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Additive manufacturing of reconstruction devices for maxillofacial surgery: design and accuracy assessment of a mandibular plate prototype

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Abstract
Additive manufacturing (AM) presents unique opportunities for medical applications and in particular in maxillofacial surgery for developing patient specific implants. The quality assessment of additive manufactured products is an essential aspect for the real introduction in health services. In this framework, the purpose of the present study is to investigate the possibility of developing prototypes of mandibular plates as preoperative surgical planning models, by verification of design, analysis of internal structure integrity and evaluation of the effects of variables involved in AM processes. A PolyJet three-dimensional (3D) printing system is used in the study due to its very fine resolution.

The computer aided design (CAD) models of the implants were converted to stereolithography (STL) file formats in different STL conversion resolutions and then printed using commercial prototyping polymers to observe the effect of model resolution. Finite element analysis (FEA) was conducted to study the capability of the designed mandibular plate to support the involved biomechanical loads. Micro-computed tomography (micro-CT) analysis was performed to verify the dimensions and the internal defects of the printed objects, considering that the presence of defects can affect the quality and compromise the final performance. Results were analyzed to understand the effect of the 3D printing process flow conditions on the obtained prototypes. Relative error in reference to the CAD models mainly evidenced the difference in resolution due to STL files and the effect of the design. No anomalies and defects were detected inside the evaluated samples.

Key words
- additive manufacturing
- 3D printing
- micro-computed tomography
- mandibular plate
- maxillofacial surgery

INTRODUCTION

Healthcare innovations require a great attention in the assessment of all the aspects related to the quality of devices and applications in order to consider the introduction in health services.

Maxillofacial surgery (MFS) includes a series of different subfields, such as craniofacial corrective surgery, orthognathic surgery, maxillofacial trauma, reconstructive surgery and maxillofacial oncological surgery [1, 2]. In general, the main aim of MFS surgery is to restore the normal anatomical structure and function after a trauma, an oncological resection or a facial malformation.

As evidenced by some authors [3-5], 20-42% of all facial bone trauma are mandibular fractures. Indeed, many studies have been carried out to investigate the efficacy of different techniques in the treatment of mandibular defects and fractures [6], proposing mandibular plates as osteosynthesis devices for the stabilization, reconstruction and rigid fixation of cranio-maxillofacial fractures. Different types of reconstructive plates and screws, usually manufactured by traditional processes, and mainly made of metallic alloys, have been proposed and compared [6-8], also considering systems with multidirectional screw placement [5]. However, it has to be taken into account that the reconstruction of mandibular defects has to restore not only facial aesthetic form but also functions of speech and mastication [9, 10]. Moreover, the main benefits in the use of reconstruction systems are achieved by a right choice of the device in terms of geometry, thickness, and dimensions, fitting the specific clinical patient conditions that, in the case of mandibular applications, can be various and not

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always respected using series-manufactured products. Consequently, some devices have to be adjusted during implantation by surgery manipulation in order to fit the clinical case and/or the fracture position. This step introduces critical aspects and high risk factors that are, in some cases, correlated only to the surgeon experience and, thus, difficult to control and improve.

For these reasons, the use of computer-aided design/computer-aided manufacturing (CAD/CAM) method, which includes virtual surgical planning and rapid-prototyping procedures for the design and manufacture of the customized surgical devices [11, 12], is gaining a lot of attention, presenting great applicability in MFS sector. This type of approaches changes, in some cases completely, the surgeons' method to work, hospital processes in the management of a patient, and clinical procedures. It could represent a change from large-scale centralized production to local production models, saving shipping time by allowing production at the site of use.

In particular, additive manufacturing (AM), also called 3D printing [13], presents several applications in surgery, primarily in maxillofacial sector (50%), to produce anatomic models (71.5%), surgical guides (25.3%), and implants (9.5%) [14]. The production of mandible preoperative models by AM, to simulate reconstruction plates prior to mandibular resection or to better visualize the effect of surgery operation, was found to be a useful technique [15]. Indeed, the use of mandible models allows reducing the operating time [16] and improving the esthetic outcome with respect to conventional mandibular reconstruction [17]. Most of the preoperative approaches consider only the creation of mandible model by rapid prototyping in order to determine the pre-bending and the position of serial reconstruction plates [17-19]. At the same time, custom designed implants are becoming the best option for reconstruction of craniofacial defects [20]. The combination of mandible models and custom reconstructive plates, also designed using the original external cortical bone, results promising to simulate surgery with respect to conventional methods [12, 21].

