Processing and analysis of freeform implants obtained by additive manufacturing from MRI data

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Abstract. This work introduces the processing steps for manufacturing implants in substitution of human body parts based on additive manufacturing. The parts were designed with data from Magnetic Resonance Imaging (MRI) of a defective cranium and the deviation analysis of the cranial implants was carried out to characterize the process. At the initial stage, the results of MRI exam of a defective patient’s skull were downloaded from internet in DICOM format. Next, segmentation was applied to separate the soft tissues from the bone one of the MRI data. The cranium bone CAD model was created and implemented in a 3D printer to manufacture the part in polymeric material. The produced part was measured in a 3D laser scanner to collect a surface cloud of points and the quality was evaluated by comparing data points with CAD model. Descriptive statistical analysis was applied to determine the behavior of the deviations. A statistical filter was proposed to remove the outliers using the boxplot graph and the filtered sample was analyzed again to define the statistical parameters of the implant surfaces. The proposed methodology is recommended to characterize the deviations of cranium implants manufactured by additive manufacturing and the determined deviations allow the execution of cranial surgeries with a minimal intervention of the surgeon.

Key words. Error evaluation, reverse engineering, freeform surfaces, magnetic resonance.

1. Introduction

Advances in medicine instrumentation are boosting the implant and prosthesis manufacturing as high resolution images from human body can be directly used to produce parts by additive manufacturing or 3D printing. Implants and prosthesis are being developed and applied to substitute human parts like bones, cranial surfaces, teeth, among others. The process of additive manufacturing, by its nature of adding material to build the part, can reach the dimensional characteristics close to the designed one and this makes surgeries more efficient as there is no need of finishing operations.

Recent papers in literature relate the growth in additive manufacturing processing. The Wohlers American Association presented a study showing that 13.7% of items produced in 2014 were in medical and dental area [1]. This is associated to the ability of produce parts with personalized dimensions, close to that of individual needs. This approach can simplify the surgeon task during surgery. Other benefits are the speed of processing, low cost, high precision and wide variety of used materials [2].

There are some studies involving the manufacturing of implant parts. Maricevich et al. [3] presented examples of craniomaxillofacial surgery with implants made by rapid prototyping process. A patient with a cranium defect with 192 m² in area was submitted to a cranioplasty to repair the defect with a
part made by Additive Manufacturing (AM) in polymeric material. Materials like polymethyl methacrylate (PMMA) mixed with hydroxyapatite and reinforced with carbon fiber are reported as suitable to use in these applications, as well as polypropylene and polyester [4].

Chrzan et al. [4] evaluated the CAD/CAM technologies in the cranioplasty implant manufacturing. Data from Computerized Tomography was used to build the CAD model and a part was manufactured in polypropylene-polyester by rapid prototyping process and CNC milling. The authors concluded that implant part produced by rapid prototyping reduces the time spent in surgery when compared to that manufactured in milled mold. This result was associated to the reduced adjustment efforts needed to fit the part in cranioplasty surgery.

Additive manufacturing processing has common steps that can be summed up as: 1) obtaining the Computer-Aided Model (CAD); 2) conversion of CAD model format to STL; 3) verification and preparation of CAD model to print; 4) part building in a 3D printer; and 5) finishing operations [5]. The improvement in this process demands knowing these steps for components applied to medical and dental areas. In this context, the technology plays a very important role since the scanning of the images obtained by medical instruments during examinations, such as magnetic resonance (MRI) and computed tomography (CT), allows to record files with adequate data for development of computer models (CAD).

Additive manufacturing begins by the development of part CAD model, that is personalized for each patient since the CT and MRI scans are recorded in digital format known as DICOM (Digital Imaging Communications in Medicine). These files must be filtered to separate the bone tissue from other ones present in the image examination and converted into image format to work in 3D modeling. These tasks can be performed using Mimics or InVesalius software [6]. Next, the model needs to be worked on some modeling and commercially software like Catia, SolidWorks and Blender. A technique used to obtain implant geometry in CAD software is called mirroring, where the skull is divided in two parts by a median plane that is the reference to remove the defective side, copying the healthy inverted side and delimitate the defective part [7]. This model is finally implemented in an AM machine to produce the part.

