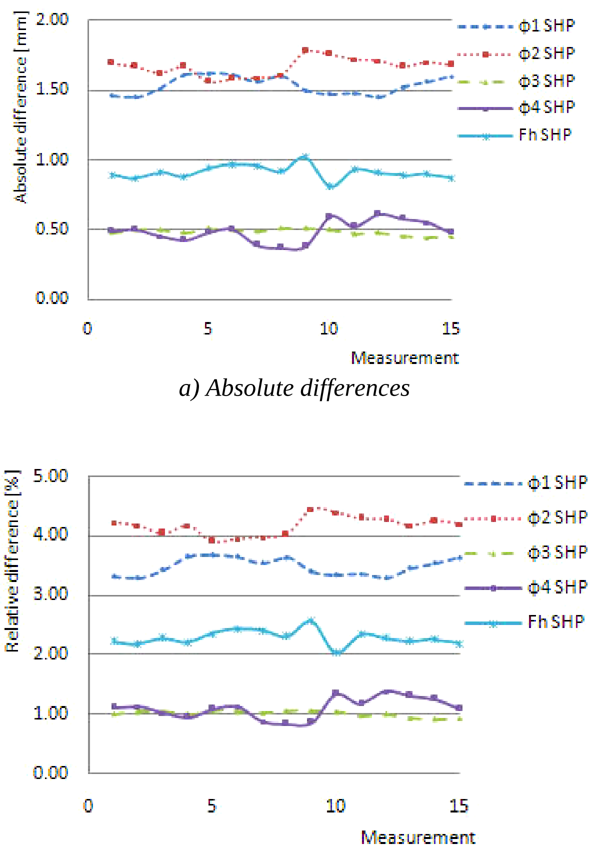
- $\phi 1$ – external diameter of the shell;
- $\phi 2$ – internal diameter of the shell;
- $\phi 3$ – external diameter of the liner component;
- $\phi 4$ – internal diameter of the liner component;
- Fh – femoral head diameter.

Mean absolute and relative differences (error) for the measured dimensions of both SHP and LHP are presented in Fig. 11.

Mean absolute difference ranges from 0.02 ± 0.111 mm for internal diameter of the liner component of LHP to 2.13 ± 0.085 mm for internal diameter of the LHP shell. The maximum absolute errors were recorded for internal diameters of the shell, in both SHP and LHP parts. These large contractions are caused by the larger dimensions of these parts. The minimum absolute errors were recorded for the internal diameter of the LHP liner component and thickness of the SHP stem. The smaller contractions of these components are caused by the thin wall design (lower volume).

Mean relative difference ranges from 0.04 ± 0.191 % for internal diameter of the liner component of LHP to 4.17 ± 0.161 % for internal diameter of the shell of SHP. The maximum relative errors were recorded for internal diameters of the SHP and LHP shells. The minimum relative errors were recorded for internal diameter of the liner component of LHP and thickness of the SHP stem.

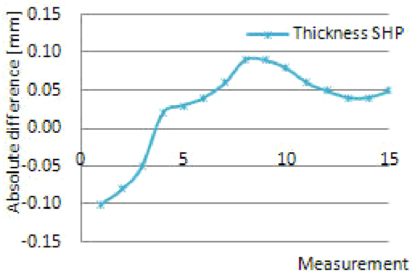
Excepting the internal diameter of the liner component ($\phi 4$) and SHP thickness, none of the dimensions were joining the assembling requirements. This issue led to the conclusion that scaling factors chosen in all directions are not appropriate for these constructions. Because the dimensions mainly have positive mean errors (measured dimensions are smaller than the corresponding nominal values), the scaling factors in all directions have to be enhanced. The value of enhancement can be established either empirical or by simulation of the shrinkage phenomenon.



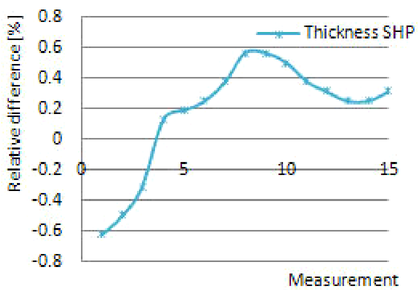
a) Absolute differences

b) Relative differences

Fig. 8. Absolute and relative differences between nominal and measured dimensions of the SHP.

