INTRODUCTION

Additive manufacturing (AM), widely known as three-dimensional printing—3D printing, represents a disruptive innovation in healthcare sector. It is an innovative technology with great potential and economic implications. During the past few years, the improvement in 3D printing technologies and the availability of various printable materials (Stansbury & Idacavage, 2016; Youssef et al., 2017) have resulted in an increase in the number of companies that are leasing 3D printers to the users or on-demand printing services. The economic implications of such possibilities are significant in healthcare (Frost & Sullivan, 2019) because the manufacturing can be outsourced to a third party that may be providing manufacturing services onsite or off-site from the patient-specific custom models. The possibility to apply AM in the biomedical sector is extremely interesting for medical device manufacturers because on-demand manufacturing allows eliminating inventory and printing only the components that are needed at a given time. Personalized medical devices, specifically based on CT-scan

Ti6Al4V mandibular devices by additive manufacturing: Assessment of as-built quality

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Abstract

Additive manufacturing (AM) represents a promising healthcare innovation. Clinicians need ready-to-use devices in short time, which means high as-built quality and low uncertainty. Medical devices need to respect stringent quality requirements ensuring safety and effectiveness. The medical practitioners often outsource the manufacturing to hub services. This study aims to assess the as-built quality of AM mandibular plate prototypes manufactured by direct metal laser sintering technology using Ti6Al4V alloy and highlights several challenges that emerge from using the commercial printing services where user does not have control over the actual manufacturing process. Verification of dimensions, morphology, surface finish and mechanical properties is conducted. Finite element analysis on computer-aided design (CAD) models was performed for stress analysis. Non-destructive analysis by micro-computed tomography (micro-CT) allowed measurement of the dimensions, ascertaining the dimensional accuracy in reference to the CAD models, and the presence of pores and internal defects, while destructive analysis allowed determination of the mechanical properties. Although no large internal defects were detected, some regions of micro-porosity and incomplete fusion of feed particles were observed. Accurate production of fine details was also a concern in the printed parts. The proposed framework establishes a structured assessment scheme, which could be useful for other AM medical designs and for stakeholders involved in AM for biomedical applications.

KEYWORDS
3D printing, additive manufacturing, as-built quality, mandibular reconstruction plate, medical devices, micro-computed tomography, Ti6Al4V
image reconstruction (Chepelev et al., 2017; Rengier et al., 2010), are becoming mainstream in the biomedical sector. Healthcare organizations have started collaborations with manufacturers to satisfy specific operative conditions and to evaluate possible reimbursement associated with the 3D printed devices. As evidenced in recent publications (Durfee & Iaizzo, 2019; Singh & Ramakrishna, 2017) and in the KCE Report 2018 (Vinck et al., 2018), the AM technology can serve several specific purposes in the medical field. It can be used to print a patient-custom implant (e.g., fixation plates and jaw implant) or to print patient-specific moulds to manufacture prosthetics (cranial implants), or print anatomic models in order to understand the pathology and the patient's anatomical representation. In surgery, there are different cases that can be treated and solved easily, for example planning pre-operative surgery actions by the use of prototypes that reproduce the anatomical site, restrictions, limits, abnormalities, and other masses in cancer patients, or supporting the surgeons in performing surgeries on unique clinical cases (Malik et al., 2015; Martelli et al., 2016). Cranio-maxillofacial surgery (CMFS) represents one of the major sectors of AM applications (Martelli et al., 2016). As evidenced (Louvrier et al., 2017), the main advantages of AM in this field are the improvement in precision and reduction of surgical time, while one of the main disadvantages is the cost of the printed objects. A great amount of maxillofacial (MF) bone trauma is related to mandibular fractures (Boffano et al., 2015; Schneider et al., 2015); thus, many studies are conducted to investigate the efficacy of different techniques in the treatment of mandibular defects and fractures based on mandibular plates for the stabilization, reconstruction and rigid fixation.

