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Design and Fabrication of Customized Tracheal Stents by Additive Manufacturing

Alessandro Colpani[a]*, Antonio Fiorentino[a], Elisabetta Ceretti[a]

[a]*Department of Mechanical and Industrial Engineering, University of Brescia, via Branze 38, Brescia 25123, Italy*

* Corresponding author. Tel.: +39-030-371-5538; fax: +39-030-370-2448. *E-mail address:* a.colpani003@unibs.it

Abstract

Additive Manufacturing (AM) is already becoming part of our life from a technological, economic and social point of view. Nowadays, it is applied in several manufacturing sectors. In particular, AM shows huge opportunities in the medical field and for healthcare applications. Due to its capability to produce complex geometries directly working on medical 3D images and thanks to the possibility to 3D-print biocompatible materials, AM is a key technology for the fabrication both of external and internal medical devices. In particular, the use of AM for medical applications is typically articulated in three steps: 3D-scanning of the patient anatomy, segmentation the medical scan and elaboration through CAD software for the preparation of a STL file suitable for the AM process. One of the main research topic in this field is the definition and optimization of procedures that, taking precise data from an individual patient, could be applied to the design and fabrication of customized components for medical applications. Therefore, this paper presents a project aimed at the fabrication of customized tracheal stents starting from the actual patient anatomy. In particular, it follows an approach based on molds FDM fabrication followed by biocompatible silicone casting. Molds were designed to obtain a tracheal stent based the patient anatomical tracheal lumen and were fabricated using FDM technology. Moreover, since the surface roughness is one of the most critical aspects related to the FDM, the produced molds were finished with a chemical surface post-treatment based on the use of acetone vapours. Overall, the whole developed procedure results in an effective custom-made medical devices realization.

Keywords: Additive Manufacturing; customization; medical devices; silicone; surface treatment.

1. Introduction

Additive Manufacturing (AM) is becoming part of our daily life from a technological, economic and social point of view. Nowadays, it is applied in several manufacturing sectors. In particular, AM shows huge opportunities in the medical field and for healthcare applications [1, 2]. Due to its capability to produce complex geometries directly working on medical 3D imaging data and thank to the possibility to 3D printing biocompatible materials, AM is a key technology for the fabrication both of external and internal medical devices [3]. The use of AM for medical applications is articulated in the 3D-scanning of the patient anatomy, the subsequent use of CAD software and the preparation of a suitable STL file for AM

fabrication. Clinicians use Computed Tomography (CT) technology to obtain 3D images for a complete and deep view of the anatomical region of interest in order to better understand any associated medical condition. However, CT in not the only technique working in the 3D domain, since several other approaches are possible, including 3D magnetic resonance (MRI), positron emission tomography (PET), 3D Ultrasound and 3D laser scanning (for external imaging) [4]. The use of 3D medical imaging techniques and processing software greatly increased and advanced in the last 20 years [5]. The 3D medical imaging data were originally exploited only for diagnostic purposes, but the technological advances quickly opened the opportunity to manage this data with CAD systems and, accordingly, to combine all these phases with the AM, which is

the most effective solution for medical models realization thanks to its characteristics. In fact, the joint use of these techniques with AM resulted for example in the production of free-standing patient specific models for use in surgical planning as instance for hip, knee or shoulder operations [6] and opened to the possibility to deepen the use of AM for customized medical devices and prosthesis [7].

Exploiting AM solutions for productions based on the medical data obtained from specific patients allows to fabricate unique devices, customized to answer individual needs. Moreover, AM-based fabrication shows a particular attitude in processing medical data and the possibility to significantly contribute to medical applications (e.g. surgical and diagnostic aids, prosthetics development, manufacturing of medically related products) [8]. The improvements both in 3D medical imaging and 3D printing technology play a fundamental role. In fact, the medical 3D data combined with the low resolution of earlier AM technology initially resulted in models that may have looked anatomically correct, but that were not accurate when compared with the actual patient anatomy. As the technology improved in both areas, models became more precise and now it is possible to fabricate devices close-fitting the anatomical regions of interest. As instance, CT-based measurement error is 0.2 mm when compared with the actual value. Although the patient comfort is subjective, it is clear that the resulting models, when properly built, can be enough precise and suitable for several applications [9].

