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Prosthesis customization in maxillofacial surgery by means of Additive Manufacturing

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Abstract

Additive Manufacturing (AM) offers great potentialities in the medical sector, particularly when part customization is sought after. Maxillofacial surgery has to deal with complex bone fractures and facial reconstructions, hence the need of metallic prostheses to help in the process of bone growth and fracture healing. Commercial prostheses, even if available in different sizes, might not fit the patient's anatomy, and thus should be adapted directly in the operating room. This paper provides an insight on how AM approach, by designing and producing customized prosthesis from computer tomography scan data, can lead to predictable and reliable results reducing the stress on both surgeons and patients.

Keywords: Orthopedic surgery; Maxillofacial surgery; Orbital prostheses; Additive manufacturing; Forming; Finite element method

1. Introduction

Oral and maxillofacial surgery is a surgical specialty dealing with facial bone fractures, tumors and catastrophic events, leading to the necessity of re-establishing patient's condition previous to the trauma. Typically, the surgeon requires a prosthesis to enable fracture healing in the correct position. In a similar context, every patient requires highly customized solutions, in terms of prosthesis shape, meant to adapt to his/her anatomy as faithfully as possible. Nowadays, to adapt standard prostheses to specific patients, these are manually shaped on their same bones often during surgery itself; leading to higher surgery duration and blood loss [1].

Therefore, for the past years, surgeons have been looking for a way to perform this step before the starting of the surgery, to limit its duration and consequently patient's stress. Additive Manufacturing (AM) could represent a solution to these needs, enhancing prostheses customization and reducing surgical stresses. AM actual readiness level enables its use in real medical applications. In fact, AM has already been used in several applications related to maxillofacial surgery, showing optimal results out of these trials. According to ASTM F2792-12a, AM is the process of building an object layer-by-layer directly from a three dimensional (3D) computer-aided design (CAD) model [2]. In AM processes, material is only added where needed, in contrast to conventional manufacturing processes. This new paradigm shakes the foundations of the manufacturing world, thanks to its capability of managing complex shapes without using specific tools. Thus, AM can easily fabricate components with articulate geometries, such as organic ones, both in polymers and metals, perfectly fitting human anatomy [3]. Moreover, extreme flexibility allows the fabrication of different components by simply changing their CAD model. This is due to the absence of physical tools. Therefore, part's mass customization, ensuring unique parts for unique patients, is at hand.

The medical sector, and in particular the orthopedic one, has been growing its interest in AM over the past years [4]. Mainly because the medical sector requires parts with high geometrical complexity and degree of customization. Several studies have stressed this interest already. Wong [5] has clarified three main AM applications in the medical field: surgical models, patient-specific instruments (PSI) and 3D printed custom implants. Javaid and Haleem [6] presented a procedure, spanning from image acquisition to material printing, to better take advantage of AM potentialities. Culmone *et al.* [7] listed AM main

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features to be considered: customization, cost and disposability, accessibility, production time, biocompatibility, and magnetic resonance imaging (MRI) compatibility. Arce *et al.* [8] formalized the benefits coming from the introduction of point-of-care (POC) manufacturing, taking advantage of decentralized production offered by AM. Finally, Daoud *et al.* [9] stated the need of regulations covering every aspect of the AM usage in the medical field, from the material used to the time elapsing from the start to the end of the procedure. Focusing on maxillofacial surgery only, several articles showed successful case studies where AM played a major role in facilitating patient's treatment. Farre-Guasch *et al.* [10] reviewed the procedure of creating fully customized mandibular prostheses by AM. VanKoevering *et al.* [11] designed 3D printed plates to cap Tegmen defects, whose fitting was temporary tested on three patients. Finally, after the confirmation of the goodness of the procedure, the plate was removed and substituted by bone grafts. Jardini *et al.* [1] reconstructed a large cranio-maxillofacial deformity, after a motorcycle incident, by means of a large, 3D-printed, titanium plate. Lassausaie *et al.* [12] and Longeac *et al.* [13] evaluated the feasibility of using polymer 3D-printed patients' skulls to shape commercial prosthesis before the surgery, minimizing this way the operation's time.