Computer-aided design/computer-aided manufacturing (CAD/CAM), virtual surgical planning and rapid-prototyping represent the main techniques for the design and the manufacturing of MF devices (Ciocca, Mazzoni, Fantini, Persiani, Marchetti et al., 2012; Mazzoni et al., 2015; Singare et al., 2004). Mainly, mandibular plates are realized by traditional processes using metallic materials (Ciçmen et al., 2016). Recently, the potential to use AM with biocompatible alloys (Avila et al., 2018; Bose et al., 2018), such as Ti6Al4V, has opened new possibilities in the production of metallic implantable medical devices (Ciocca, Mazzoni, Fantini, Persiani, Baldissara et al., 2012; Durfee & Iaizzo, 2019; Li et al., 2019; Sharma & Soni, 2020). Regarding the production, the Delphi study projection (Jiang et al., 2017) suggests that by 2030 less critical parts will be produced locally by AM, while critical parts will be made at specialist hubs with specific quality control skills. These projections are relevant in the context of biomedical products and particularly in correlation to the regulatory aspects (Morrison et al., 2015). Recently, the time sensitivity required in the response of COVID-19 pandemic has accelerated the role of AM healthcare solutions by developing personal protective gears and equipment deployed in the healthcare setting. Some limitations and critical aspects (Manero et al., 2020; Sinha et al., 2020) have thus become evident in relation to the supply chain and relative risks (Gupta et al., 2020). Moreover, the possibility to produce objects starting from reverse engineering operations using machine-learning opened up new critical challenges related to intellectual property protection and anti-counterfeiting (Yanamandra et al., 2020).

Indeed, the main challenge for AM is related to the quality of the product. The possibility to obtain high dimensional accuracy, optimal mechanical properties and low uncertainty of the results in terms of final properties, reproducibility and repeatability are the goals of AM developments. Even if many studies were performed focusing on the evaluation and enhancement of AM materials, on the microstructure as for the Ti6Al4V alloys (Liu & Shin, 2018), little information is available on the assessment of printed objects at the various stages of manufacturing and mainly at corresponding uncertain initial settings. Furthermore, traditional methods for sampling the devices during testing may not be appropriate for AM medical devices because of very small production runs and individual customization. It is essential to have the possibility for assessing the quality by a validated methodology that is able to detect geometrical characteristics of the printed objects, compliance with technical specifications, defects and mechanical properties. In a previous study (Campioni, Cacciotti et al., 2020), the authors started the definition and validation of a possible methodology assessing the design and the accuracy of a mandibular plate prototype, 3D printed by a PolyJet system in a research context for a presurgical application. In the same context, the purpose of the present study is to extend the methodology by investigating the as-built quality of AM mandibular plate prototypes manufactured in a realistic production environment for healthcare systems by using a manufacturing hub with direct metal laser sintering (DMLS) technology and Ti6Al4V biomedical alloy. The as-built quality is analysed in terms of design accuracy, structural integrity, surface finish and mechanical properties. In small and thin size parts such as mandibular plates that require precision manufacturing, there are significant challenges in using the current state of the art AM techniques, and the assessment of the as-built quality, which is highlighted in this work, is relevant.

2 | MATERIALS AND METHODS

The study includes two selected models, their realization by a DMLS printer using commercial Ti6Al4V powder and application of integrated methodologies. Finite element analysis (FEA) was conducted to verify the design properties in relation to biomechanical loads. Micro-computed tomography (micro-CT) was performed to analyse the dimensional accuracy of the printed objects and the three-dimensional internal structure. Tensile tests were carried out to determine the mechanical properties and failure mode of the selected L-shape printed specimens. The fracture surface of the specimens, as well as the external surface, was investigated by means of a scanning electron microscope (SEM). Details about designs, materials, processes and characterization are reported in the following sections.

2.1 | Mandibular plate models design and FEA

Plate models, shown in Figure 1, for medial and lateral fixation (L-shape, dimensions 22 × 10 mm², Model-L and straight L-shape, dimensions 22 × 4.5 mm², Model-l) were designed using the software...
SolidWorks 2016. The design of the Model-L was previously optimized for advanced AM with polymeric materials (Campioni, Cacciotti et al., 2020), and it is here assessed again for metal printing. Dimensions and geometry were defined considering many commercially available devices usually applied in MF surgery for mandibular reconstruction (Kakarala et al., 2018).