The cost of CAD/CAM method for mandibular reconstruction is recovered by gains in terms of surgical time, quality of reconstruction, and reduced complications [22]. Indeed, Resnick *et al.* [23] evidenced that virtual surgical planning and 3D printing of surgical splints are becoming the standard of care for orthognathic surgery and this option is less expensive than standard planning.

AM could have the potential to allow the realization of patient-matched or specific custom made implantable devices, based on patient anatomy and pathology, but respecting all quality and regulatory aspects, usually checked for traditional medical devices. At the state of art, it is a good solution for preoperative models, useful in the validation phase of new designs in short time, to optimize the device design also adapting it to the patient anatomy. Imaging devices are providing new capabilities to the AM industry by converting the image stacks into solid models that can be used for implant or device production [13, 24]. Moreover, worldwide, the sale of AM products and services is expected to grow rapidly and the industry is forecasted to be worth over $ 6 billion by 2019 [25]. When hospitals and healthcare systems will start to include reimbursement for 3D printing performed in clinical context for patients, it will be probably an explosion of applications by healthcare professionals. Thus, it is necessary to assess the products, in particular for the adoption in public health systems.

A current limitation for AM is that the methodology for the assessment of additive manufactured products is not well defined. This aspect is relevant for the manufactures, for the assessors but also for considering the introduction of 3D printing services and products in healthcare systems. Various aspects should be considered in the quality assessment: the design of the CAD model, the quality of representation of the original model by the STL files [26], the direction of printing [26, 27], the selection of the printer and the printing material. Thus, the accuracy [28], the repeatability and the reproducibility for additive manufactured products represent critical aspects that need to be investigated in details.

In this context and considering the potential impact of AM in MFS, the purpose of the present study was to investigate the appropriateness of a PolyJet system in developing mandibular plates prototypes mainly usable during the design validation phase and as preoperative surgical planning models. PolyJet has one of the finest resolutions among the current commercial 3D printers and is capable of producing application-ready parts.

The present study includes the design of selected models by CAD, the realization of them by AM PolyJet system using two different commercial materials (i.e. Stratasys VeroBlue (VB) and Stratasys VeroClear (VC)). Finite element analysis (FEA) and micro-computed tomography (micro-CT) analyses were performed to verify the appropriateness of the design. FEA was carried out to verify the capability of the designed mandibular plates to support the involved biomechanical loads and the micro-CT to measure the actual dimensions and to capture the internal structure of the printed objects. Design modifications were elaborated in order to evaluate possible improvement in the accuracy and resolution of 3D printed objects, taking into account that steps such as converting CAD models to STL format cause loss in information and affect the final product quality.

METHODS

Mandibular plate models: design and FEA

A plate model for medial and lateral fixation (L-shape, dimensions 22×10 mm^2, Model1) was designed using Solidworks 2016. Dimensions and geometry were defined considering many commercially available devices usually applied in MFS for mandibular reconstruction [29]. A second design (Model2) was created properly modifying Model1, in order to verify the possibility to improve curved printed surfaces (*Figure 1*). *Figure 1* illustrates the CAD models, where the main differences are localized in the critical sections that are marked as A, B and C (see also *Figure 2*). Model1 has smaller sections than those in Model2 (relative difference of about