Therefore, one of the main research topic in this field is the definition and optimization of procedures that, taking precise data from an individual patient, could be applied for the design and fabrication of customized components for medical applications. In this approach, the patient data should be furnished by a medical specialist that, following also the design phase, could be able to report all the medical requirements and necessity. These interdisciplinary approach gives the opportunity to optimize the component design using specialized software in order to manage the patient data and incorporate all the necessary customizations into the final medical device. The design flexibility offered by AM systems is therefore one of the main characteristic in this context, as well as the capability to actually process well-defined geometries for customized devices that would be difficult and impractical with traditional manufacturing methods [4]. For the external medical devices (which are removable), several different polymers and metals can be used. A greater attention in the material choice must be paid when the device has to be implanted in the human body [6]. Finally, AM-produced customized devices lead also to a greater level of comfort for the patient. In fact, several traditional approaches can be used to create parts that can be used as casting patterns or reference patterns for other manufacturing processes. Several prostheses are realized as a series of components with different sizes in order to fit a standard population distribution [10]. However, this means that precise fitting is not possible, often causing postoperative difficulties for the patient. These difficulties can further result in additional steps for the device redefinition and correction, which increase the cost of the medical treatment. Therefore, the customization through the use of actual patient data could guarantee a remarkable increase in the device comfort and

performances. Custom-made devices would reduce the above mentioned problems more precisely matching the original geometry and therefore the patient anatomy [8].

This paper presents the application of AM technology in order to realize customized medical devices. In particular, a general procedure for customized devices production by AM can be defined and then adapted for a specific production. In fact, the general approach is based on the obtainment of the 3D patient anatomy, the elaboration of this geometry in order to reconstruct an STL file that can be managed with proper software, the design and the optimization of the customized medical device and the subsequent fabrication with AM technologies. This general workflow can be applied to specific medical cases, optimizing the procedure for the production of customized components which can answer to specific needs and requirements.

Therefore, this work is related to the application of this procedure for the realization of customized tracheal stents. In particular, it was studied a fabrication approach based on the realization through the Fused Deposition Modeling (FDM) technique of customized molds for the casting of the biocompatible silicone chosen as material for the stents. Moreover, due to the fact that the surface finishing is probably the greatest drawback related to the FDM, it was decided to employ a chemical surface finishing post-treatment for the molds [11], in order to reduce the roughness of the 3D printed components and, therefore, increase the surface finishing also for the final stents.

The application of this procedure is presented in the paper with a focus on the fabrication of anatomical tracheal stents. The anatomical region of interest is schematically presented in Fig. 1. In this context, stents can be a definitive treatment for patients with tracheal stenosis who are not candidates for surgery or used as a palliative measure in advanced malignancy to provide symptomatic relief.
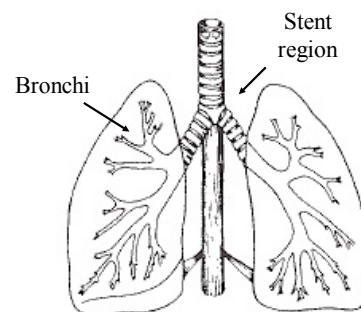

Fig. 1. Anatomical region of interest.

According to interviews conducted with different Italian medical doctors, the most important characteristics for an ideal stent are the easy to place and remove, the possibility to customize it (not choosing within a series of components with different sizes produced form data obtained by a standard population distribution, but using a device customized on the actual patient anatomy), the stability of the stent in the anatomical region of interest and the low cost [12]. In particular, a previous work showed that anatomical stents result

in an increase of the stability against migration and in a reduction of the stresses acting on the trachea tissues [13]. Being the work focused on the stent geometry, a general purpose silicone was adopted for the part production. In this paper, the focus is set on the processing of a two-component and biocompatible silicone. In particular, it was decided to produce the components with molds fabricated by AM and not directly producing the components with the 3D printing due to the actual immaturity of the direct AM approach in the fabrication of complex 3D components with two components silicon material (as discussed in [14]).

