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Evaluation of the accuracy of the resection template and restorations of the bone structures in the mandible area manufactured using the additive technique

Paweł Turek[1], Klaudia Jońca[2], Marcelina Winiarska[2]
[1]Faculty of Mechanical Engineering and Aeronautics, Rzeszów University of Technology, Rzeszów, Poland
[2]Faculty of Mathematics and Applied Physics, Rzeszów University of Technology, Rzeszów, Poland

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ABSTRACT

The article presents the current possibilities in the field of modeling and manufacturing models of anatomical structures, surgical templates, and implants in terms of planning surgical procedures in the area of the mandible. In the first stage, the 3D reconstruction of the mandible geometry using the 3D-Slicer software was presented. The next step of the process consisted in modeling resection templates and supplementing the loss of the bone structure of the mandible. The last stage consisted of manufacturing models using the additive FDM method from PC-ISO material and performing an accuracy assessment. The models' accuracy using the additive FDM technique is within the tolerance range of +/- 0.2 mm. It is sufficient to use models when planning a procedure.

Corresponding Author:

Paweł Turek
Faculty of Mechanical Engineering and Aeronautics, Rzeszów University of Technology, Rzeszów, Poland
Email: pturek@prz.edu.pl

1. Introduction

Traditional modeling uses Computer-Aided Design systems (CAD) (Boboulos, 2010). The problem in the design process arises when we do not have the technological, construction, or material documentation of a given product. Thanks to the rapid development of measurement systems, data processing software, and modern manufacturing techniques, the solution to this problem have become possible through Reverse Engineering (RE) process (Raja and Fernandes, 2007; Bagci, 2009). Reverse engineering is used in many fields, including the aviation industry (Fedorova et al., 2019), and architecture (Raja and Fernandes, 2007), Kumar et al. (2013). It is also often used in medicine - e.g., in reconstructing the geometry of anatomical structures (Cohen et al., 2009; Stojkovic et al., 2018; Turek, 2019; Vitkovic, 2021), designing surgical templates (Ciocca et al., 2012; Liu et al., 2014), implants (Figliuzzi et al., 2012; Orabona et al., 2018; Korunovic et al., 2019; Stojković, 2022), and scaffolds (Milovanović et al., 2020).

The mandible is the most specific bone structure in the craniofacial region. It is the only movable bone subjected to multidirectional dynamic loads during the biting and chewing process. As a result of breaking the continuity of the mandible geometry, there is a significant impairment of airway patency, swallowing, speech, chewing disorders, and distortion of the lower part of the face. Currently, in the process of reconstructing the continuity of the mandible geometry, surgical plates are used. In the 1990s, microsurgical techniques of free tissue grafts containing a bone component were introduced (Maciejewski et al., 2005). The fibula (Wang et al., 2016; Tsai et al., 2014; Turek et al., 2021) or part of the iliac (Cuellar et al., 2014; Ayoub et al., 2014) is often used for these procedures. The introduced changes in the conduct of operations resulted in reducing the surgical plates to an auxiliary function, ensuring stabilization during the healing period of the vascularized graft (Goyal et al., 2012). Thanks to the use of models of anatomical structures obtained in the

RE process, the procedures have been significantly improved by, among others, prior fitting of a surgical plate (Turek et al., 2021; Lethaus et al., 2012) or a titanium mesh (Ikawa et al., 2016) to the model. Research is also being conducted on the implementation of mandible implants (Lethaus et al., 2012; Bertol et al., 2010) resection templates (Weitz et al., 2018; Dahake, 2017), and the proper structure of the scaffold for stem cell implantation is currently being developed (Otawa et al., 2015). The presently used computer-aided design systems also allow for virtual planning of the procedure (Ciocca et al., 2012; Hou et al., 2012). In the case of designing and manufacturing models for planning a surgical procedure in the mandible area, three main stages can be distinguished. The first step is related to the acquisition of volumetric data. Then the collected data is transformed into a 3D model and further edited (Turek, 2021). The physical model can be obtained using, e.g., subtractive (Budzik et al., 2015), or additive techniques (Turek and Budzik, 2021).