The stereolithography (STL) files were exported for both models using SolidWorks software preset resolution ‘Fine’. The Fine resolution provides a more accurate representation in STL format than coarser resolutions, although even higher resolution is possible by using ‘Custom’ settings. The number of polygons is 1144 for the Model-L and 1212 for the Model-I.

Static mechanical simulations were performed by ANSYS Mechanical. The objects were designed as prototype MF mandible devices; therefore, the loading conditions were defined considering the application in a normal mandible under physiological occlusal loading (Barão et al., 2013; Grohmann et al., 2015; Hakim et al., 2014; Narra et al., 2014; Vajgel et al., 2013; Wang et al., 2017). The meshing with fine parameters was selected to more accurately capture the curvature present in the models (Model-L: 2136 elements, 12056 nodes; Model-I: 1854 elements, 10558 nodes). In order to investigate the critical area around the plates’ holes, the following loading case with specific boundary conditions was considered: force of 100 N, compression loads on screw positions and plate back surface fixed (Figure 2). The material properties included in simulations were obtained from the datasheets of the EOS Ti64 as Young’s module of 112 GPa, ultimate strength of 1250 MPa and density of 4.41 g/cm³.

2.2 | Additive manufacturing process and materials

The objects were printed using an international 3D printing service based on a network of manufacturing hubs. Upon uploading the STL files, the platform allows to select the material, the desired printing technology to be used and then suggests the best manufacturing service with comparative price, located in various countries. For the Model-L (10 specimens, nomenclature ‘Lspecimen number’) and Model-I (5 specimens, nomenclature ‘Ispecimen number’), the selected printing service was able to print the specimens by using EOS M280 with an achievable final accuracy of ±50 µm (EOS GmbH, 2014), using EOS Ti64 biomedical grade alloy metal powder with nominal spherical particles diameter of 30 µm.

2.3 | Characterization: micro-CT, tensile tests and microscopy

3D micro-CT scans were performed using a high-resolution scanner (SkyScan 1172; Bruker microCT). The objects analysed in this study were acquired by oversize scans due to the length of the specimens. The main imaging parameters were source voltage 95 kV, source current 104 µA, image pixel size 12 µm and rotation step 0.45°. For all acquisitions, Al-Cu filter was applied. A dedicated software, NRecon (Bruker microCT), was used to reconstruct the cross-section images (slices) of the objects. The slices were evaluated by the software CT-Analyser (Bruker microCT) to obtain the 3D models and morphometric parameters. Specifically, the closed porosity data were obtained using CT-Analyser software on the binarized images reconstructed with micro-CT. The pore size range was calculated considering the perimeters of all pores detected in each slice of the central volume of interest—about ∆z = 6.7 mm for Model-L and ∆z = 2.8 mm for Model-I, (Figures 1 and 3).

DataViewer software (Bruker microCT) and the volume rendering program, CTvox (Bruker microCT), were used to acquire dimensional measurements and to display the 3D object from reconstructed slices. The following formula was applied to calculate the relative error:

\[
\text{Relative Error} = \left( \frac{\text{measurement} - \text{CAD dimension}}{\text{measurement}} \right) \times 100
\]
where measurement is the dimensional value acquired by means of the software and considering the average among three repetitions to take into account spatial snap resolution, and CAD dimension is the reference value defined by design (Figure 1).

In order to test printed specimens of the mandible plate prototypes, a custom fixture was realized. The fixture was designed to fit with the specific shapes of Model-I (Figure 3). A computer numerical control (CNC) machine allowed reproducing the shape of the plate’s model in the fixture surface. Mainly, the fixture is composed of two parts to fix the specimens in the right position and then to be inserted in the testing system. Tensile tests were performed on as-printed specimens of Model-I using Instron 5566 at an initial strain rate of 0.01 s$^{-1}$. Specimens were analysed in order to visualize the external surfaces and, after the mechanical tensile test, the failure surface and in particular the tensile fracture surface of Model-I specimens using Hitachi S3400-N SEM.