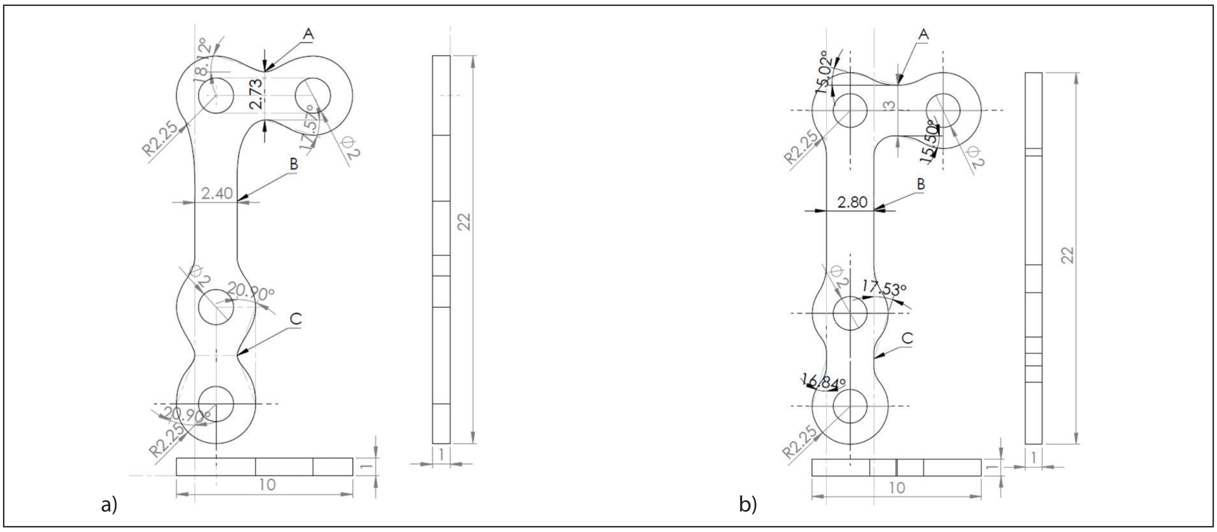

Figure 1
CAD models with dimensions in mm: a) Model1, b) Model2. A, B and C indicate the critical sections which differ between Model1 and Model2.

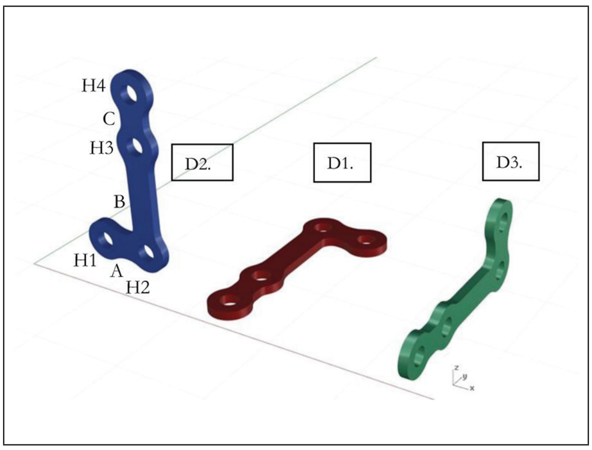

Figure 2
Printing orientations (D1, D2, D3) and points of interests (A, B, C, H1, H2, H3 and H4) marked on the left plate model.

10% in A and 16% in B). The external edges in A and C sections were designed with a difference in curvature angles of about 2°-3° in A and 3.5°-4° in C. Model2 has more straight edges in the critical sections, particularly in C. Two STL files were exported with different resolutions – "Fine" and "Coarse" – for each design, in order to analyze possible modifications in printed objects based on the STL file resolution. "Fine" and "Coarse" are two preset options in SolidWorks software for exporting files to STL format, although higher resolution is possible by using "Custom" settings. The Fine model has higher number of polygons, about 50% more that the Coarse one: Model1-fine has 1212 polygons; Model2-fine has 1144 polygons. Static mechanical simulations were performed by ANSYS – Mechanical. The objects were designed as prototypes for design validation and with a possible application in preoperative surgical planning on mandible models. Therefore, the simulated entity of loading was defined considering the application in a normal mandible under physiological occlusal loading [30-32]. Different types of meshing were implemented with particular attention to the area close to the plate holes. The meshing with fine parameters was selected for curvature (Model2; 2136 elements, 12056 nodes) and the considered loading and constraints conditions were:

- Loading-case1: force of 100 N, compression loads on plate upper surface; plate back surface fixed.
- Loading-case2: force of 100 N, compression loads on screws positions; plate back surface fixed (*Figure 3*).
- Loading-case3: displacement of 10 mm/min in the middle area (edge) of the upper surface [33]; end of plate back surfaces fixed.

The material properties considered in simulations were: Young Modulus: 2500 MPa, density: 1.18 g/cm^3 and tensile strength: 60 MPa, which were obtained from the datasheets of the commercial materials selected for the mandibular plates printing, i.e. Stratasys VeroBlue (VB) and Stratasys VeroClear (VC).