2. Materials and methods

The presented publication focuses on two cases of patients. In the first case, the left mandible segment was removed during resection due to neoplastic diseases, including part of the body and condyle. A temporary solution was to join the two damaged sections of the mandible with a surgical plate. In the case of the second patient, a tumor was diagnosed in the right part of the mandible, which required removal by resectioning the mandibular bone structures in this area. In the first patient's case, the aim was to model the restoration of the defect in the left part of the mandible, and in the second patient, the resection templates were in the right part of the mandible. In both cases, obtaining the geometry of the existing bone structures of the mandible was possible based on the acquired Digital Imaging and Communications in Medicine (DICOM) data. The geometry reconstruction process based on DICOM data was carried out in the 3D Slicer software. To obtain the best accuracy of the geometry reconstruction from the available data packages, in both cases, a series was selected with the highest spatial resolution possible to be used based on the chosen measurement protocol. After loading the selected DICOM data series, the segmentation process was started. The first patient's case was divided into three stages: segmentation of the mandible with the plate, segmentation of the plate itself, and the logical operation of segment subtraction (Fig.1a). In the case of the second patient, the segmentation process included only one stage, i.e., the reconstruction of the mandible geometry (Fig.1b). In the process of structure segmentation, thresholding method was used. Two segmentation thresholds from 99 HU to 200 HU were established for the mandible and the surgical plate from 2300 HU to 3071 HU. In addition, in the segmentation process, in both cases, it was necessary to correct the segments due to the presence of artifacts manually. In the case of the first patient, it was also required to use a boolean subtraction tool, resulting in a segment containing bone tissue without a surgical plate. The final stage of the process was the direct export of the segmented 3D models to the STL(STereoLitography) file format.

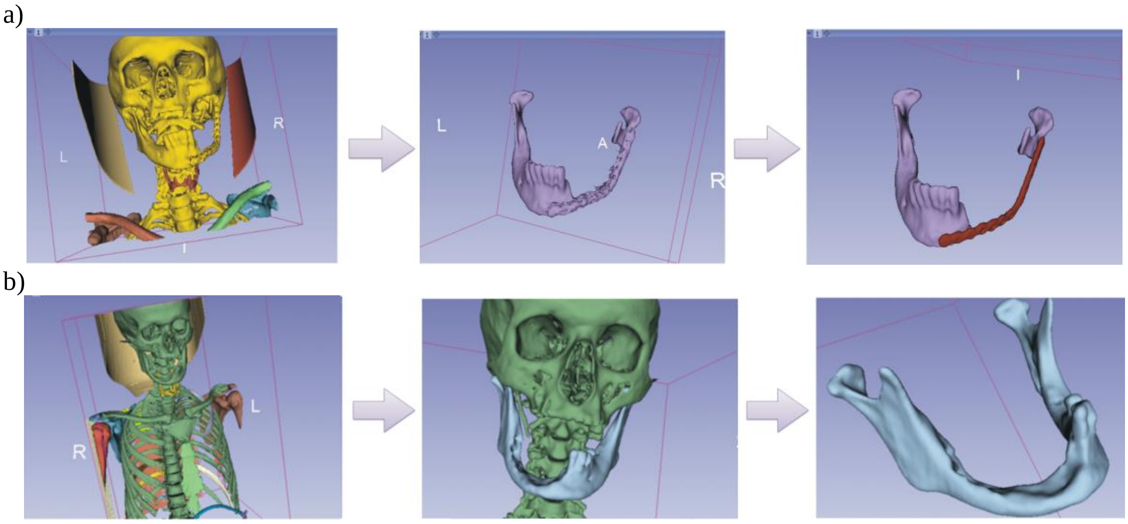

Figure 1. Reconstruction process in 3D Slicer software for a: (a) first patient; (b) second patient

In the next step, based on the reconstructed geometries, a model was designed to supplement the loss of bone structure (first patient) and resection templates (second patient). Meshmixer was used for this purpose.