2. Materials and methods

The material used for this project is the SILBIONE RTV 4439 A&B, a two-component silicone elastomer which cures at room temperature by a polyaddition reaction [15]. The silicone material is delivered as two low viscosity liquid components which must be mixed in a ratio depending on the specific application (in this case 1:1) to obtain the final elastic and resistant material. Polymerization occurs without formation of heat. Degassing is performed to avoid air inclusions. After the two components mixing, the polymerization starts. In particular, according to the material datasheet, the silicone polymerizes at 23°C in about 20 minutes [16]. The curing time can be accelerated at high temperatures or reduced at low temperatures [14]. Table 1 reports the main characteristics of this material.

Table 1. SILBIONE RTV 4439 (A&B mixed) characteristics [16].

Color	Translucent
Hardness	40 Shire
Elongation	400%
Tear strength	2.3 N/mm
Viscosity (at 23°C)	8000 mPa·s
Polymerization time	20 min (at 23°C)

The fabrication strategy employed in this project is based on the use of customized molds precisely reproducing the patient anatomy. Therefore, after the two components mixing, the biocompatible silicone is poured into the ABS molds for the polymerization. The solidification of the silicon occurs into the molds, so allowing to obtain the customized tracheal stents once the molds are opened and the cured silicon is extracted. The whole procedure developed for the final customized medical devices fabrication is summarized in Fig. 2.

Computed Tomography → 3D model generation → Molds design → Molds AM fabrication → Surface treatment → Silicone casting
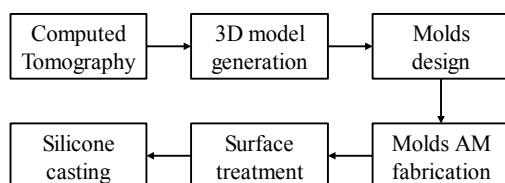
Fig. 2. Customized tracheal stents realization phases.

In particular, once obtained the patient anatomy thanks to the CT technique, the acquired point cloud is used to generate a 3D model which is then converted into an STL format file for the subsequent operations. In fact, this format is easily manageable by a software able to manipulate 3D objects. Furthermore, STL is the standard format for the AM processes. For this project the software Autodesk Meshmixer was used to work on the 3D object resulted from the patient anatomy and to design the customized molds. Then, molds were 3D printed with the FDM technology. The material used for the molds realization was ABS.

FDM technology is easy to be used and capable to produce components with complex geometries. Although these advantages, the layer-by-layer fabrication strategy strongly affects this process and causes an important limitation in terms of achievable surface finishing [10]. Therefore, one possible solution is a post-processing phase to be performed on the components produced by FDM. These treatments can be mechanical and chemical. In mechanical approaches there is the possibility to damage weaker features of the printed components. Moreover, these processes are usually characterized by relatively high costs and by the fact that some regions of the workpiece are not accessible. Due to the nature of the process, mechanical approaches often do not fulfil the requirements of a completely efficient post-processing, that should reduce the roughness of the entire surface with the lower possible cost and without changing the component properties [17]. Moreover, this kind of post-process should ideally be performable without the need of clamping the parts. Therefore, chemical treatments are usually considered better approaches, bringing to good results and avoiding the mechanical solution drawbacks. In particular, dimethyl ketone (acetone) is particularly widespread to treat Acrylonitrile Butadiene Styrene (ABS) components [18], being able to greatly reduce the surface roughness with no significant changes in the component dimensions [19]. A possibility consists in the immersion of the component in an acetone-water solution. However, being this treatment particularly aggressive, the acetone concentration and the immersion time must be accurately optimized in order to avoid any kind of damage and/or undesired effect on the treated part [20]. Therefore, usually it is better to employ acetone vapours treatments, which can be performed using cold or hot vapours [21]. In the hot vapors treatments, heat is used to accelerate the reaction between acetone and ABS surfaces, while in cold vapors treatments, there is no heat supplied to the system and the process can be performed at room temperature. Hot vapors treatments can result in a faster smoothing but also in a lower process control which can cause a non-uniform surface treatment [22]. The most stable approach in order to improve the surface quality without damaging the treated part is the cold acetone vapours treatment [11]. Therefore, it was decided to use this kind of post-process to properly treat the ABS molds before to cast the silicone in order to obtain the desired customized tracheal stents. In particular, the surface treatment was conducted at room temperature using a solution with a 100% acetone concentration.