Finally, even if the quantitative observations were reserved to the as-built configurations, the polishing of the printed specimens was performed to qualitative verify the possibility to improve the surface finish using Struers LaboPol-5 with polycrystalline diamond suspension 1 μm. The metallurgic microscope Nikon Epiphot 200 was used to observe the surfaces before and after the polishing process.

### RESULTS

In the production of objects by AM, developing the appropriate design represents the first step to obtain high-quality results. The CAD models are not set up for mere visualization of the design but are used as inputs for 3D printers. Hence, setting up the design that will correctly transition through the AM process chain and produce the exact desired physical part is very important. To this aim, the CAD models of the two mandibular plate geometries were developed with great attention to curvature shapes, flat surfaces and holes (Figure 1). The L-shape design was previously validated, by the same authors, printed with commercial PolyJet materials (Campioni, Cacciotti et al., 2020). The designs were here optimized to guarantee the uniformity of the stress distribution and avoid stress concentrations by performing FEA simulations (Campioni et al., 2012, 2013; Campioni, Cacciotti et al., 2020). At the same time, the designed plates were evaluated as prototypes of the final devices, considering loading and constraint conditions related to a normal mandible under physiological occlusal loading. For both the designs, the main attention was focused to investigate the critical area around the holes that have to fit screws as evidenced by the application of the boundary conditions, Figure 2. The specific design was also taken into account in the design of the fixture (Figure 3).

Figure 4 illustrates the von Mises stress distribution on Model-L and Model-I as a result of the applied loading condition. Table 1 compares the maximum values of von Mises stress, principal stress and the total deformation for both models. The uniform distribution of stress and displacement and the reasonable obtained maximum values confirmed the appropriateness of the designs for the mandibular plate application.

Figure 5 shows the as-printed specimens of the designed models without any post-processing treatment. From a macroscopic observation, it is possible to note the surface roughness and that the specimen edges are not well defined. Furthermore, it is visible that the shape of the holes and circular sections do not completely confirm the design. In particular, it is recognizable that the curvature of all the holes presents an almost linear edge in a side that compromises the circular shape, as also evidenced by the micro-CT models and
reverse engineered reconstructions, where coloured lines show the extracted irregular edges of the holes, which do not represent circles (Figure 6).

The as-printed surfaces of the specimens are not smooth but show roughness. The optical microscope observation allowed examining the details of the surfaces, evidencing that the roughness is due to the presence of residual and partially melted powder particles on the surfaces and along the edges, particularly evident for Model-L printed specimens. Figure 7 shows the surface of a printed Model-L specimen before and after performing the polishing process. It should be noted that the dimensions of the polished specimens are expected to be different than the originally intended design, which will be measured and compared in the next steps.

The quality of the parts in terms of dimensional accuracy was investigated by the micro-CT imaging of the printed models. The obtained dimensions were measured on models at points of interests marked in Figure 1, immediately after printing and before any kind of post-processing. The graphs presented in Figure 8 for the Model-L and the Model-I specimens, respectively, show the relative error (1) calculated with reference to CAD models’ dimensions obtained by software measurements. It can be observed that the dimensional variations in the printed parts can be up to ±12%, with many points having a variation of over 10%. For the Model-L, the dimensions at the sections B and C are not well realized: they resulted about −7% smaller than the original design. At the section A, which is dimensionally larger than the other ones, the relative error is limited to −1.5%. The thickness for all the ten L-shape specimens analysed is less than 1 mm, with a medium relative error per cent value of −31.34%. The length of the specimens is instead considerable respected with a mean relative error of +1.63%, without polishing the external surfaces. Details for the Model-L are reported in Figure 8a. For the specimens printed according to Model-I, the situation is similar. In particular, at the sections S1, S2 and S3 (Figure 1) that are the smallest in the original design, the relative error is also greater, about −10% (Figure 8b). The graph of Figure 9 reports angular measurements with step 30° of a hole for the reconstructed geometries of Model-I specimens showing in detail the range of the radii dimensions detected and relative diameters—for example for I1, HS4, diameter max 2.24 mm and min 1.68 mm (Figure 9). The maximum diameters are the corresponding ones acquired by DataViewer software at the well-defined parts of holes for the calculation of the dimensional error (Figure 8b).