In the first patient's case, the process itself was divided into three steps (Fig.2a). The first one consisted of a symmetrical reflection of the non-pathological part of the mandible and correction of its position in such a way as to ensure the best fit of the mandible surface and the prosthesis. The second modeling stage was trimming the reflection and modeling the contact surface of the prosthesis with the mandible. This process was done by modifying the triangle meshes on the mandible model created in the previous step. The third step modeled parts connecting the prosthesis with the mandible. Hybrid modeling was used for this, combining surface modeling, reconstruction of geometric primitives based on point clouds, and modeling based on a triangle mesh. The result of this stage was to obtain a digital model that complements the loss of bone structure. In the case of the second patient, preparing the resection templates consisted of three steps (Fig.2b). The first one marked the area where the templates are to be adjusted. Then the marked areas were separated from the geometry of the mandible. In the second step, using the surface extrusion option, the thickness of the templates was given. In the last stage, the final cutting line was established on the templates against which the bone resection would be carried out.

a)

b)

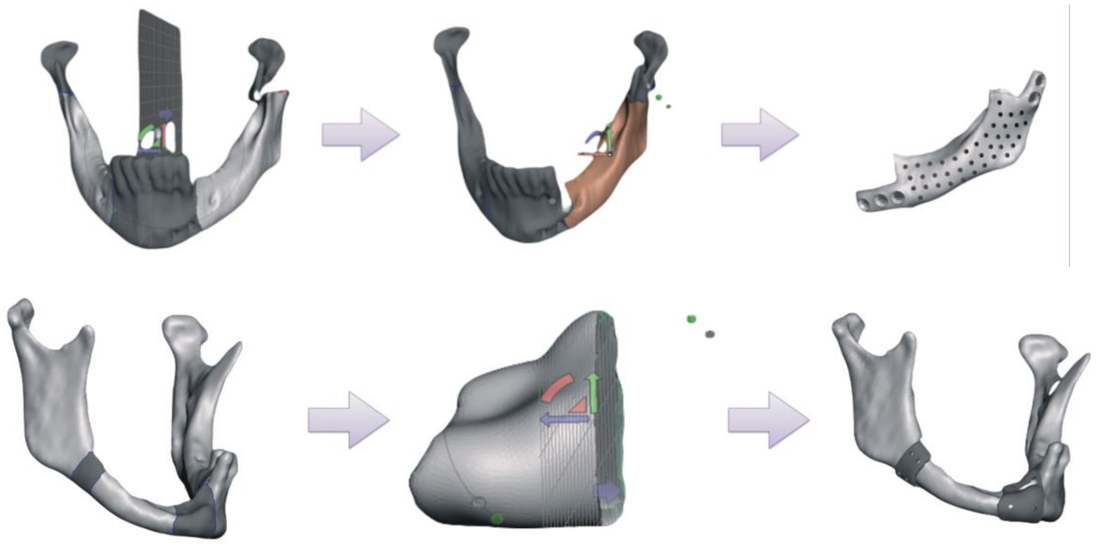

Figure 2. Modelling process in 3D Slicer software for a: (a) first patient; (b) second patient

Then, the models were manufactured for the first (Fig.3a) and second patient (Fig.3b) on the Fortus 360-mc printer using FDM technology. The main elements of the Fortus 360 mc printer are movable printheads and a working table. The material supplied to the printheads from the cartridges is melted and pumped to the heated printheads. The numerically controlled device alternately applies the model and support material to the working table according to the successive levels of cross-sections generated until the entire model is completed.

a) b)