Hence, in maxillofacial surgery, additive manufacturing can be used both to directly fabricate the final prosthesis or to produce the equipment needed for the shaping of the prosthesis. According to the type of fracture, i.e. to the type of prosthesis needed, the fabrication of the prosthesis or the fabrication of its shaping tools pose different advantages and disadvantages. In general, one of the most critical factors is the time needed to engineer the process, not always compatible with surgical requirements. As for the direct or indirect production strategies, the choice depends on the availability of standard non-preformed prostheses and on their formability. Prosthesis shaping is the option further analyzed in this paper. Although interdisciplinary teams made of doctors and engineers are becoming more aware of AM potentialities, from an engineering point of view some limitations are still present. Simulations concerning prostheses forming process are completely absent, with no questioning of prosthesis internal stresses and springback effect at the end of the process.

In this paper the main objective is the definition of a procedure supporting surgeons in maxillofacial operations, when a standard prosthesis has to be shaped to fit the patient's anatomy. In this procedure, custom dies are realized by additive manufacturing from patient's data. A reverse engineering approach is followed, starting with data acquisition by computed tomography (CT). From here, dies are designed accordingly to shape a commercial prosthesis to the desired geometry. The forming process is matched by finite element (FE) simulations; helping to predict the load to be applied, the internal stresses in the prosthesis after deformation and the elastic springback. Profits and critical issues related to the procedure are evaluated in terms of required time, tools, and knowledge. The method here proposed has been validated on the basis of a case study making use of commercial preformed and non-preformed orbital prostheses, to identify the advantages ensured by the method.

2. Methodology

The main objective of this paper is to provide surgeons with a helpful method in the preparation of maxillofacial surgeries. In the field of maxillofacial surgery, the specific case of the fracture of the orbital plate is here analyzed. Whenever the fracture of the orbital plate is significantly extended, prostheses are needed to help with the healing process. A closer resemblance between prosthesis and patient's morphology allows a correct healing of the fracture. Thus, surgeons are forced to adapt commercial prostheses on patient's bones during the same surgery. As already explained, this way of acting significantly extends the length of the procedure, impacting both patients and surgeons stress levels. Commercial orbital prostheses should then be shaped in advance, allowing the medical team to start the surgery already having the correct prosthesis geometry to install. This could be achieved by means of custom-made dies, realized by means of AM techniques. The method here proposed should drive the clinic activity from the digitalization of patient's morphology up to the operating theatre, as in Fig. 1.

Ideally, CT scan data coming from the patient himself are used as primary source of information in maxillofacial surgery. In order to be able to recreate the morphology of the patient previous the trauma, the intact part of the cranium could be mirrored over the damaged one. This mirrored half represents the reference geometry for all further steps in this method. From the triangulation file (3D mesh), result of the CT scan, the surface of patient's orbital plate can be extracted. This surface is then used as starting point in the proposed method for the modelling of patient-specific dies for prosthesis shaping. When a satisfying 3D CAD model of the dies is achieved, this is inserted in a FE forming simulation. Two simulation steps are performed: a first forming step and a following springback simulation. During the forming step the tool which is moving is called punch, whereas the die is the

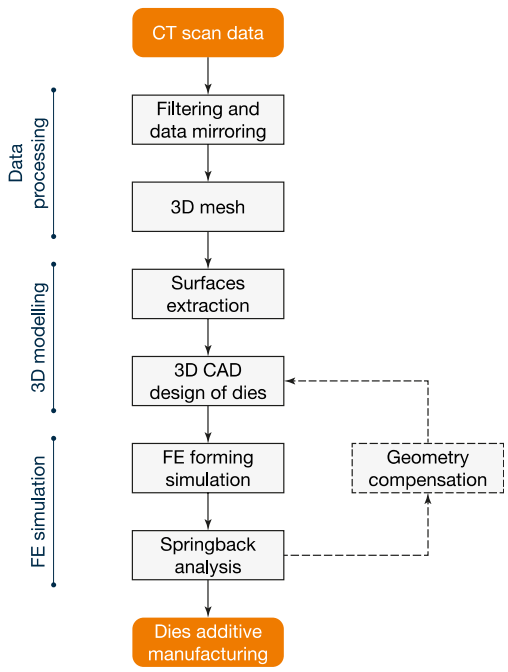

Fig. 1. Flow chart of the proposed methodology.