Tables 2 and 3 report the measured morphological parameters of the specimens—structural thickness, number of closed pores, surface and volume of closed pores, per cent of closed porosity—with reference to the central volumes (Figure 1). A high number of pores were detected in some of the specimens, mainly of Model-L. 102 pores with a volume of 0.0061 mm³ for L1, and 89 and 88 pores for L9 and L4 with a volume of closed pores about 0.0045 mm³. The pore sizes are in the range (30–290) µm with the mean 118 ± 13 µm for Model-L and range (34–260) µm and mean 109 ± 16 µm for Model-I. The specimens have similar structural thickness. Figure 10a,b illustrates an example of detected pores—indicated by the white circle line—at two selected slices of the specimens, with pore size about 180 µm for a section of Model-L and with pore size about 224 µm for Model-L extended for more than a slice of the specimen.

Tensile test results for the Model-I specimens are shown in Table 4 (four out of five printed specimens were successfully tested) with mean values of tensile strength 674.16 ± 19.40 MPa and strain 0.34 ± 0.03 mm/mm. Figure 10c illustrates a fractured specimen after test.

Finally, the tensile fracture surface of the broken specimens and external surfaces were assessed in the scanning electron micrographs presented in Figure 11. Closed porosity in the inner surfaces and powder particles on the external layer and at border edges were identified. The difference among the specimens was identified in particular in terms of surface roughness—mainly detected at the specimens of Model-L design—and due to the presence of partially melted particles.

### Table 1: Finite element analysis results for loading case-2, Model-L and Model-I

| Models  | Max. von Mises stress (MPa) | Max. principal stress (MPa) | Max. shear stress (MPa) | Total deformation (mm) |
|---------|-----------------------------|-----------------------------|------------------------|------------------------|
| Model-L | 118.7                       | 130.8                       | 64.1                   | 0.0005                 |
| Model-I | 109.9                       | 121.6                       | 58.9                   | 0.0005                 |

### Figure 5
3D printed: (a) Model-L and (b) Model-I

### 4 | DISCUSSION

The promising use of AM for medical applications requires strong evidence about the reliability and the quality of printed objects in terms of accuracy, surface finishing, and functional and biomechanical properties. Furthermore, an inaccurate device means not fitting with the specific patient anatomy as the surface roughness, its effect on osseointegration has been extensively studied in the literature (Brånemark et al., 2001; Götz et al., 2004; Shibata & Tanimoto,
The assessment of the manufacturing processes, as well as the inspection of the products, is essential in a medical context to guarantee safety and efficacy. The laser-based technology DMLS considered is one of the most advanced AM techniques that can print production grade parts. Delegating the printing to hub services is commonly adopted by users as hospitals and professionals (Attaran, 2017; Burton et al., 2018; Jiang et al., 2017) and it has many advantages, but the quality of the results can vary from vendor to vendor. Design properties, powder quality, the setting up of process parameters and post-processing are some of the aspects that may affect the final quality and performance of the printed objects. In a context of regulated and critical products as the medical devices, the possibility to assess the achieved quality also at intermediate steps, before post-processing, is essential, to detect the effect of eventually not well-determined process parameters (Center for Devices & Radiological Health, 2017) and mainly to define the final applicability of the single device. Therefore, in this study, the as-printed quality of AM metal prototypes of mandibular plates, printed using a manufacturing service, was investigated considering integration of methods by the verification of design, morphological integrity, mechanical properties and non-destructive and destructive analyses. Standard print settings are used, without a specific optimization, to investigate the result achievable with no additional options in a common context and, thus, microstructure is not considered as a study.
parameter and the focus is maintained on the geometrical parameters such as shape, size and defects.

