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Design and manufacturing workflow of a patient specific 3-dimensionally engineered tracheobronchial stent

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Abstract: Airway stenoses, such as vanishing bronchus syndrome, are routinely treated by airway stent implantation. Off-the-shelf stents are appropriate for the treatment of most patients. However, in some cases, these commercially available stents do not fit the patient's airway anatomy sufficiently, resulting in a high risk for dislocation and infection. In this article, we present a process for design and manufacturing of patient-specific tracheobronchial stents that allows treatment of patients in whom standard treatment is not appropriate.

I. Introduction

Patients suffering from airway stenosis or increased collapsibility are routinely treated by implantation of silicone airway stents. To achieve adequate alignment within the airway lumen, off-the-shelf stents are available in numerous shapes and dimensions. In the majority of cases, adequate fitting within the airway can be achieved and the stent helps to significantly relieve symptoms. In certain cases however, the patients' airway anatomy does not allow a proper fitting of the stent, leading to an increased risk of infection, tissue granulation or dislocation within the lumen. This is particularly the case in patients with distorted or overly enlarged airways and uncommon airway branching angles. To allow successful treatment of these patients, customized stent geometries are necessary. [1]–[4] Here we describe a developed design and manufacturing procedure for the production of patient-specific silicone stents that exactly fit the airway anatomy.

II. Material and methods

CT imaging data of a patient, suffering from a "vanishing bronchus" syndrome after lung transplantation was acquired. The data set was segmented, to obtain a digital 3D model of the patients' respiratory tract, using Mimics Innovation Suite 23.0 (Materialise, Leuven, Belgium). On the patients' airway model, a customized, fitting stent geometry was designed in close cooperation with clinicians (see Fig. 1). For stent design, the cross-section of the stenotic region was expanded by adding a cylinder (7 mm in diameter) to the segmented lumen, using the Boolean union operation tool. This diameter was chosen to provide sufficient airflow. Starting from an initial stenotic diameter of 3.5 mm, a lumen double as large was selected (this leads to sixteen-fold decrease of airflow resistance). Theoretically, this dimension could be even larger, however, the surgeon did not consider this feasible according to his previous experience with balloon dilatation. The transition area between the cylinder and the segmented airway was then smoothened by placing a fillet with 2 mm in radius. After trimming the ends of the geometry to the desired dimensions of the stent, the final stent geometry was then generated by using the hollow tool for adding a 1.25 mm thick wall around the 3D model. This wall thickness was added to the segmented lumen to give mechanical stability to the stent, to create a press fit and avoid possible dislocations and also to compensate for possible imaging-related dimensional errors.

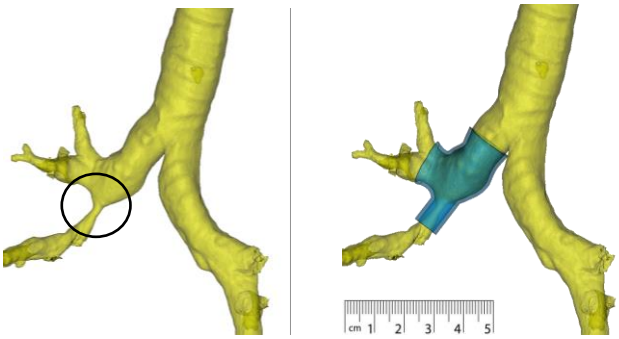

Figure 1: (left) Segmented lumen of the respiratory tract (circle highlights the stenotic region). (right) Segmented lumen with created 3D stent design (shown in blue color)

For manufacturing of the silicone stent, a three-component mold was designed, utilizing Materialise 3-matic (Materialise, Leuven, Belgium) (see Fig. 2). The parts of the mold

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were then printed from Dental SG Resin (Formlabs Inc., Somerville, USA) on a Formlabs Form 2 SLA printer (Formlabs Inc., Somerville, USA) (see Fig. 2). Printing and Postprocessing was performed in strict compliance with the biocompatibility requirements guidance of the material manufacturer. A medical grade silicone (MED-4244, Nu-Sil, Carpinteria, CA, United States) was used for molding. After manufacturing, the stent underwent visual inspection, simulation of distention and clamping maneuvers to assess mechanical stability and dimensional evaluation.