fixed one. The forming step should ensure the formability of the prosthesis, highlighting in advance any possible critical feature. At the end of the forming step, during the springback step, the punch is virtually removed, and the prosthesis is let free to recover its elastic deformation. After the springback step, the shape of the prosthesis is meant to be slightly different from the one at the beginning the same step. If this difference is significative, the information could be used to remodel punch and die, compensating for the springback effect and ensuring a final shape of the prosthesis closer to the actual desired one. Overall, this simulation phase provides information about prosthesis formability, enhancing the control over the process. Once the final model of the dies is obtained, this must be prepared for the additive manufacturing process. The model must be oriented on the building platform and accessory structures, such as supports, added according to the AM technology involved. Finally, the slicing of the model is prepared, and the job is submitted to the machine.

3. Case Study

The method proposed in this article assumes the availability of clinical data from real life patients. Three dimensional descriptions of patients' morphology are the starting point of the evaluations here proposed. Nevertheless, in the present paper input data did not come from clinical patients. This was caused by the shortage of patients' data caused by the difficult COVID-19 pandemic situation. Instead of using real craniums data, a preformed orbital mesh was scanned and used as alternative to a real cranium, to shape a non-preformed orbital prosthesis. This solution provided a solid source of input data and did not affect the general validity of the method. Studied prostheses were produced by DePuy Synthes, company of Johnson & Johnson (New Brunswick, USA). These were the 04.503.801 MatrixMIDFACE preformed orbital plate and the 04.503.306 MatrixMIDFACE orbital plates, 0.2 mm thick, shown in Fig. 2. Both prostheses are realized in commercially pure titanium (CP Ti - ISO 5832-2). The absence of alloying elements, such as aluminum and vanadium, makes this kind of prostheses suitable for long term use [14]. The geometry of the preformed prosthesis was acquired by the phoenix v|tome|x s240 by GE (Boston, MA, USA) x-ray inspection system, equipped with a 240 kV / 320 W microfocus tube. The voxel resolution was 50 μm. The scan settings were 200 kV, 80 μA, with 0.5 mm thick Sn beam filter, and 1,000 acquisitions were taken in a full 360° rotation. At each position, three images were acquired, of which the first one was discarded and the other two averaged. The data processing was performed in VGSTUDIO MAX 3.4 by Volume Graphics (Heidelberg, Germany) software.

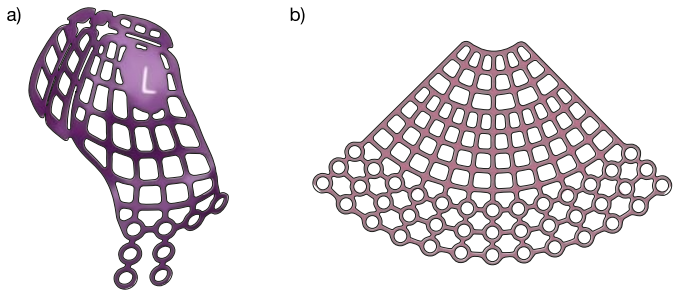

Fig. 2. (a) MatrixMIDFACE preformed orbital plate and (b) non-preformed orbital plate.

Later, Rhinocheros, by Robert McNeel & Associates (Seattle, USA), was used to extract a point cloud from the triangulation, and to define a surface interpolating these points. The same software was then used to model the whole dies. Once the dies models were ready, they were used to simulate the forming process. Abaqus FEA (finite element analysis), software package by Dassault Systèmes (Véliz-Villacoublay, France), was used during this simulation phase. As previously described, simulations were made of an initial forming step followed by a springback one. GOM Inspect, software package by ZEISS (Oberkochen, Germany), was used to evaluate the deviations between the geometry of the prosthesis, after the springback simulation, and the surface of the die.