Micro-CT analysis is considered as one of the major tools for the product quality assessment of AM products (Bibb et al., 2011; Campioni, Cacciotti et al., 2020; Campioni, Pecci et al., 2020; Center for Devices & Radiological Health, 2017). Micro-CT images showed that the hole dimensions and the shape were changed (coloured edges of some holes are evidenced in Figure 6); this kind of inaccuracy is present in all the specimens analysed. Furthermore, the diameter accuracy at the well-defined parts of holes resulted in a positive relative error, from about 5% to 10% greater than the original diameter for L-shape specimens and similar for I-shape ones (Figure 8). The radii dimensions at angular steps of 30° of the hole HS4 for the reconstructed geometries of Model-I specimens (Figure 9) graphically evidenced the not well-defined circular shapes and the corresponding main diameters. The lack of precisions at holes is a critical aspect, not allowing the fitting with screws. In general, the analysed specimens are significantly thinner than those designed and it is evident that there is significant complexity associated with obtaining high dimensional accuracy in these parts of small dimensions.

Morphological analysis performed at all the specimens revealed a uniform thickness and the presence of closed porosity, in particular closed pores at the slices of the central volume, (Figure 10a,b). Given the resolution limitation of micro-CT scan, and any imaging technique in general, there may be additional smaller pores, which may not have been resolved in these images to account for them. The high number of pores but a small volume fraction of porosity (<0.05% for L1) was mainly detected for Model-L specimens (Table 2). Variability among the specimens was identified especially for the Model-L design rather than the Model-I (Table 3). The two models have different volumes due to the difference in the designs. The surface area of the models is also different, which causes variability in the amount of residual material at the external surface. The central volume is for the Model-I, the same considered for tensile tests and fixture positioning. It should be noted that the morphological parameters were calculated without performing the polishing of the specimens. Therefore, the number of pores detected also included the residual particles at the surfaces and edges.

The surface finishing represents an essential aspect for a medical device for the risks related to the interaction with human tissues (Jin et al., 2016; Li et al., 2019). Currently, the biocompatibility and osseointegration of a final device, not investigated at this stage of the study, are sometimes not achievable by direct manufacturing but they require further surface modifications improving the biological response (Kunrath, 2020). In general, it is difficult to control the as-built surface quality in objects printed by the current generation powder bed fusion technologies. Surface roughness in a laser-based printing process is typically characterized by the formation of partially bonded surface particles and it could be due to various conditions, to the surface orientation with respect to build direction, printing parameters, material quality and particle size, AM system, etc. (Averardi et al., 2020). The microscopic observation of the surfaces during the polishing process (Figure 7) shows that the surface finish can be improved by removing the residuals and partially melted powder particles. Obviously, this process introduces dimensional reduction, which should be taken into account in the design phase.

In general, the final mechanical properties of Ti6Al4V alloy depend largely on its microstructure and on the presence of defects (Liu & Shin, 2018). Testing the prototype before the post-processing allows the primary detection of critical aspects and a better definition of subsequent treatments. The tensile strength measured Model-I specimens showed comparable performance (Table 4), lower than the expected ones for the commercial Ti6Al4V alloy, indicating the presence of small defects in these specimens, which

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**FIGURE 8** Relative error in reference to CAD model dimensions shown in Figure 1 for Model-L (a) and Model-I (b)

**FIGURE 9** Dimensional measurements of the hole HS4 radii with the step 30° for Model-I
TABLE 2  Morphological 3D analysis, central volume, Ti64, Model-L specimens

