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Structural Performance and Hydrodynamic Resistance of a New Silicone Auricular Cannula Tip

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Abstract — **Development of a new generation pneumatic of Ventricular Assist Device (VAD) required the design of cannulae to improve its optimal performance. In this case, a relevant restrictive design parameter was the material of the cannulae. Silicone was the best choice in a hemocompatible focus, but this is a material with very low stiffness. If the material is flexible, the most important parameter that affects either the structural performance or the hydrodynamic resistance is the amount of side holes on the cannulae tip, known as the effective drainage area. In order to obtain an estimation of the structural performance and of the hydrodynamic resistance, a study based on two independent analysis is needed: the structural and the *in vitro* drop pressure analysis. Structural analyses based on computer simulations were made in order to estimate the bending behavior of four silicone prototypes of cannulae tips. On the other hand, experiments under hydrostatic conditions were made to test and compare the pressure loss and flow rate relationship. A cannula tip with six side holes showed good hydrostatic performance, having almost the same as the one with nine side holes. Plus, it presented and a satisfactory structural behavior. This study assisted the design process of an auricular silicone cannula, recommending the use of cannulae with six side holes for a specific VAD.**

I. Introduction

Ventricular Assist Devices (VADs) are a real and current alternative in the treatment of cardiovascular disease, which is becoming one of the leading causes of death in numerous countries in the world [1, 2]. Acute heart failure, cardiogenic shock, cardiac surgery and rehabilitation are candidate diseases in the use of VADs. In the past decades, several VADs have being developed [3-5]. A specific design of VADs was recently reported by Sacristan et al. which has been tested *in vitro* and *in vivo* with satisfactory hydrodynamic and hemodynamic results [5-7]. Cannulae are critical components in VAD performance and have been reported in the literature with an extensive variety of designs and materials [8-13]. Flow rate, loss pressure and hemolysis are examples of cannulae-dependant VAD design parameters which are related to hydrostatic resistance [14, 18]. Another important consideration for the proper design of a cannula is the material.

This work deal with a specific design of a cannulae for a VAD, which is made mainly of silicon rubber. Among the spectrum of available materials, this material has shown superior hemocompatibility properties [19]. Another important advantage of silicon rubber is the reduction of manufacturing cost due to the facility of injection process. Therefore in order to reduce the cost, a very important design requirement for the cannulae was to be made of medical grade silicone rubber, the same material of the VAD.

The low structural stiffness of the siliconne rubber could compromises a good connection between the VAD and the patient, due to the fact that it is needed certain stiff in the cannula tip, with a minimum of bend, to enable a connection in the auricula. If the cannula tip bends, could exist difficulties in the connection to the patient during surgical procedure or it could be collapse during working. This evidence compromises the choice on geometry and configuration of holes of drainage, in order to achieve a design of a product with satisfactory stiff performance without sacrificing a low hydrodynamic resistance.

The larger amount of holes, the less hydrodynamic resistance, however in case of a material of low structural stiffness, the larger amount of holes, the largest bending, and the worst scenario in connection procedure.

In order to get an estimation of the structural performance and of the hydrodynamic resistance, it is needed a study based on two independent analysis: the structural and the *in vitro* drop pressure analysis.

This work presents the results of a structural analysis comparison for four auricular cannula (AC) tip prototypes, and *in Vitro* test of drop pressure, with the aim of explore the effective area effects on the mechanical and hydrodynamic performance of a new silicone rubber auricular cannula tip.

II. Methods

In an early stage of the AC design, a prototype with eight side holes was manufactured and tested (Fig.1a). It presented suitable hydrodynamic resistance, but its poor structural performance, which compromised the connection procedure, led to a redesign process and tests described in this work, in order to improve its bending behavior.

Three customized medical grade silicone rubber cannulae types were manufactured in durometer 70. All the cannulae were 36 fr, 11 mm ID, with an axial central hole of 8mm (Fig. 1). The only difference among them was the setting of the holes, which resulted in the variation of the effective drainage area.

The first prototype manufactured, had eight holes, four were circles and four were ellipsoid holes (Fig. 1a). The second one had a row of three equidistant radial holes (Fig. 1b). The second one had an additional three holed row (Fig. 1c), and the third one had one more (Fig. 1d). The tips were considered to have the same length. CAD models for the design of the cannulae were made by using *Inventor*™ software. Figure 1 shows the features of the models studied.