3D Printing process and materials

A Stratasys Object30 Pro PolyJet system was used to print the developed models. Two different commercial materials, i.e. VB and VC, were employed [34]. The printer has a declared resolution of 600 dpi along X- and Y-axes and 900 dpi along Z-axis and an accuracy of 0.1 mm with a minimum layer thickness of 16 μm for the VC material and of 28 μm for other commercial materials.

VB was used only for Model1, whereas VC, with glossy surface refinement, was used for both models. Three different printing directions were considered, i.e. D1, D2 and D3 (*Figure 2*) in a preliminary evaluation to define the optimal printing orientation.

Micro-computed tomography analysis

3D micro-CT scans were performed using the Skyscan 1172, a high-resolution scanner.

The objects analyzed in this study were acquired by oversize scansions due to the length of the samples. The

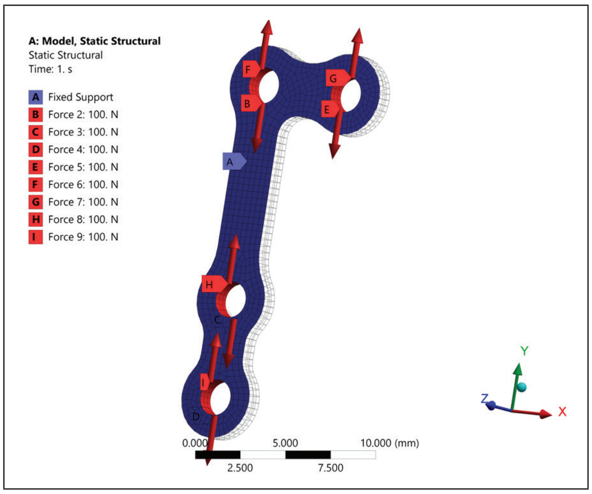

Figure 3
FEA Loading-case2, Model2.

main acquisition parameters were the following ones: source voltage 44 kV, source current 222 µA, image pixel size 12 µm, rotation step 0.3° for the objects printed with VC material. For Model1 printed by VB, the parameters are 47 kV, 212 µA, 13.6 µm, 0.4° ; 44 kV, 222 µA, 5 µm, 0.1° for the Coarse and the Fine models, respectively. For all acquisitions, no filter was used. A dedicated software, SkyScan NRecon, was used to reconstruct the cross section images (slices) of the objects. The slices were evaluated by the software Skyscan CT-Analyser to obtain the 3D models and morphometric parameters. The volume rendering program, Skyscan CTvox, was used to display the 3D object from reconstructed slices.

RESULTS

First, the geometry of the designed models of mandibular plates (Model1 and Model2) was optimized to avoid stress concentrations and ensure the uniformity of stress distribution by performing simulations by FEA. In particular, the applicability of the designed plates as prototypes to be used in preoperative surgical planning on mandible models was evaluated, considering loading and constraints conditions related to a normal mandible under physiological occlusal loading. The considered different loading cases underline the main conditions to investigate the plate models resistance, in particular around holes that have to fit screws.

In *Figure 3* and *Figure 4*, FEA results related to the loading-case2 (compression on screws positions, *Figure 3*) for Model1 and Model2 are reported, respectively. The stress distribution and deformation are similar for both designs, in all the considered loading cases, and only those obtained for Model2 are reported in *Table 1*, where the maximum values of von Mises stress, principal stress, shear stress and the total deformation are compared for the three different loading cases. The magnitude of stress is appropriate for the PolyJet material used in printing the specimens. Loads applied in loading-case2 (compression on screws positions) create stress concentration around holes. *Figure 4* shows total deformation in Model1 and von Mises stress in Model2, for loading-case2. Loading-case3 (displacement in the middle area of the plate upper surface) is useful to investigate the stress distribution correlated to a displacement applied on the plate, simulating the effect of the bending test on the plate [33]. Stress concentration was not observed in the designed models under these loading conditions. Thus, the designed models and the considered materials are appropriate to be manufactured by additive manufacturing.