The present investigation did not compensate dies geometry for the springback effect. Functional prototypes were finally modelled and fabricated for the evaluation of the production phase. No further experimentation was carried out: it is worth recalling that the aim of the study has been to define a procedure and to test for its feasibility considering that not experimental campaign would have been possible considering the current pandemic situation.

4. Results and Discussions

Triangulation data resulted in 31,132 triangles with a maximum edge length of 0.49 mm. Rhinoceros was used to create an editable surface out of the triangulation. This editable surface was then extended, to accommodate the whole MatrixMIDFACE orbital plate. Finally, from the extended editable surface the remaining parts of the dies were modeled. These models included features to reference the MatrixMIDFACE orbital plate on the die, ensuring it to be formed with the correct alignment. Dies and undeformed orbital plate are shown in Fig. 3.

As already introduced, a core activity of the procedure is the simulation of the orbital plate forming process. The geometries of the active surfaces of die and punch, and the one of the undeformed orbital plate were inserted into Abaqus FEA, and the simulation was setup and run. The active surfaces of dies were modeled as shells and set as rigid elements, neglecting their possible deformations. This because attention was only paid to orbital plate deformation, not considering dies elastic behavior. This hypothesis dramatically simplified the simulations, but at the same time introduced a certain amount of error. The amount of the introduced error depends on dies material too. If metal is used for dies, this assumption is justified, whereas tools made of reinforced polymer may present an elastic contribution that might not be negligible. Considering the metal solution, the present model neglected the part of elastic-plastic deformation which would have been absorbed by the dies; assigning it to the orbital place instead. Accordingly, forming-induced stress into the orbital plate will be slightly higher than the real ones since the whole system deformation must be accounted by the orbital plate itself. It can be concluded that although performed simulations included an error, this error makes the same simulations more conservative,

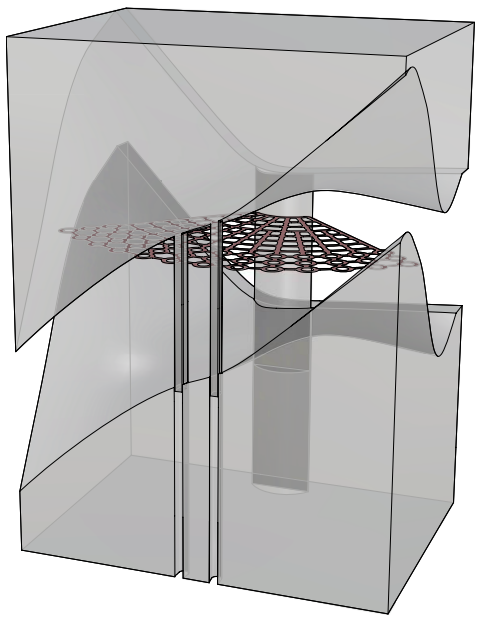

Fig. 3. Modelled dies and undeformed MatrixMIDFACE orbital plate.

overestimating orbital plate internal stresses. Another simulation aspect worth mentioning is orbital plate meshing phase. First simulation trials used a mesh size of approximately half millimeter. After mesh convergence analysis this size was