It is important to note that, as the deviations between the part and the assembly component are small, shorter the surgery time and safer the procedure for the patient. Improvement in process is required to reduce the time spent in surgery, so accuracy is mandatory. A dimensional analysis must be carried out to check the accuracy of produced implant part, which has a freeform surface. This type of surface is not so simple to analyze because it does not have an equation known by geometry to calculate the deviations from the desired one. Each freeform part has its own unique geometry and the method of analysis should allow for the verification of either.

2. Methodology
A data file containing the information of MRI exam was downloaded from a database on internet [8] in DICOM format. The file contained information of the patient skull defect but mixed with other head structures. The open source InVesalius software was used to handle the file and to separate the bone from the skin, muscles and spongy tissues that were present in the MRI data. The selected tissue was then exported as a 3D surface and it was saved as STL format for further work.

The STL file was opened by Blender software to generate the defect CAD model, so called implant part. The implant CAD model was obtained by mirroring the cranium image, after dividing the cranium in two parts by taking a medium plane passing by the nose. The cranium side with no defect was copied and overlapped with the defective side. Therefore, the cranium defect becomes visible and easily identified and it was separated from the cranium by subtraction. The generated surface was transformed in a 3D model by adding thickness according to the cranium data information and saved in STL format.

Three-dimensional printing of the implant was executed by sending the STL file to a 3D printer manufactured by Stratasys and model Object 30 Prime. This machine prints objects in polymers like polypropylene, rubber and bio-compatible materials, having a standard uncertainty of 0.1 mm, according to the datasheet. The part maximum accepted dimensions must have 294 x 192 x 148 mm, operating at temperatures ranging from 18 to 25 °C and at relative humidity between 30 and 70 %. The material used...
in this research was the acrylic-based polymeric material MED 620, an opaque photopolymer with biocompatibility characteristics, suitable to be used in medical and dental applications. This material has strength resistance between 55 to 65 MPa, Elastic modulus of 2300 to 3300 GPa and total elongation of 15 to 25 %.

Dimensional verification of the produced implant was carried out with a 3D laser scanner of NextEngine manufacturer, comparing the measured data points with the designed CAD model. A cloud of points was determined considering the following setup on ScanStudio HD Pro software: single view, 4 divisions, HD resolution, Clear, mean distance from scanner. The standard uncertainty in this configuration is 0.246 mm. The determined cloud of points was saved as IGS format file.

The analysis of the deviations of the determined points with respect to the CAD model was accomplished using Catia software. The files IGS and STL were imported and aligned applying the commands ALIGN USING THE COMPASS and ALIGN BY BEST FIT. Next, the deviations from CAD model in 3D space were determined using the command DEVIATION ANALYSIS. These deviations were exported in TXT format file, right clicking the mouse positioned over the generated tree marked as DEVIATION ANALYSIS.

A refinement of the analysis was carried out with the MatLab software. Firstly, a descriptive analysis was executed to determine the mean, the standard deviation, the range and conformity to the Normal probability distribution. A Boxplot graph was applied as a statistical filter to check the outlier presence that is expected in laser scanner measurements. The identified outliers were excluded from the data deviations and a new descriptive analysis was carried out and compared with the initial one.

3. Results and discussion
The data of the studied cranium with defect are presented in Figure 1. The red and yellow images show the mirroring of the cranium that was performed in Blender software to overlap the images and obtain the image of the defect by difference.

Figure 2.(a) presents the defect in green color, detached from the cranium image. The defect CAD model was then saved as STL file and implemented in 3D printer. The produced part is presented in Figure 2.(b), positioned over Scanner basis to perform measurements. The defect CAD part fulfil the hole in the cranium, but some differences may appear as consequence of the manufacturing process and must be examined.

Figure 1. Mirroring of the patient cranium in Blender software.
After first analysis performed in Catia software, data from deviation between CAD model and measured data points was saved and a Box plot graph was used to carry out verification. Figure 3 shows the results and a significant number of outliers was detected. These outliers should be result of the dispersion of laser beam reflected by part rough surface and its consequence is increase the data dispersion. So, it must be filtered to determine the part statistics that effectively qualify the implant surfaces produced by 3D printer. The Boxplot graph was considered as a filter to separate the outliers and the points in red were excluded to obtain a new deviation data file for measured surface characterization.