For the manufacturing process, the printing orientation was investigated in a preliminary evaluation. Three different printing directions, i.e. D1, D2 and D3 (*Figure 2*), were considered in order to identify the optimal one. D2 and D3 configurations resulted inappropriate for this type of geometry, for several reasons: it was necessary to use a great amount of support to print the objects; the objects presented some discontinuities due to the support material; the time necessary in printing

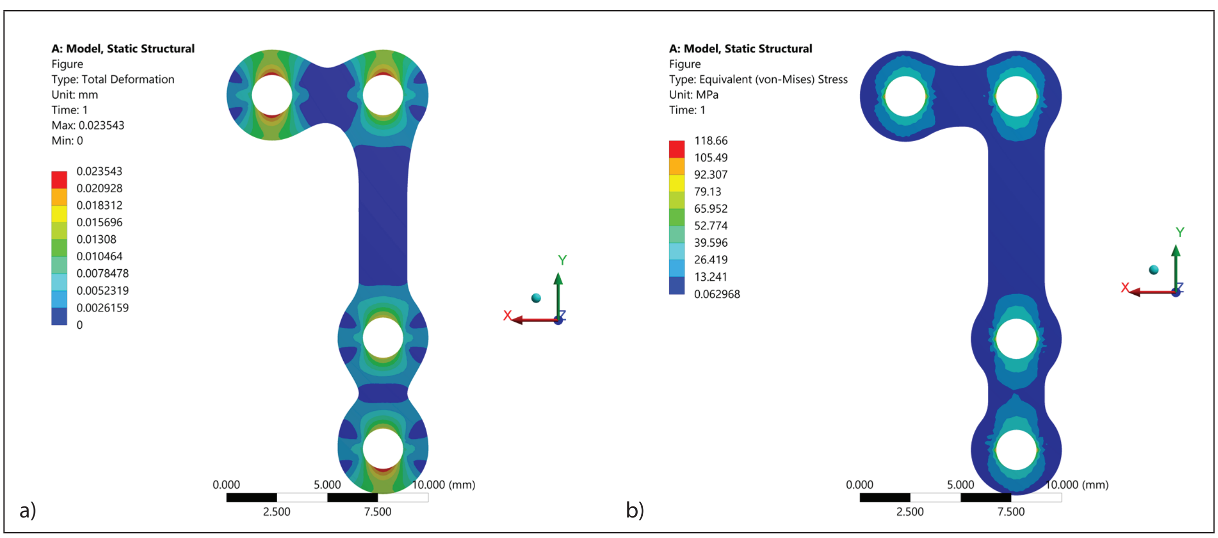

Figure 4
Loading-case2: a) Model1 – Total deformation; b) Model2 – von Mises stress.

Table 1
Finite element analysis (FEA) results for Model2

FEA	Model2			
Loading case	**Max. von Mises stress (MPa)**	**Max. principal stress (MPa)**	**Max. shear stress (MPa)**	**Total deformation (mm)**
Case1	1.8	0.2	1.0	0.0006
Case2	118.6	130.8	64.1	0.0235
Case3	29.7	41.1	15.3	0.1704

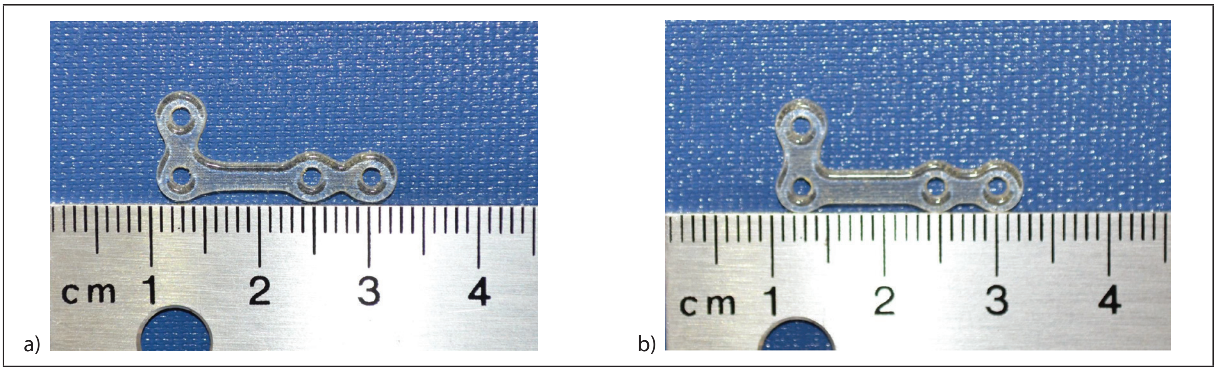

Figure 5
Models printed for STL Fine, configuration D1: a) Model1, b) Model2.

was about twice that required in the D1 configuration. Thus, in the study only the models printed in D1 configuration (*Figure 2*), where the object is printed flat on the 3D printer build plate, are discussed.