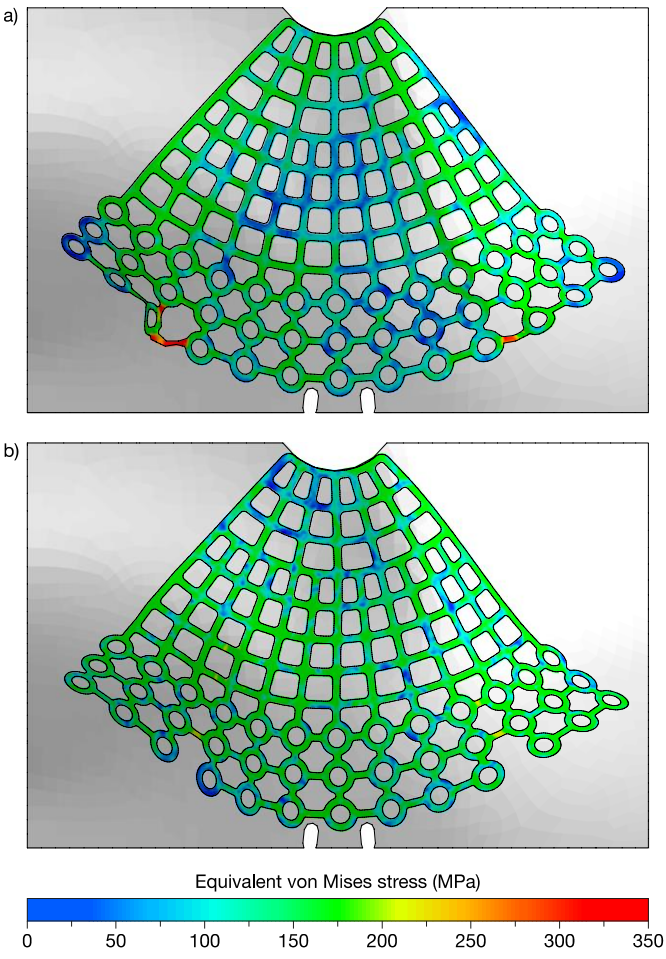

Fig. 4. Equivalent von Mises stress at the end of (a) the first and (b) second forming simulations.

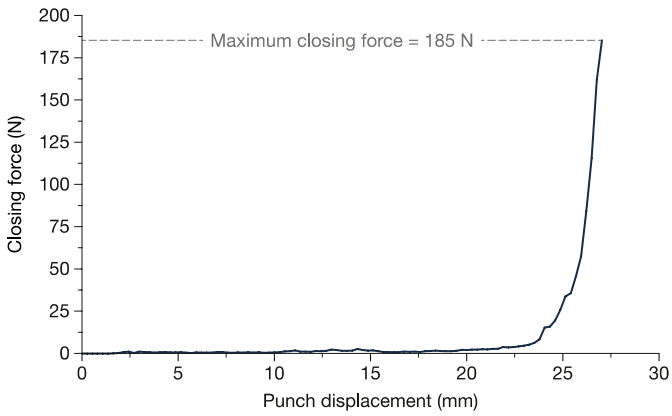

Fig. 5. Closing force acting on the punch during the forming operation.

reduced up to 0.2 mm to obtain more reliable results. Finer meshes would not highly increase the computational cost of the simulations, without providing more accurate predictions. The first forming simulation, whose output is reported in Fig. 4a, resulted in extremely high stress at specific areas of the prosthesis, far above the ultimate tensile strength (UTS) of the material. These same areas showed an excessive and unnatural deformation. This implied the fracture of the material at those connections. Prosthesis was then remodeled by removing the failed connections, and forming simulations performed once again. Connection removal is an actual surgical option to adapt the prosthesis to patient's morphology. Being able to identify these criticalities before entering the operating room would probably simplify surgeons' job during the procedure. This time no critical areas were highlighted by the simulation, as per Fig. 4b. No areas are reaching the UTS of the material whereas a large area of the orbital plate has entered the plastic region, meaning the forming process has been successful; validating the orbital plate formability. Fig. 5 reports the closing force applied by the punch during the forming operation. The highest value at the end of the stroke was around 185 N. This value could be even obtained by hand pressing, without the need for additional tools.

At the end of the forming step, simulation's result was used as input for the following springback simulation. This second

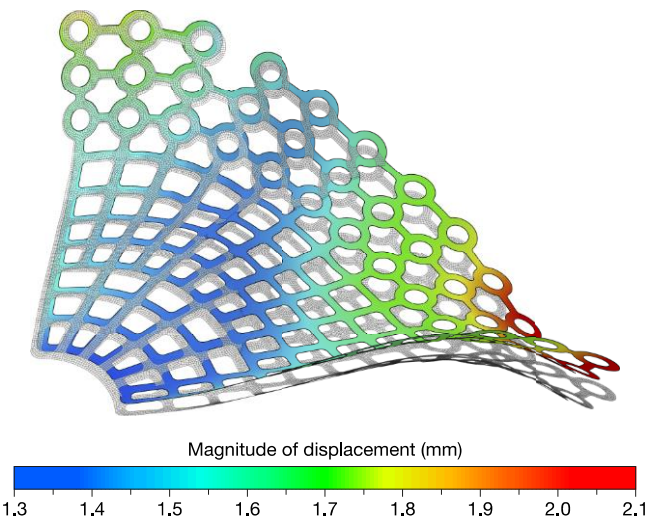

Fig. 6. Orbital plate displacements after the springback simulation.