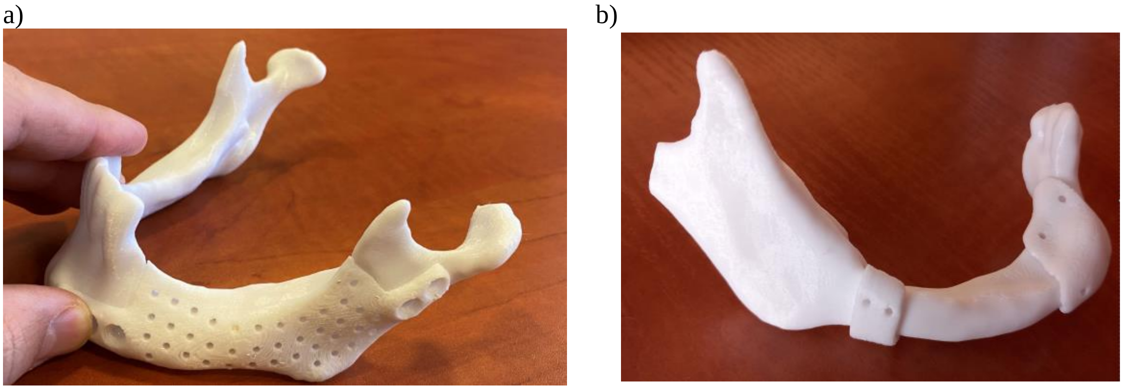

Figure 3. Manufactured models for a: (a) first patient; (b) second patient

The support material after the manufacturing process is usually removed mechanically. In the process of manufacturing the models, the thickness of the print layer was 0.178 mm. The models are made of polycarbonate – PC-ISO. This material is used in the pharmaceutical industry, in biomedical engineering, and for the creation of food packaging. PC-ISO is a rigid, heat-resistant thermoplastic construction material. It is biocompatible, can be sterilized, and is certified to ISO 10993 and USP Class VI.

In the next step, models of the mandibular bone structure and surgical templates were additionally analyzed for accuracy. For this purpose, the Metris Nikon MCA II measuring arm system with the MMD100 laser head was used (Fig.4a). The prototypes were measured in two positions on the measuring table with an applied resolution of 0.01 mm. In the first stage, the outer side of the model was measured (Fig.4b), and in the second, the inner side, because it was impossible to mount it in such a way as to gain access to all its surfaces during one measurement procedure. The process of verifying the accuracy of the models was carried out with the Focus Inspection software. The matching of the nominal model obtained at the RE/CAD design stage and the reference model created at the measurement stage using an optical system was carried out using the best-fit method with an accuracy of 0.001 mm.

a) b)

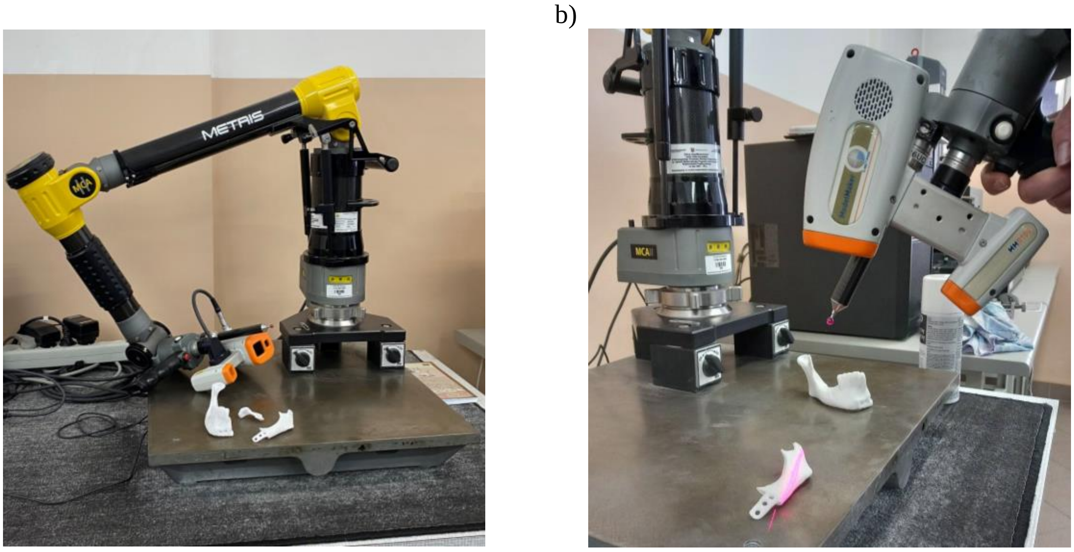

Figure 4. The stage of analysis of the accuracy of the models: (a) articulated arm with the MMD×100 laser head; (b) measuring process

3. Results and discussion

As a result of the comparison, a surface of models designed in the RE/CAD systems and 3D printed, deviation maps (Fig.5 and 6), histograms (Fig.7), and statistical parameters were obtained (Tab.1). Additionally, in Table 1 presented asymmetry (skewness) and kurtosis of the received data.