Model1 was first printed using Coarse and Fine STL files and VB material in printing direction D1. It was observed that the dimensions of the part at the backside were not accurate as the front side. The same Model1 printed with VC material, that has a specified printing resolution better than VB, did not present this problem at the back surface when printed in the same configuration. As an example, *Figure 5* shows Model1 and Model2 prototypes printed with STL Fine and configuration D1, using VC material, evidencing the respect of the designed shape and dimensions.

In order to evaluate the printing quality, the obtained dimensions were measured on models reconstructed by micro-CT analysis at points of interest marked in Figure 2 (H1, H2, H3 and H4), as well as the object thickness. A representative set of micro-CT images is shown in *Figure 6*, where slices reconstructed by micro-CT in the area of the hole H3 for Model1_VB, and in the B-area for Model2_VC are reported. The entire object (Model1_VC) is reconstructed in *Figure 6c* for measurement. The graph in *Figure 7* shows the relative error calculated in reference to CAD models' dimensions (three repetitions to consider spatial snap resolution) obtained by software measurements.

Morphological 3D analysis of printed samples was performed in reference to the selection, B-volume, for

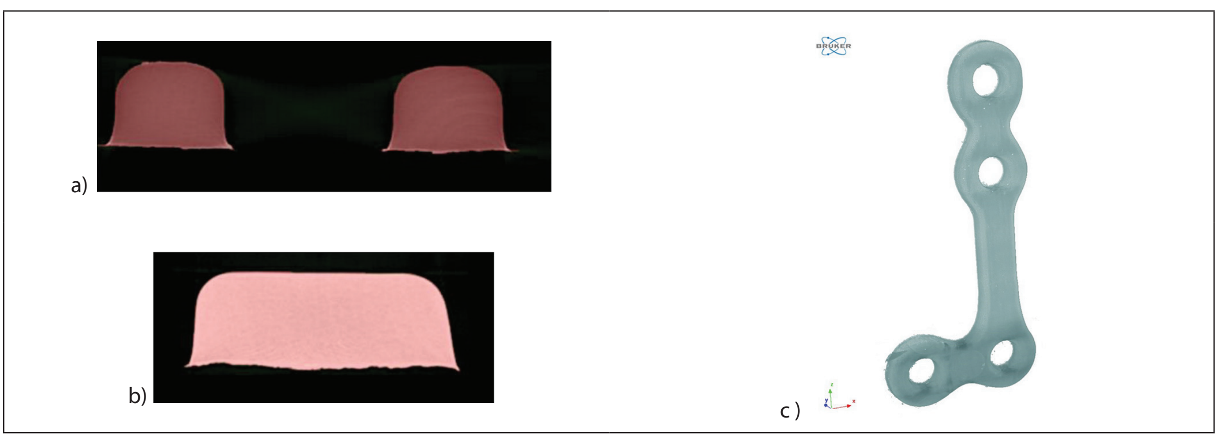

Figure 6
Micro-CT analysis: a) Model1_VeroBlue, H3 selection; b) Model2_VeroClear, B-selection; c) Model1_VeroClear reconstructed.