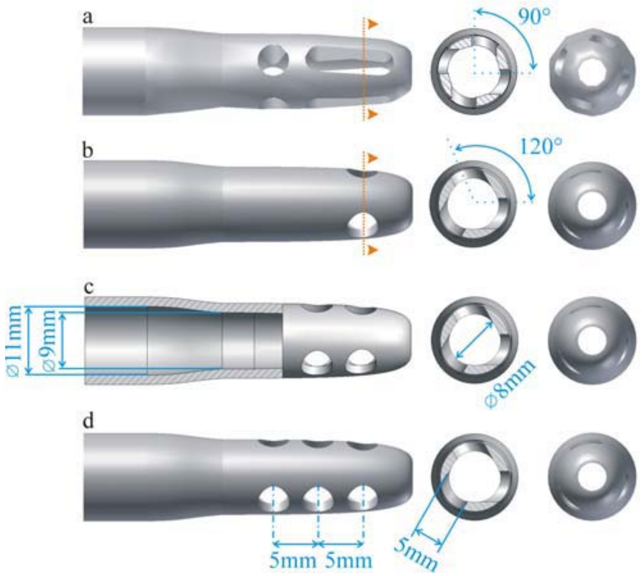

Figure 1. Features of the models studied.

Structural Analysis

Structural finite element analysis (FEA) of four auricular cannulae was made in order to compare quantitatively the structural stiffness performance of the different cannulae tips.

Material properties used for the analysis in the imported CAD models were: Young modulus = 3.6x10^6 Pa, *v*=0.49 and density= 1110 kg/m^3. Due to the elastomeric nature of the involved material, non-linear analyses were used in this study. The mesh elements were low-order tetrahedral. Two loading conditions were applied for each prototype to simulate critical working conditions (Fig. 2). *Ansys™* software was used for this purpose. A perpendicular load of 600x10^-3 Newton with respect to the cannulae axes was used as. All degrees of freedom were restricted at the base of the tip. The first loading condition was designed with the aim of evaluate the tip in a typical bending case.

On the other hand in the second loading condition, the same load of 600x10^-3 Newton was used, the difference of this condition relies on the angle that the line of action of the force creates with respect to the cannulae axes. This loading condition was set to pretend a more realistic condition: to simulate the cannulae being plugged to an auricula patient during surgical procedure when the surgeon has to open a little slit made normally with an bistoury.

These two loading conditions were applied to each cannula tip model in order to get a quantitative comparison of the bending behaviour.

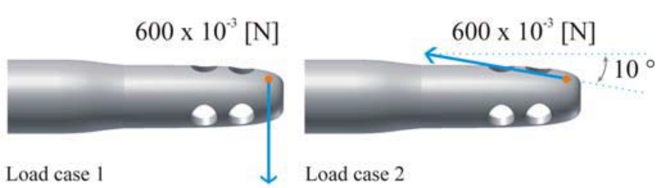

Figure 2. Loading conditions used for the structural analysis.

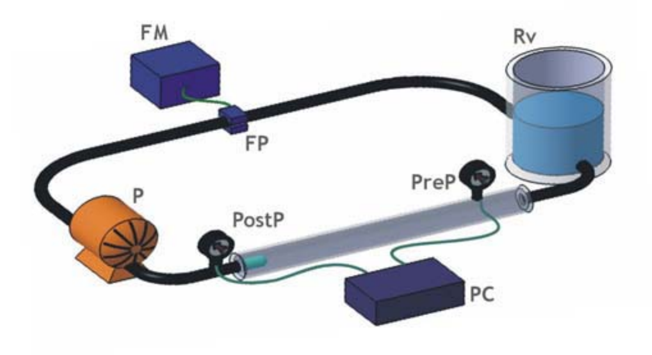

Figure 3. Hydraulic circuit for testing the cannulae prototypes. Centrifugal Pump (P); flow probe (FP), flow measure (FM), reservoir (Rv); pre-cannula pressure (preP); post-cannula pressure (postP), monitor (PC).