3. Customized molds

3.1. Molds design

The molds were designed from the patient actual anatomy obtained with the CT technique. In particular, the software used in this phase was Autodesk Meshmixer. Moreover, three different geometries were considered in this study (Fig. 3). They are based on the same anatomy but differ for the addition of details on the external edge, designed with the purpose to guarantee a better adhesion of the final device in the anatomical region of interest.
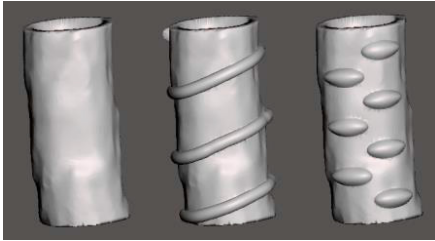

Fig. 3. Three different geometries considered in this work.

Therefore, three different molds were fabricated, following in all cases the same design procedure based on Boolean operations on solid parts. In particular, upper and lower molds were designed according to the tracheal geometry performing a Boolean difference between the mold and the tracheal anatomy, in order to obtain a device fully customized for the specific patient. The upper mold was designed smaller than the lower one, in order to be inserted and locked by interlocking with the structure of the lower one. In order to obtain internally hollow stents, it was necessary to design an internal core according to the internal geometry of the patient actual anatomy. Therefore, additional features were added in all molds in order to furnish stable surfaces for the internal core insertion (Fig. 4). Accordingly, additional extremities were added to the central part with a Boolean union in order to insert this internal core into the molds and keep it stable (Fig. 5).

The same procedure was applied for the other geometries in order to obtain the STL files to be used for the 3D printing (Fig. 6).
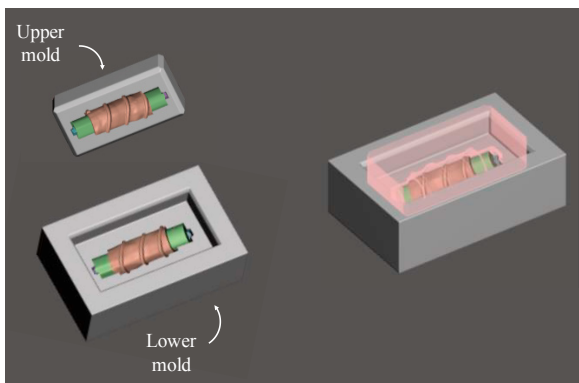

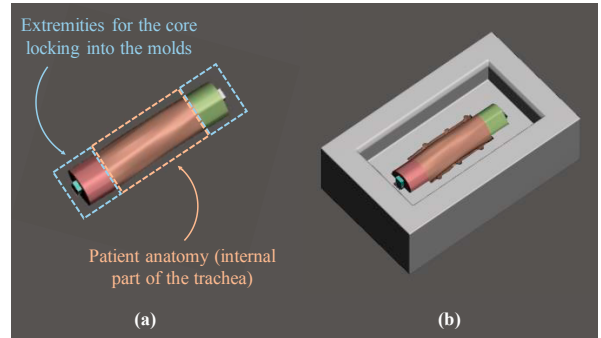Fig. 4. Upper and lower molds.

Fig. 5. (a) Internal core: Boolean union between the central part corresponding to the patient anatomy and the extremities added for the insertion into the mold; (b) internal core inserted and locked into the mold.
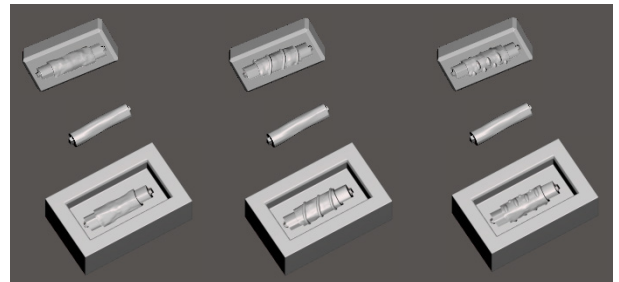

Fig. 6. Molds geometry.