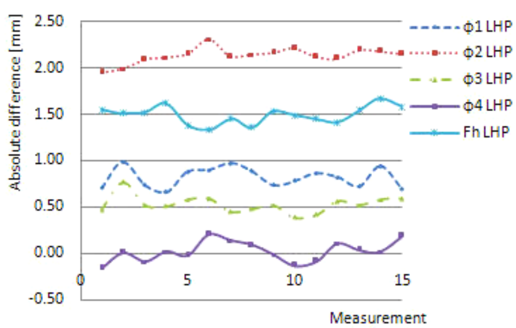


a) Absolute differences

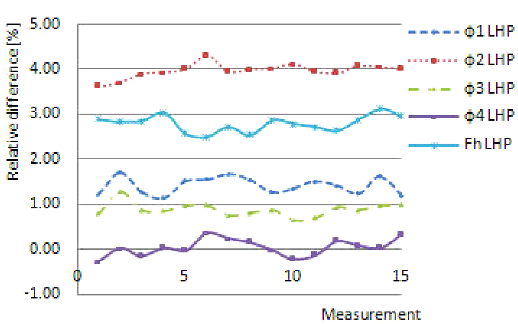


b) Relative differences

Fig. 9. Absolute and relative differences between nominal and measured dimensions of the SHP thickness.

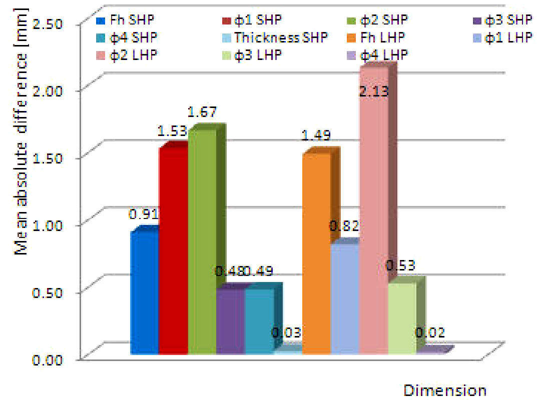


a) Absolute differences

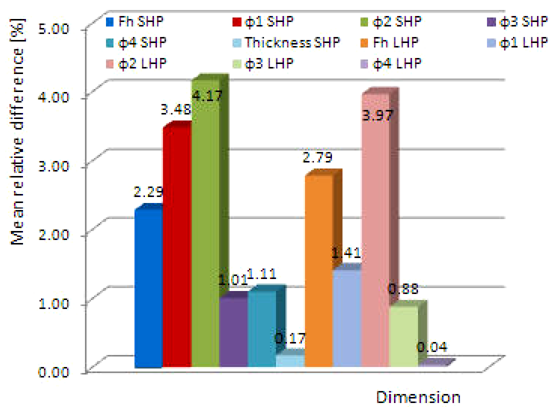


b) Relative differences

Fig. 10. Absolute and relative differences between nominal and measured dimensions of the LHP.



a) Absolute differences



b) Relative differences

Fig. 11. Mean absolute and relative differences of the SHP and LHP dimensions.

5. Conclusions

The quality of the fabricated customized prosthesis depends on both the quality of the CAD model (quality of CT scans and quality of 3D reconstructions of anatomical structures) and the quality of the prototyping process.

The presented study investigates the capabilities of producing some customized medical components made of Fine Polyamide PA 2200, in Laboratory of Rapid Fabrication of Politehnica University of Timisoara, on EOS Formiga P 100 machine. The developed research was performed based on the idea that improvements in design and manufacturing of customized prostheses will lead to a greater durability and functionality of the prosthesis in the implantation site.

A tenth of millimetre dimensional accuracy is acceptable taking into account the purpose of the model and geometrical assessed clearance between the spherical parts. The improvement of the dimensional accuracy represents a challenge in RP fabrication and it involves dealing with a series of variables: the refinement of the *.stl* file, selection of scaling factors according to the part size and shape, process parameters, quality of the powder, and cooling conditions.

The rapid prototyping technology enhances the manufacturing customization of a part, especially of those related with living structures. This technology allows creating of complex geometrical parts, almost identical to the anatomical structure. The limitation of this technology in customized part manufacturing is represented by the tight range of materials yet available.

Further research will be focused on the improvement of the dimensional accuracy using the same technology, machine and material. A set of special benchmark samples will be prototyped using different process parameters. Dimensional accuracy and surface quality, as well as bulk density, internal microstructure and mechanical properties will be analyzed. A global evaluation of the studied features will lead to set up the optimal process parameters.

Repeatability represents another limitation of RP technologies. Thus, taking into account the influence factors that affect the dimensional accuracy, a study of the process repeatability will be developed.

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