Pressure Loss Experimental Set Up

An experimental set up of continuous flow rate was made with the aim of evaluating the hydraulic resistance of the four cannulae tips. This test describes the relationship between pressure loss and flow rate. A hydraulic circuit was built, consisting of a centrifugal constant flow rate pump (Lifestream Centrifugal Pump System 2100CM, USA), a testing zone, an ultrasonic flowmeter, and a reservoir. The testing zone consisted of rigid tubing containing the cannula tip and two pressure transducers (Edwards Lifesciences, USA) connected to a bedside monitor (Nihon Kohden BSM 4111J, Japan) as shown in Figure 3. The flow rate was measured with a Transonic flow probe 16A540 connected to a T-106 Transonic flowmeter (Transonic, USA) which was calibrated by using a standard flow measuring method.

A 65% saline and 35% glycerin (by volume) solution at room temperature was used to mimic the properties of blood at 37°C as referred by Sturm et al. [21].

The testing zone was designed to simulate an auricular connection. The cannula can easily be connected to a bigger tube in diameter which has a negligible resistance compared with the cannulae and one pressure transducer to measure the pre cannula pressure.

Each cannulae model was set in the testing zone and prevalve and postvalve pressures were measured in a static condition of flow. The independent variable was flow rate, and the dependant was the difference between pre and post cannula pressure.

III. Results And Discussion

Structural Performance

A load of 600x10^-3 N was estimated using a dynamometer. This estimation was intended to simulate the handling of the cannulae during a surgical procedure. This load was used as an input for the FEA to study the structural behavior of the four cannulae. The magnitude of the applied force was intended to have a closer measure to reality and a better comparison between the models.

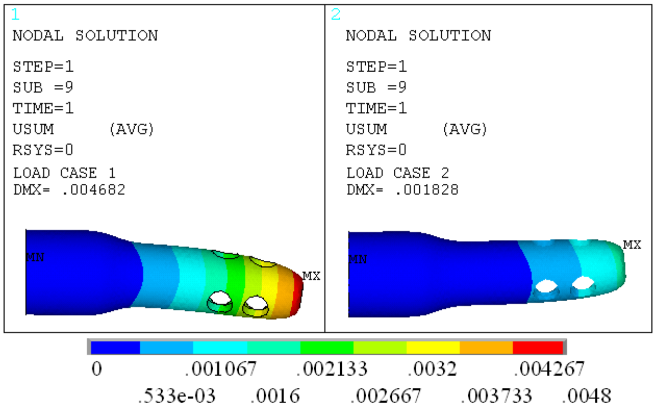

Figure 4. Maximum deformations showed of the "c" model of cannulae studied, under load case 1 and load case 2.

Figure 4 shows a typical image of the finite element analysis postprocessor stage, it is shown the maximum deformations of the bending behavior of one of the four models studied, the "c" model (see figure 1). These images can help to determine the zone and the way of maximum bending. Figure 5 shows a summary of the maximum deformations computed for the four cannulae tips. The dependence of the effective area on the deformation can be observed. The more holes at the cannula tip, the less structural stiffness was found. This behavior could compromise the cannulae performance, by collapsing it or squeezing it and, as consequence, affecting the VAD performance during a real situation. If the design structural restrictions are not satisfied, a further study on the hydrodynamic performance or an optimization of the drainage area is senseless.

Although the first case represents a more critical loading condition than the second one, being the latest closer to a realistic condition, both present similar asymptotic trends in their structural behavior, with the decreasing of holes.

Pressure Loss Experiments

Figure 6 shows a relationship between pressure and a hydraulic index that was defined as the total drainage area over the cannulae body hydraulic area. Table 1 shows the hydraulic index related with each model.

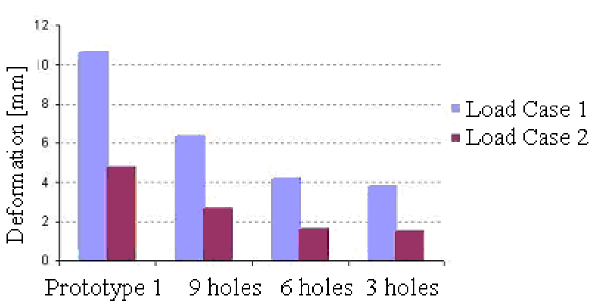

Figure 5. Summary of the maximum deformations showed of the four models cannulae studied.