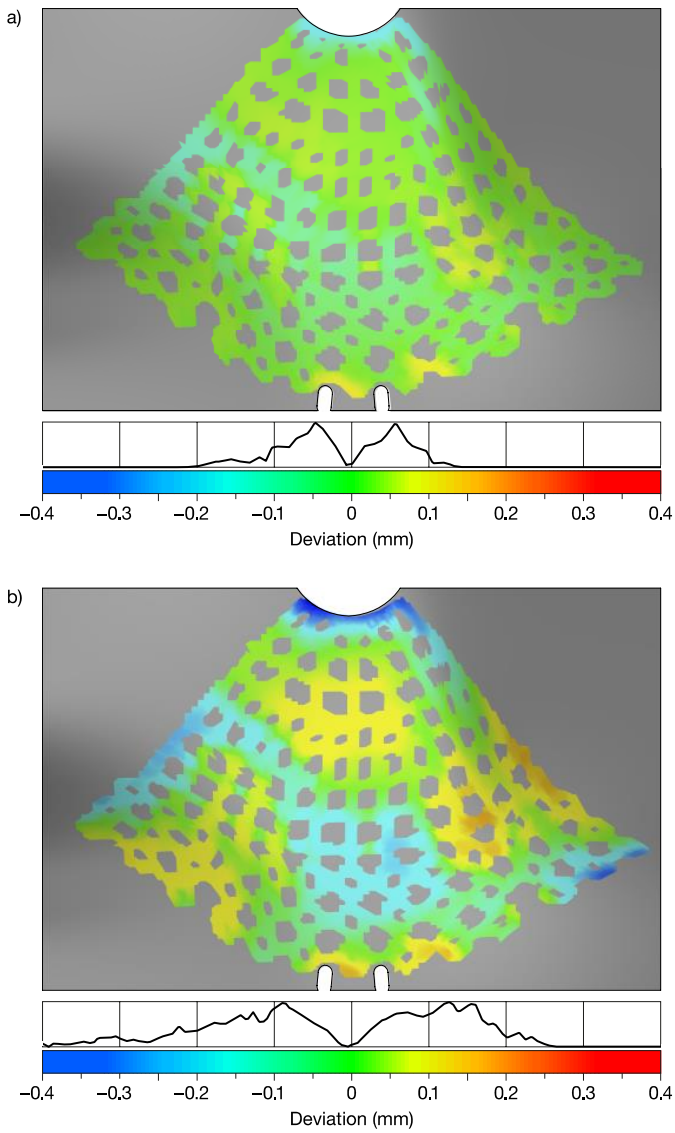

Fig. 7. Orbital plate deviations from die surface after (a) the forming phase and (b) the springback phase.

simulation step was considered necessary to assess the accuracy of the final obtained result. The springback effect considers the elastic deformation recovered by the part once the cause of the deformation is removed. In this case, all constraints were removed from the model at the end of the forming step, letting the orbital plate free to recover its elastic deformation. Fig. 6 shows the difference between orbital plate shape at the beginning, transparent in the picture, and at the end of the springback simulation, in colored map. Although shape differences before and after the springback simulations did not seem to be extremely meaningful, an inspection tool was used to deepen the analysis. GOM Inspect was used to compare the geometry of the active surface of the die with the shaped orbital plate, before and after the springback. Results of the orbital plate-die surface comparisons are shown in Fig. 7. It could be noticed that after the springback simulations, deviations ranged in a much wider interval than after the only forming simulation. However, deviations were still limited in the range between ±0.5 mm. This information could be used to compensate for the active surface of the dies shape, if desired. This way, a result