3.2. Molds fabrication

Once the final STL files for all the molds and internal cores were obtained, they were 3D printed using the Stratasys BST 1200es. The layer thickness was equal to 0.254 mm, the nozzle temperature was 300 °C and the components were printed in a chamber with a controlled temperature (75 °C). The material used was ABS and the support material was polystyrene (Stratasys P430 and P400R™ Break Away Support respectively).

3.3. Surface chemical finishing

After the 3D printing by FDM, the ABS molds were post-processed with a chemical treatment in order to improve the surface quality. In particular, in a previous work [11] a cold acetone vapors treatment was characterized in order to determine the optimal process parameters that must be used to obtain a specific target roughness level. In the mentioned study, target surfaces of 3D printed samples were treated by keeping the ABS parts in a close container with an acetone bath on the bottom in order to have a uniform interaction between vapours and ABS surfaces after the acetone evaporation from the liquid bath (Fig. 7). In particular, the treatment is able to remodel and smooth the surface asperities. Once the treated time is reached, the components are removed from the container. Then, they must rest in open air in order to obtain the evaporation of the acetone from the treated surfaces and the definitive ABS part re-solidification. The study tested surfaces that were fabricated with different building angle (which is measured as the angle between the direction orthogonal to the worktable and the

printed surface) and, consequently, with different initial roughness (Fig. 8). Moreover, it showed that the finishing process is able to reduce the Ra till the 98% of its initial value in all cases, identifying the optimum process parameters for the treatment.

According to the results of [11], the molds of the present research were treated adopting a concentration of acetone equal to 100% for a treatment time of 120 minutes. Then, they were dried for 12 hours in air before being used.
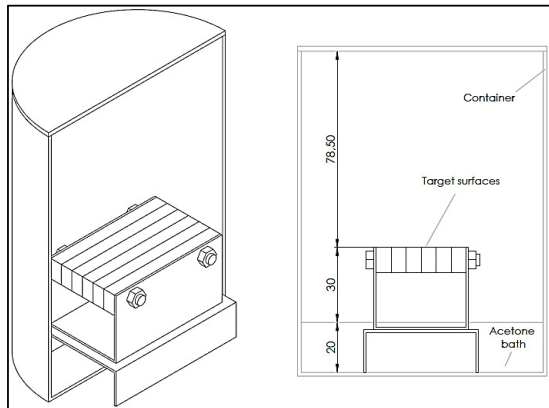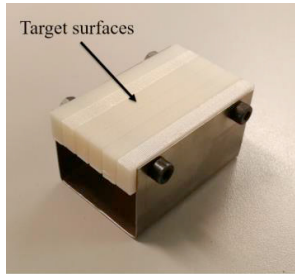

Fig. 7. Experimental setup for the characterization of the chemical surface finishing process.

Fig. 8. Untreated samples roughness as a function of the building angle (points correspond to a single sample and the line connects the average values).

4. Results

4.1. Molds

The results of the molds fabrication and treatment are reported in Fig. 9. In particular, the figure shows the molds for the three different stent designs before and after the post-treatment, confirming the capability of the chemical process in smoothing a general 3D surface.
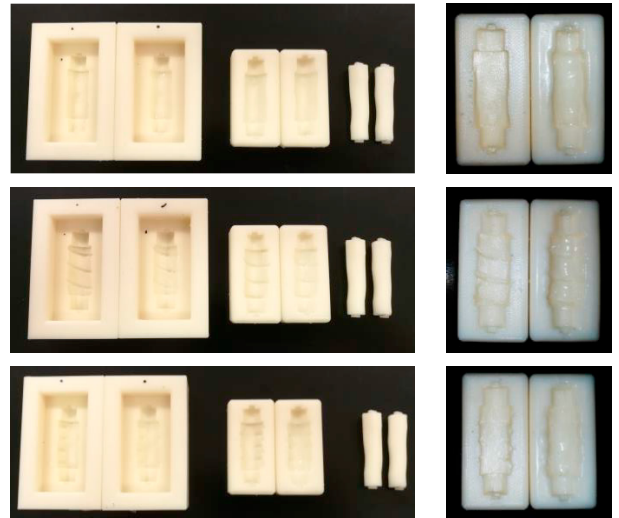