| Specimen number | Object volume (mm$^3$) | Structural thickness (mm) | Number of closed pores | Surface of closed pores (mm$^2$) | Volume of closed pores (mm$^3$) | Closed porosity (Vol. %) |
|-----------------|------------------------|--------------------------|------------------------|-------------------------------|-------------------------------|--------------------------|
| L1              | 12.527                 | 0.705                    | 102                    | 0.6865                        | 0.0061                        | 0.0485                   |
| L2              | 13.036                 | 0.738                    | 35                     | 0.1503                        | 0.0011                        | 0.0087                   |
| L3              | 12.915                 | 0.733                    | 22                     | 0.2454                        | 0.0019                        | 0.0147                   |
| L4              | 12.775                 | 0.716                    | 88                     | 0.5488                        | 0.0045                        | 0.0350                   |
| L5              | 12.683                 | 0.709                    | 85                     | 0.4228                        | 0.0030                        | 0.0236                   |
| L6              | 13.197                 | 0.751                    | 27                     | 0.1481                        | 0.0012                        | 0.0088                   |
| L7              | 12.900                 | 0.728                    | 62                     | 0.3795                        | 0.0031                        | 0.0237                   |
| L8              | 12.979                 | 0.737                    | 47                     | 0.1639                        | 0.0009                        | 0.0070                   |
| L9              | 12.697                 | 0.719                    | 89                     | 0.5411                        | 0.0042                        | 0.0330                   |
| L10             | 12.935                 | 0.746                    | 30                     | 0.1669                        | 0.0011                        | 0.0085                   |

TABLE 3  Morphological 3D analysis, central volume, Ti64, Model-I specimens

| Specimen number | Object volume (mm$^3$) | Structural thickness (mm) | Number of closed pores | Surface of closed pores (mm$^2$) | Volume of closed pores (mm$^3$) | Closed porosity (Vol. %) |
|-----------------|------------------------|--------------------------|------------------------|-------------------------------|-------------------------------|--------------------------|
| I1              | 5.066                  | 0.688                    | 18                     | 0.1488                        | 0.0014                        | 0.0274                   |
| I2              | 5.084                  | 0.701                    | 14                     | 0.0816                        | 0.0006                        | 0.0113                   |
| I3              | 5.136                  | 0.697                    | 13                     | 0.0816                        | 0.0007                        | 0.0129                   |
| I4              | 5.179                  | 0.725                    | 7                      | 0.0252                        | 0.0001                        | 0.0024                   |
| I5              | 5.087                  | 0.711                    | 11                     | 0.1122                        | 0.0007                        | 0.0149                   |

FIGURE 10  Micro-CT images of Model-L (a) and Model-I (b) at two selected slices of the specimens; closed pores detected are indicated by the white circle line; (c) fractured specimen I3 after tensile test

corroborates with the porosity measurements. The image of a fractured specimen (Figure 10c) evidences the failure close to the area of the hole in a section characterized by pores and powder particles on the external layer and at border edges (Figure 11a,b,d,f). Devices may have different characteristics with respect to the ones of standard specimens of the material evidencing the importance of testing them at the various stages of the AM manufacturing processes. Due to the diversity of the manufacturing processes, a direct comparison between the tensile strength at the as-built stage with the one of similar devices conventional manufactured is not evaluable.

The difference in the surface finish, as well as for the accuracy, may have been caused by several factors. Since the manufacturing is conducted by a third-party commercial service, this work cannot be aimed to assess the causes of inaccuracy and defects, as well as not optimized settings or parameters such as printing orientations, but the attention was maintained on the quality achieved by the detection and quantification of the effects. The use of a hub service represents the lack of control by the model creator and to know all the parameters involved in the printing process, allowing the investigation of the real typical situation where such variations may occur. In all cases, also in limiting the mentioned
variations by the appropriate or/and optimized use of the current AM systems, it is important to better understand the performance of AM parts in relation to the specific geometry and without any surface enhancements before testing as demonstrated by the structured assessment proposed and carried out. Post-treatments of metal specimens to improve the microstructure (Shipley et al., 2018), such as the Hot Isostatic Pressing (HIP), and post-machining to redefine the final shape of holes allowing the use for the final application, are available and can be used by expert users until the next-generation printers can provide as-built quality improvements without the need of specific optimization of the settings or all-in-one solutions ready to be used also by non-expert users. The dimensional variations observed in this work can also help in creating tolerances in the initial CAD models to provide a product that is closer to the specifications. All the aspects discussed are significant for the definitive development of AM medical applications.