Figure 3. Boxplot graph showing outliers.
Figure 4 presents a graphical analysis of the part deviations after outlier elimination, showing the determined distance from the part surface. The maximum and minimum deviations and its location on this freeform surface are presented, as seen, close to the surface borders, suggesting that some small finishing operations are needed to remove between 0.2 to 0.3 mm before or during surgery.

Table 1 presents the descriptive statistics. It was observed that 96.76% of original data was used to evaluate the part, after removing the outliers. Statistics were determined by mean of 0.036 mm and standard deviation of 0.119 mm, having range of 0.656 mm. The implant surface is a freeform, thus the range can be considered as representing this geometric deviation. In most medical applications, it is important that the deviations are smaller than one millimeter, making possible surgical procedures for implanting requiring minimal or no adjustments.
Table 1. Statistical parameters from cranium implant deviation after removing outliers.

| Statistical parameter | (mm)  |
|-----------------------|-------|
| Mean                  | 0.036 |
| Standard deviation    | 0.119 |
| Maximum               | 0.365 |
| Minimum               | -0.291|
| Range                 | 0.656 |
| Number of points (unfiltered data file) | 31407 |
| Number of points (filtered data file)       | 30390 |
| Number of deleted points                  | 1017  |
| Percentage of original data                | 96.76%|

Figure 5 shows the Normal probability plot of the deviations determined after outlier filtering. According to the graph, most of the deviations are close to the straight line, specially at the center, with some points detached at the inferior and superior limits. Therefore, the hypothesis of Normal probability distribution cannot be rejected and the analysis is considered valid.

4. Conclusion
A processing sequence applied to produce implant parts for substitution of defects in human body was presented involving additive manufacturing and CAD modelling from MRI exam data. An analysis procedure for determination the accuracy was proposed based on measurements with 3D laser scanner and data filtering with a statistical filter based on boxplot graph.
The proposed sequence proved interesting as CAD modelling can be carried out directly from medical exams like Magnetic Resonance Imaging and Computerized Tomography, making it personalized for each patient.

The performance of the manufacturing process was determined by standard deviation and the range of the deviations between CAD model and data points measured with laser scanner. These values were determined as 0.119 mm for standard deviation and 0.656 mm for range, the first was close to the 3D printer uncertainty of 0.1 mm. This variability was associated to the freeform surface irregularities and roughness of cranium implant studied, that made difficult the measurement with laser scanner by the presence of many outliers, but the statistical filter adopted using the boxplot graph reduced this effect.

These results proved suitable to promote a surgery with a minimum part finishing operation and new researches can be performed in manufacturing of another human body part like bones.

References
[1] Wohlers T and Caffrey T 2015 Wohlers Report 2015: 3D Printing and Additive Manufacturing State of the Industry (Wohlers Associates, Fort Collins, CO, USA)
[2] Javaid M and Haleem A 2017 Additive manufacturing applications in medical cases: A literature based review Alexandria Journal of Medicine, 2017.
[3] Maricevich P et al 2015 Prototipagem: aplicações na cirurgia de crânio-maxilo-facial do Instituto Nacional de Traumatologia e Ortopedia (INTO) Revista brasileira de cirurgia plástica, 2015. (in portuguese)
[4] Chrzan R et al 2012 Cranioplasty prosthesis manufacturing based on reverse engineering technology. Medical science monitor: international medical journal of experimental and clinical research (University Cracow, Poland)
[5] Chua C K and LEONG K F 2015 3D Printing and additive manufacturing principles and applications (4º Ed, Singapore, Nanyang Technological University: Word Scientific)
[6] Jardini A L et al 2016 Improvement in Cranioplasty: Advanced Prosthesis Biomanufacturing The Second CIRP Conference on Biomanufacturing
[7] Moiduddin K et al 2017 Structural and mechanical characterization of custom design cranial implant created using additive manufacturing Electronic Journal of Biotechnology
[8] Centro de Tecnologia da Informação Renato Archer. Available in: <https://www.cti.gov.br/pt-br/invesalius#download>. Accessed in June 20, 2018.