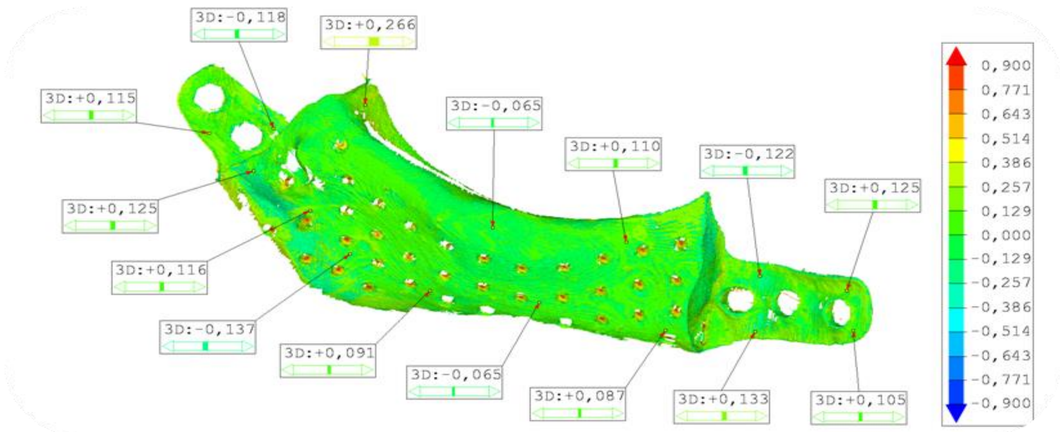

Figure 5. Generated map of deviations for a model supplementing the loss of the mandible

In evaluating the normality of the distribution of the received data, the value of the test statistic equal to W = 0.919 was obtained and is greater than the critical values, which gives us the basis for not rejecting the hypothesis of the normality of the distribution. The distributions obtained in the tests evaluating the model's accuracy in FDM technology will be treated as normal distributions.

a) b)

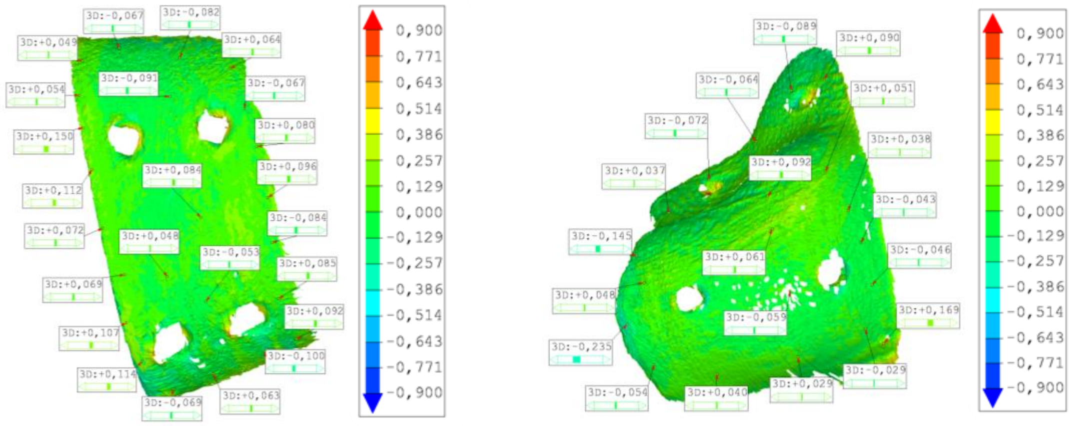

Figure 6. Generated maps of deviations for a resection template: (a) no.1; (b) no.2

The histograms presented in Figure 7 are unimodal. The data in Table 1 show that the most significant distribution of results around the mean value was noted in the model reproducing the defect in the structure of the mandible. For resection templates, the standard deviation values are comparable. For all models, right-sided asymmetry can be observed, and in the case of measures of concentration (kurtosis), it can be concluded that the distributions are leptokurtic. Based on the obtained results, it can be seen that over 90% of the points representing the printed models are within the tolerance of ± 0.2 mm.

a) b) c)