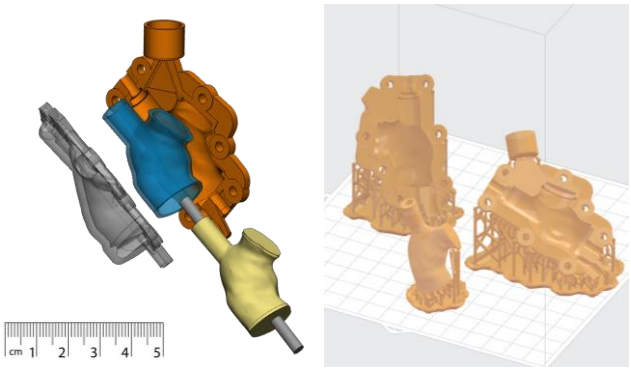

Figure 2: (left) 3D illustration of mold components. Grey and orange color: outer parts of the mold. Yellow color: mold core. Blue color: 3D geometry of the silicone stent; (right) Orientation of the mold components on the Formlabs Form 2 build platform.

III. Results and discussion

Manufacturing of the final silicone stent was performed under cleanroom conditions. Compared to room temperature vulcanizing (RTV) silicones as used by Colpani et al. (see [4]), processing of the used MED-4244 silicone poses additional challenges due to the required vulcanizing temperature of 120°C. A first manufacturing attempt using a RTV silicone was successful. Using the medical grade silicone, the mold process however failed, as the silicone had bonded with the molding material. To overcome this issue, a release agent (Mono-Coat 1989W, Chem-Trend GmbH, Germany) was applied. The medical grade silicone was prepared by mixing of two components under vacuum to remove residual air bubbles from the material. Injection of the silicone into the mold was performed using a syringe. For curing, the mold was then placed at 120°C in a furnace for 16 hours in compliance with the processing parameters, stated by the silicone manufacturer. After cooling to room temperature, the stent was carefully demolded (see Fig. 3). The stent did not show any air and particle inclusions and cracks when inspected under twentyfold magnification. Performed tear resistance tests, simulating stress exposure during implantation, did not lead to defects on the stent material. Dimensional investigation of the outer part geometry was performed using a vernier caliper and showed match to the requirements as defined by the surgeons (± 0.2 mm). The designed material thickness (1.25 mm) was checked with a thickness gauge and compared well with the nominal dimension with ± 0.05mm tolerance. It must be noted that the stent thickness could only be evaluated at the biggest diameter of the stent. For an overall dimensional investigation a 3D scanning would provide more information about the part accuracy. After successful quality inspection, the stent was sterilized using steam sterilization.

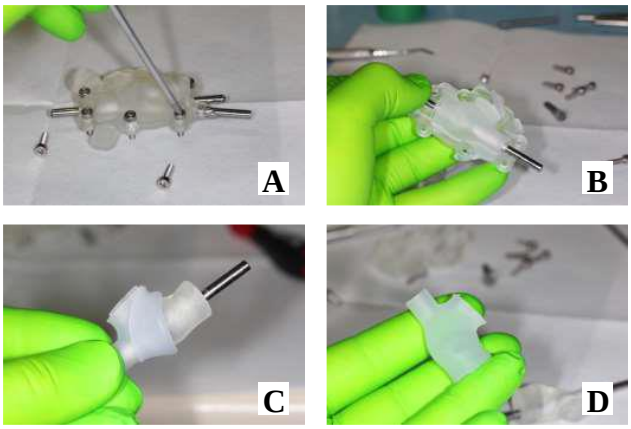

Figure 3: Demolding procedure of the silicone stent. (A) & (B) Disassembly of the mold halves; (C) Removing the stent from the mold core; (D) Finished (unsterile) stent

IV. Conclusions

A design workflow for manufacturing patient specific airway stents was successfully implemented. Quality inspection has shown that the manufacturing process is qualified to produce patient specific silicone stents in a quality that would allow its use in patient treatment. The herein presented combination of classical molding techniques with modern additive manufacturing technology provides a high dynamic and cost-efficient process. While directly 3d-printing of silicone stents would be desirable, there are currently no biocompatible materials available for additive manufacturing showing similar mechanical characteristics (especially in terms of tear resistance and elasticity) as silicone materials.

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Author's statement

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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