### 5 | CONCLUSIONS

The realization of AM medical devices is promising, but more evidence about the as-built quality and the standardization of methodologies for the assessment is necessary. The study demonstrated the as-printed quality of Ti6Al4V plates AM prototypes

| Specimen number | Tensile strength (MPa) | Strain (mm/mm) |
|-----------------|------------------------|----------------|
| I1              | 650.43                 | 0.35           |
| I2              | 697.66                 | 0.31           |
| I3              | 676.88                 | 0.36           |
| I5              | 671.69                 | 0.36           |
| Average         | 674.16                 | 0.34           |
| Standard deviation | 19.40                 | 0.03           |

**TABLE 4** Tensile test results for Ti64 alloy printed specimens, Model-I

![FIGURE 11](image-url) Scanning electron microscope micrographs: (a) tensile fracture surface, specimen I3, Model-I; (b) magnified view of tensile fracture surface upper edge, specimen I3, Model-I; (c) external flat surfaces of the specimen L1, Model-L; (d) external flat surfaces of the specimen I3, Model-I; (e) magnified view of external surface upper edge, specimen L4, Model-L; (f) inner tensile fracture surface of the specimen I3, Model-I.
for intended use as reconstruction mandibular devices and defined a methodology for the assessment of the objects in terms of design accuracy, structural integrity and mechanical properties by the integration of imaging methods and destructive and non-destructive analyses.

Two CAD design models of mandibular plates prototypes were printed by laser powder-based technology DMLS, using a commercial metal powder, that is titanium alloy Ti6Al4V, in order to investigate the as-built quality of the objects as possible devices for applications in maxillofacial surgery. It was observed that the holes were not well defined in the printed parts and in general, the specimens are thinner and smaller at the main sections of the designs. A consistent number of small pores were detected in some specimens by micro-CT scanning. The tensile strength of the I-shape models was assessed. A lower tensile strength was obtained with respect to the declared performance of the commercial material. Surface roughness and agglomerates of powder particles were observed at SEM and optical microscope. Furthermore, the SEM analysis allowed the confirmation of the presence of pores in the inner fracture surfaces. The polishing process was performed to remove the first layers and to observe the cleaned surface of the printed titanium alloy. The limited accuracy at holes, the reduced thickness, as well as the resulted surface roughness and strength, can be enhanced by more accurate control of the printing parameters and by post-processing (treatments and machining). The obtained dimensional variations should be taken into account in the elaboration of the initial design, in order to make possible the use as medical applications, in particular for custom and patient-specific cases.

The study underlined the critical aspects associated with not well-controlled manufacturing processes and the importance to define a methodology for the quality control of the results particularly essential when the initial conditions are not completely certain. The variability of the results emphasized the relevance to assess the single devices printed before the final application. Clinicians, surgeons and the manufactures at various levels, that are involved in the growing demand of AM devices also associated with emergency needs and in the definition of 3D printing point of cares, specifically designed for the elaborations of presurgical models and medical devices, could benefit of the results achieved by this study for a fast, safe and routine use of AM in healthcare systems.

ACKNOWLEDGEMENTS
The authors acknowledge the Department of Mechanical and Aerospace Engineering Tandon School of Engineering, New York University for the facilities and support provided for this study. The author I. C. thanks Giorgio De Angelis at the Italian National Institute of Health (Istituto Superiore di Sanità) for the technical support in machining the tensile test fixture.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS
Conceptualization, I.C. and N.G.; methodology, I.C.; validation, I.C.; formal analysis, I.C.; investigation, I.C. and N.G.; resources, I.C. and N.G.; data curation, I.C.; writing—original draft preparation, I.C.; writing—review and editing, I.C. and N.G.; visualization, I.C.; supervision, N.G. All authors have read and agreed to the published version of the manuscript.

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How to cite this article: Campioni I, Gupta N. Ti6Al4V mandibular devices by additive manufacturing: Assessment of as-built quality. *Med Devices Sens*. 2021;4:e10153. https://doi.org/10.1002/mds.3.10153