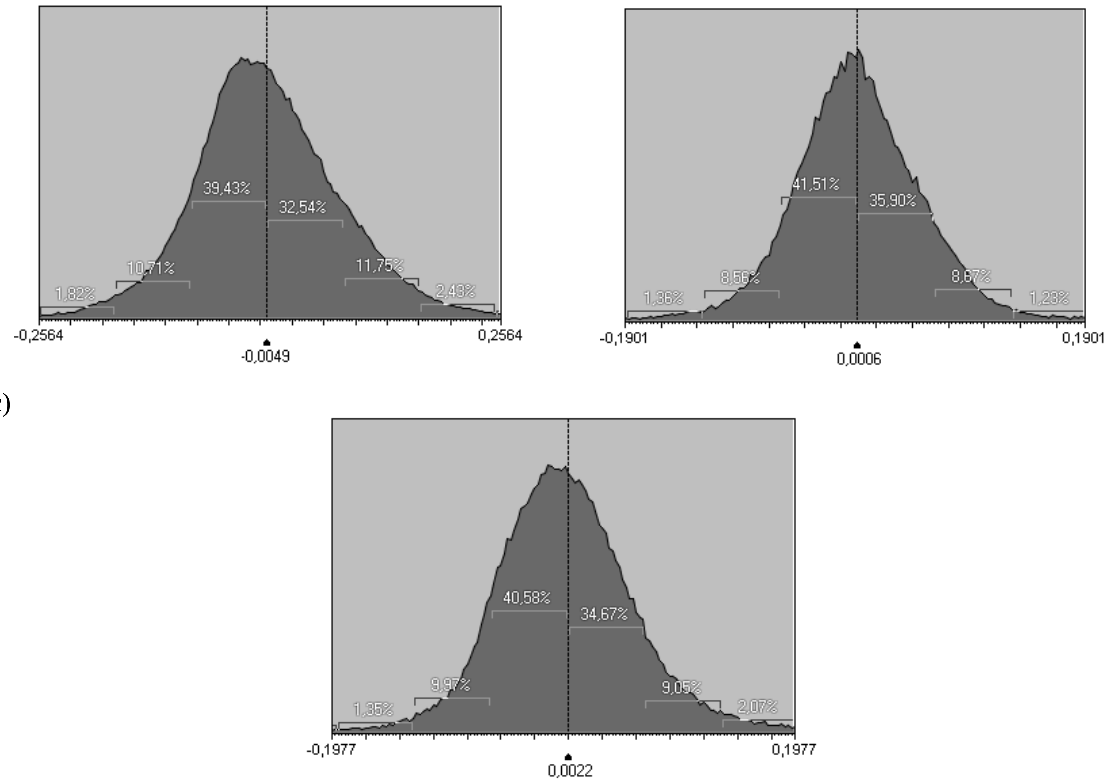

Figure 7. Histograms represents a: (a) model supplementing the loss of the mandible; (b) resection template no.1; (c) resection template no.2

The research aspect in the presented publication is crucial. Obtaining the most accurate mapping of the case of damage to the mandible area using additive techniques can not only significantly increase the precision of the procedure but also significantly minimize the time of the operation itself. Currently, research is being conducted on the dimensional and shape verification of models of anatomical structures made with additive techniques. The change of linear dimensions is most often assessed. Linear measurements on a model are typically made using a caliper (El-Katatny et al., 2010), or coordinate measuring machine (Salmi et al., 2013; Huotilainen et al., 2014). An optical system that illuminates the measured part with structured (Budzik et al., 2019) or laser light (Turek et al., 2021) is most often verifying form deviations used. Considering the presented research, it was established that models 3D printed within the mandible area must be manufactured within the tolerance of ± 0.25 mm (Hazeveld et al., 2014; Lee et al., 2015). Considering the results presented in the article are within the tolerance of ± 0.2 mm, this accuracy is acceptable in planning surgical procedures.

Table 1. Obtained statistical parameters determining the accuracy of the models

Type of model	Mean deviation [mm]	Standard deviation [mm]	Skewness	Kurtosis
Supplementing the loss of the mandible	-0.004	0.084	0.532	3.301
Resection template no.1	0.001	0.063	0.241	3.421
Resection template np.2	0.002	0.065	0.320	3.254

4. Conclusion

Knowledge of the methodology of designing and manufacturing models of anatomical structures can significantly help in the controlled preparation of templates and surgical instruments in terms of the accuracy expected during the procedures. They can also be supportive in the process of carrying out, e.g., operations reconstructing the continuity of mandible geometry, as well as treating other diseases of the skeletal system. The models' accuracy using the additive FDM technique is within the tolerance range of +/- 0.2 mm. It is sufficient to use models when planning a procedure.

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