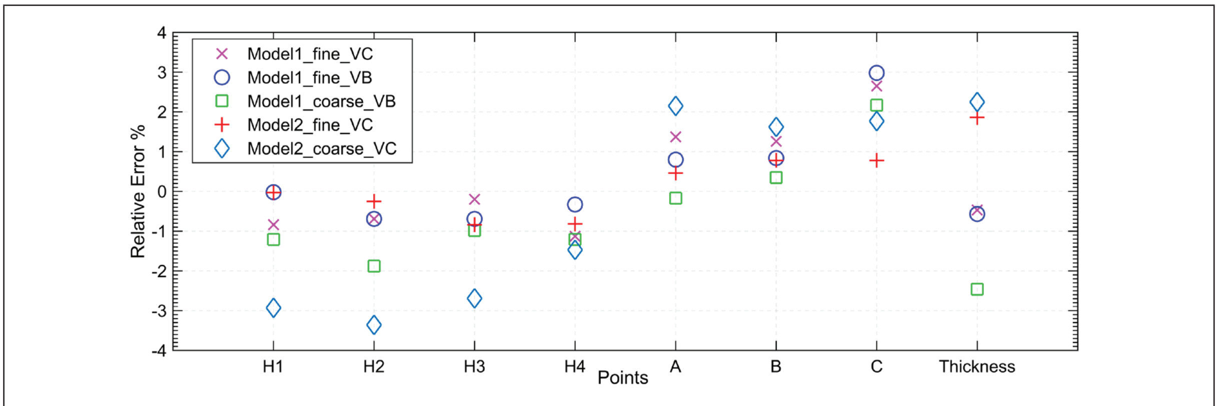

Figure 7
Relative error percent in points of interests for Model1 and Model2, Fine and Coarse, materials VB and VC; reference CAD dimensions.

a number of reconstructed layers equivalent to a distance in z of 0.360 mm (*Figure 2*). *Table 2* reports the morphological data for the samples printed by using VC material. In the analyzed models, the enclosed porosity is not observed and it well represents the uniformity of PolyJet material, whereas the surface porosity values are mainly correlated to the residual support material around the models that is detectable by micro-CT analysis. The structural thickness values were comparable, demonstrating the uniformity of the structure and the analysis did not detect voids inside the solid parts.

DISCUSSION

In planning a surgery operation or in developing a specific device to optimize the medical intervention, it is necessary to consider the variability introduced by the use of a technology, e.g. to find if it is possible to reproduce the same operation at the same conditions. Thus, the suitability of an additive manufacturing design software and printing system in developing prototypes of mandibular plates was investigated, by verification of design, internal structure integrity and evaluation of the effects of variables involved in AM processes. The used PolyJet is considered appropriate to also reproduce anatomic details due to its fine resolution [35, 36] and is commonly used to develop prototypes and preoperative surgical planning models. It is worthy to underline that the printing direction influences the result and represents a quality aspect that has to be controlled, also requiring different process times. Moreover, this is one of the aspects that are correlated to cybersecurity challenges and to the difficulty of defending conventional intellectual property of AM products [37]. For this reason, three different directions were considered, where the D1 print orientation resulted in the best quality part for both investigated models. The directions D2 and D3 showed surface discontinuities in the part.

The preliminary simulations performed in this study showed that the plate designs, as well as the model materials properties, can be considered appropriate for the realization of mandibular plates prototypes (*Figure 3* and *Figure 4*, *Table 1*). Indeed, FEA is a useful method to predict properties of 3D printed objects in reference to design and materials [38].

Micro-CT analysis was carried out to verify the internal structure of the printed objects and the accuracy of the designed geometry. Micro-CT is considered as one of the major tools for the product quality assessment and for the quality control of AM products and materials [39]. In fact, the FDA in the guidance about technical considerations for additive manufactured medical devices [40] indicates micro-CT as appropriate methodology for the verification of geometry, morphology, and some performance characteristics of printed products.

The micro-CT results obtained for the investigated specimens showed no anomalies or defects inside the printed objects for both the materials (VB and VC) used for printing (*Figure 6*). However, a different curvature along edges was recognized around holes of the objects printed with VB material. For the same material, the printed plates presented an amount of residual support that affects the dimensional measurements obtained by micro-CT because the support was made of the VB material as the plate.

Table 2
Morphological 3D Analysis, Volume-B (Δz = 0.360 mm) for Model1 and Model2 printed with VeroClear material

Model	Object volume	Structural thickness	Closed porosity P_{cl}	Open porosity P_{op}
	(mm³)	(mm)	(%)	(%)
Model1_fine	0.922	0.372	0.0000	45.26
Model2_fine_r1	1.148	0.367	0.0000	26.70
Model2_fine_r2	1.130	0.370	0.0001	52.39
Model2_coarse	1.083	0.371	0.0000	80.36

Morphological 3D analysis performed for the printed objects allowed to investigate their internal structure and to identify possible defects. The distribution of the used material during the printing process was uniform in all printed samples. The micro-CT analysis showed that for the designed models the critical aspect is correlated to respect the flat upper surface. Indeed, for the Model1 printed with VB the flat upper surface presented a curvature not included in the design, but due to the material deposition during printing. By using VC material, this aspect was less evident even if present. The use of VC instead of VB improved the back surface of the objects and it allowed obtaining a surface as well-defined, accurate and smooth as the upper one. Thus, the used PolyJet materials seem to be similar in resolution, considering Model1 printed with both materials and STL Fine.