Fig. 9. 3D printed molds for the three different stents geometries and details to highlight the difference in the surface finishing before and after the cold acetone vapours treatments.

4.2. Customized tracheal stents

The application of the developed surface finishing was effective on the treated molds (Fig. 9). In order to evaluate the difference also on the final device, tracheal stents were produced using both the treated and the untreated molds. The results are shown in Fig. 10.
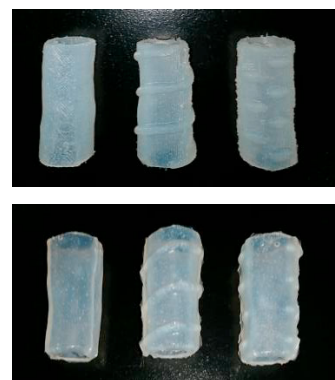

Fig. 10. Stents produced using untreated (above) and treated (below) molds.

In particular, after the mixing phase of the two silicone components, the resulting material was poured into the molds which were kept closed until the end of the silicone curing. In particular, the curing time of this material is 20 minutes at room temperature (Table 1). In order to obtain a full solidified material, the silicone was maintained into the molds for 2 hours. Then, the molds were opened, the stents extracted and the internal cores removed (Fig. 10).

4.3. Procedure

The developed procedure was globally analyzed with the aim to evaluate the time necessary to obtain the final component. In particular, the duration of each step was measured. Since the CAD design is characterized by a learning ramp for the operator, the duration of this phase was measured after the consolidation of the design procedure. Table 2 presents the required time for each phase, while Fig. 11 compares the time required by each step on the whole procedure. In particular, the developed procedure is 24 hours long when the finishing treatment is performed (Fig. 11a), while it is 10 hours long without the chemical post-processing (Fig. 11b). In fact, as shown in Fig. 11a, the chemical treatment occupies the 60% of the whole time required for the procedure. The surface chemical treatment is particularly long due to the drying (Fig. 12). Therefore, two different approaches can be followed. In particular, in order to optimize the procedure scheduling, the 12 hours drying can be performed overnight, so reducing the time wasting. Otherwise, drying alternatives can be evaluated, considering for example the possibility to blow an air flux on the treated molds in order to reduce the drying time.

Table 2. Procedure phases and relative times.

Phase	Time (h)
Molds design	
Elaboration time	1
Additive Manufacturing	
Machine set-up	0.5
Printing time	3.57
Support material removal	
Total time	0.25
Surface finishing time	
Equipment set-up	0.5
Treatment time	2
Drying	12
Silicone casting and curing	
Casting (set-up, material preparation and mixing)	1
Curing (mixed material into the molds)	2
Part extraction and cleaning	
Total time	1

Procedure with the finishing treatment (total time = 24 hours)

a

Procedure without the finishing treatment (total time = 10 hours)
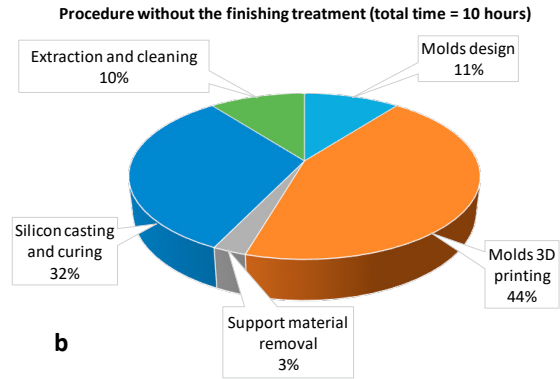
b