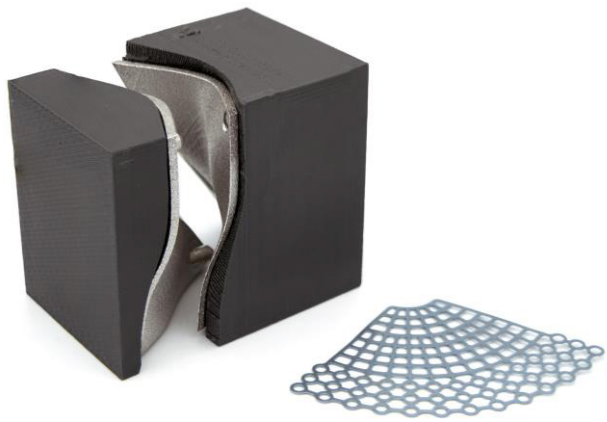

Fig. 8. Preliminary prototypes of the shaping dies.

closer to the nominal shape can be achieved, ensuring an even finer fitting of the prosthesis to patient's morphology.

5. Prototypes

Preliminary physical prototypes of the dies were realized in the initial design phase. A combination of a polymeric substrate with a metal skin limited to the active surfaces of the dies was designed, trying to balance prototype cost and mechanical properties. The active surfaces of the dies were realized in AlSi10Mg; processed by means of the Concept Laser Mlab R by General Electric (Boston, USA), a laser powder bed fusion (L-PBF) system. On the active surfaces a simple reference geometry to align die and punch was realized too. The substrate geometry was realized in acrylonitrile butadiene styrene (ABS) and processed by the Dimension Elite, by Stratasys (Rehovot, Israel), fused deposition modelling (FDM) system. A picture of the prototypes is reported in Fig. 8. The main aim of these prototypes was to validate the design by means of a first tangible representation. Prototypes allowed to better understand the required alignment features, enabling dies correct operations. As a matter of fact, prototypes did not take into account a way of referring the prosthesis on the surface of the prototype itself. Obviously, this system must be present on the actual component. The alignment features were thus introduced in the die geometry as visible in Fig. 8. The dies geometries were then completed by adding column guides.

After a deeper analysis, it became evident how the usage of two different materials would imply the need of two different, and expensive, AM machines. Especially metal-AM systems require a high level of skills from the operator, safety requirements and costs. Since the maximum contact pressure on the surface of the prosthesis was lower than 150 MPa, polymeric materials, such as PA 12, PEEK or Alumide (nylon reinforced with aluminum) could be used to directly realize the active surface of the dies. These materials can be processed by L-PBF systems.

Future studies should focus on the possibilities offered by advanced polymeric materials. Nonetheless, considering that polymers have lower stiffness than metallic alloys, such the AlSi10Mg used here, their deformation during the forming phase should not be neglected anymore, and the effect on prosthesis forming should be analyzed in the simulation model.

6. Conclusions

In this study, the potentialities of some common engineering tools in the field of maxillofacial surgery have been investigated. Additive manufacturing has already been used in the past to provide for bone model in order to plan or aid surgical procedures. Still, most previous studies did not consider the importance of having a predictable and repeatable process, leaving the surgeon the burden of dealing with unexpected problems. Here, the aim has been the definition of a procedure that would allow the shaping of commercial non preformed prostheses of the orbital floor. An individual orbital geometry was used to model dies that would give the possibility of shaping the prostheses according to patients' morphology before entering the operating room. The whole process was paired with finite element simulations predicting and ensuring the success of the process by limiting its uncertainties. Once the theoretical feasibility of the process is stated, actual dies should be realized by AM. With the purpose of reducing the required facilities, a composite material could be used for the fabrication of the dies; aiming at intermediate properties between polymers and metals.

Although future experimental works are required to evaluate this methodology in an actual clinical environment, meaningful conclusions and outlooks can already be drawn. Nonetheless, the strong multidisciplinarity of the methodology implies the presence of engineer-surgeon teams, working at close range. Moreover, the numerous steps required, from the modelling of the dies to the actual printing of them, could require a consistent amount of time. The length of the procedure, that may be reasonably estimated in 4-5 days including AM production, could not make this methodology suitable for emergency procedures, where a fast response is needed. Still, this methodology should be able to save a considerable amount of time during planned surgical procedure, reducing at the same time the stress on both patient and surgeon.

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