Misalignment due to the position of samples during the acquisition by micro-CT could affect dimensional measures, even if the possible error is minimal. For this reason, during reconstruction, care was taken to limit this effect. Besides this limitation, measurements checked by DataViewer software are representative and useful to investigate the accuracy of printed objects and the conformity to the designed CAD models.

The difference in accuracy between STL files was more evident for the Model2_VC. As shown in *Figure* 7, the difference was greater around holes with a maximum value of error of about 3% in H2, whereas it was less evident for Model1_VB. In general, the relative dimensional error reaches a maximum value of -3.36% in H2 for Model2_coarse_VC and 2.98% in C for Model1_fine_VB. The negative value means that the hole of the printed object is smaller than the designed dimension. For this kind of object design, characterized by curvatures, the major complexity is associated with dimensions and shapes of holes designed for precision fit with screws. In the evaluation of the error value, residual amount of the support material needs to be accounted for because it could be included in the obtained measurements due to its similar gray value to the object material. Minimum relative errors, i.e. 0.02% and 0.03 %, were obtained at the hole H1 for Model1_fine_VB and for Model2_fine_VC, respectively.

By the analysis of dimensions in the sections A and C, where the curvature was modified, it is possible to underline the improvement in design from Model1 to Model2. In Model2, these sections resulted with a relative error less than that revealed in Model1, with a maximum in C, where for Model1_fine_VC the relative error was 2.65% and for Model2_fine_VC the relative error was 0.78%. At these locations, the improvement in designs was more effective.

The thickness of the models was well preserved on the average and presented the maximum relative error in the Model1_coarse_VB (i.e. -2.46%) and the minimum value in Model1_fine_VC (i.e. -0.47%). The thickness of Model1 specimens resulted in general smaller than the designed thickness, vice versa for Model2 (*Figure* 7). A similar trend is detected for the holes dimensions that resulted smaller than the designed dimensions and vice versa for the sections A, B, C. The length resulted with an average relative error of 0.6%, considering all printed objects.

Finally, the repeatability of print quality of the objects is an aspect that requires more investigation. In tests conducted for Model2, i.e. a repetition of the STL Fine analyzed in direction D1 (Model2_fine_r1, Model2_fine_r2), it was noted that there are dimensional and morphological differences in printed objects correlated to the same model and printed at the same time, in the same conditions (*Table 2*). Further investigations are required to quantify the uncertainty in printing an object multiple times using the same printer and printing conditions.

All of the aspects underlined and discussed in this paper are relevant in considering the feasibility of using AM for the realization of prototypes, to perform a verification of a design and in particular to use printed objects in a medical context, also only in a preoperative surgical step.

CONCLUSIONS

In this study, two CAD models of a specific mandibular plate design were printed by an additive manufacturing system using two different materials to investigate the appropriateness of the AM technique in developing prototypes of mandibular plates for the validation of new designs and potentially as components in preoperative surgical planning models. The obtained design, the internal structure integrity and the effects of some AM process variables were investigated.

No anomalies and defects inside the printed samples structure were identified by micro-CT scanning for all models and both materials used. The shape of the models was well preserved and the surface of the specimens resulted in uniform finish, particularly in the case of VC material. Relative errors in reference to the CAD models obtained for all models showed in particular the difference in resolution due to STL files and the effect of the design. The micro-CT analysis showed that a critical aspect is to preserve the flat upper surface of the designed models.

Thus, this study demonstrates the feasibility to use AM for the realization of mandibular plates' prototypes, and preoperative surgical planning models, by identification of dimensional errors, material defects, the model that best fits the initial geometry designed and the effects of printing parameters that can compromise the use of 3D printed products.

The quality assessment of additive manufactured products is essential for medical applications. The methodology used for the assessment is applicable to others surgical planning models, to the manufacturers of custom-made devices and in general to assess additive manufactured medical applications in health services and national healthcare systems.

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