Fig. 11. Weight in terms of time of each phase on the whole procedure: (a) procedure with the finishing treatment; (b) procedure without the finishing treatment.
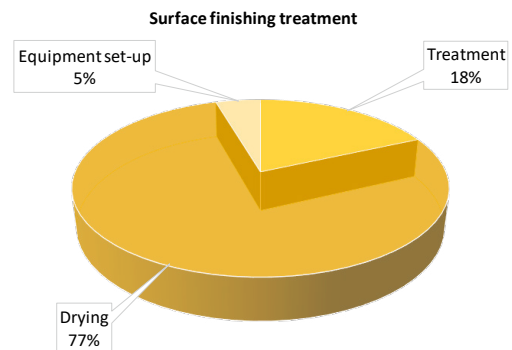

Surface finishing treatment

Fig. 12. Surface finishing treatment.

5. Conclusions

Additive Manufacturing (AM) is distinguished from traditional manufacturing technologies by its ability to handle complex shapes with great design flexibility. This feature makes the AM techniques particularly suitable to produce customized components. In fact, the production of custom made devices concerns the realization of products suitable to the specific needs of the customer, and AM allows to achieve in a simple and cheap way complex geometries to produce even a single piece (notoriously a critical aspect for traditional technology). In particular, one of the most interesting application fields regards the medical devices. The widespread of 3D data acquisition techniques and CAD elaboration software opened the possibility to exploit AM technology for the fabrication of custom biomedical devices. For example, in prosthetic applications, 3D printing could be a promising way to upend the traditional market where prosthetic devices can be very expansive and have a short expected lifecycle. In fact, AM systems can allow not only the creation of much more accessible devices from a cost perspective, but also a much more sustainable approach to the patient care through a digitally powered process using scanning and imaging technology.

Therefore, the research work presented in this paper aimed to study and develop a procedure for the realization of
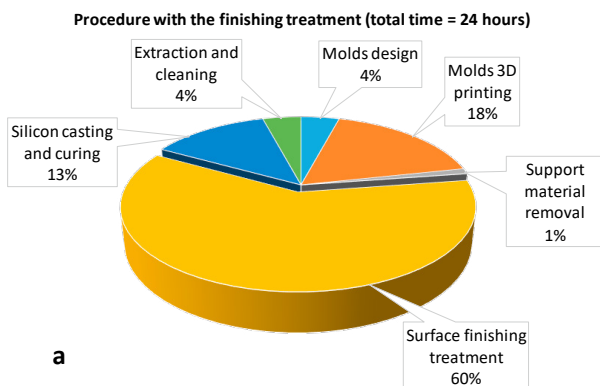
customized medical devices exploiting the AM fabrication. In particular, the focus of the work was on the realization of customized tracheal stents, realized with a two components and biocompatible silicone. The developed procedure was based on the realization by FDM of ABS molds precisely reproducing the patient anatomy. In fact, the molds design was performed on the base of the actual patient anatomy obtained thanks to a TC acquisition.

The proposed procedure resulted to be effective in the production of these tracheal stents in particular responding to the most important requirements that this kind of medical device should have. In fact, the obtained samples were evaluated as flexible and easy to be managed in medical tests, the customization level is high and it is clear that also other details can be added when necessary thanks to the high design flexibility of this procedure. Moreover, the produced stents are obtained on the base of the provided patient anatomy, so that also the comfort target could be guaranteed. Also the design of the different geometries was evaluated as effective in order to improve the stent stability. Future devolvement of this work should focus on the evaluation of technological alternatives. In particular, the idea is to focus to opposite alternatives, 3D printing the molds for the silicone casting with a machine that can guarantee a low surface roughness after the AM fabrication (e.g. Project 2500 Plus, which is a Material Jetting 3D printer characterized by a high commercial cost but also by a high quality of the final components) and with a low cost 3D printer (e.g. Ultimaker 3, that works with the Fused Filament Fabrication technique). In particular, it could be interesting the comparison between the obtained results as well as the precise quantification of the economic cost of each approach in order to evaluate the best solution both considering the production quality and cost.

Acknowledgements

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