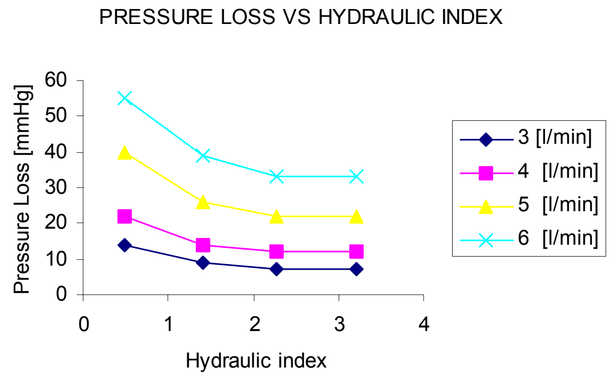

Figure 6. Pressure Loss VS Hydraulic index of the four models studied..

	Effective Area mm^2	**Hydraulic index** (effective area / cannula body hydraulic area)
1st protype	309.9	3.2
9 holes	304.7	2.3
6 holes	215.2	1.4
3 holes	133.3	0.5

Table 1. Effective area and hydraulic index related with each model.

The pressure drop becomes more significant as the flow rate increases. The results of the measurements, suggest that the hydrostatic resistance of a cannula does not depend on the shape of the side holes in the tip. It just depends on the effective area. It can be also observed that, at indexes under 1, the behavior of all the cannulae showed greater gradients of pressure loss, as compared to higher indexes, where an asymptotic trend was gotten. Specifically, a dramatic drop in the pressure loss axis is observed for the 6 l/min flow rate between the 0.5 and the 1 indexes.

On the other hand, beyond the 1.5 index, there is no benefit on pressure drop. However, this part of the plot could be addressed to evaluate the quality of the cannula connection. When the effective area is reduced, due to a collapse in part of the cannula or a blockage of holes, an offset of the values shown in the plot will be observed.

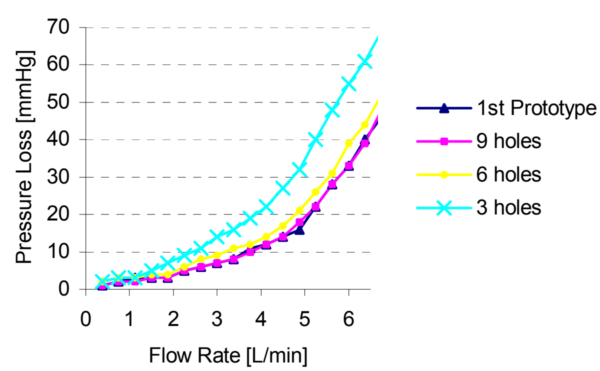

Figure 7. Pressure Loss Vs. Flow rate of the four models studied..

Figure 7 shows the typical plot of flow rate & pressure loss experiments. This image illustrates that with the decrease of number of holes, the hydraulic resistance grows. More pressure is needed to maintain the same flow rate. A highly resistive venous cannula will diminish the hydrodynamic performance of a VAD, due to the fact that filling pressure is one of the most important performance parameter.

IV. Conclusions

The cannula with the best structural performance was the one with three side holes. However, it had the worst hydrodynamic behavior. On the other hand, the cannula that presented the best hydrodynamic performance was the first prototype, which had the greatest effective area, but the great amount of holes decreases seriously its stiffness.

It is well shown as a result of this two independent studies, that there is a hard compromise between the stiffness of the tip and the hydrodynamic resistance. On this matter, based on figures 5 and 6, we conclude that the cannula with 6 holes has a convenient stiffness with a satisfactory hydrodynamic resistance, almost comparable to the 9 holes and first prototype models.

Although it can be assumed that the only parameter in the hydrostatic resistance is the effective area, the shape of that area must be designed carefully, and a matter of further studies. These studies should focus on shear stresses and other possible causes of hemolysis.

Even though the structural analysis showed that the effective area reduction ensures a better structural performance, the elastomeric nature of the material employed could be enhanced by the use of an extra rigid insert in the tip, to avoid compromising the hydraulic resistance. However this could lead in a more complex design and manufacturing process, and noticeably a more expensive product.

Acknowledgments

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