**EX VIVO ASSESSMENT OF A NOVEL INFLOW CANNULA FOR PEDIATRIC CONTINUOUS-FLOW VENTRICULAR ASSIST DEVICES**

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**INTRODUCTION**
The mortality rate for children waiting for heart transplantation is 23%, with many requiring mechanical circulatory support in order to survive while waiting on the transplant list. Although rotary blood pumps (RBPs) are ubiquitous within the adult population, the Berlin Heart EXCOR® is the only pediatric device approved to provide support. However, it is an external device that greatly restricts the patient. Therefore, there is a need for an implantable, pediatric ventricular assist device. In response to this need, a team at the University of Pittsburgh developed the PediaFlow® VAD.

While considerable effort has been invested in the development of RBPs, less attention has been devoted to the inflow cannula evident by remaining virtually unchanged from first generation pulsatile-type pumps. Since rotary VADs actively empty the heart throughout the cardiac cycle, the consequences of incomplete unloading due to premature ventricular entrapment include inadequate cardiac support, thrombosis, hemolysis, myocardial bruising, ventricular collapse, and arrhythmias. With smaller and more variable anatomical configurations, these concerns are reinforced within the developing field of next-generation implantable pediatric rotary VADs.

In response to the need for an appropriate pediatric left ventricle, RBP-compatible conduit, a novel inflow cannula was designed to resist entrapment, occlusion, stagnation, and malposition (Figure 1A). With a reinforced parabolic entrance and variable depth placement, the novel cannula combines the efficiency and flow characteristics of standard bevel-types while providing secondary flow paths similar to fenestrated venous drainage cannula.

**OBJECTIVE**
Utilizing an ex vivo, pediatric isolated-heart model, this parabolic-tip design was compared with current bevel- and fenestrated-tips to assess performance through the calculation of a positional sensitivity parameter.

**HYPOTHESIS**
It is expected that the novel parabolic-tip will perform, in terms of positional sensitivity, significantly better than the bevel-tip design and comparably or better to the fenestrated-tip (Figure 2).

**MATERIALS AND METHODS**
Juvenile ovine hearts were obtained from a slaughter-house, cleaned, and trimmed of their pericardium for use in the ex vivo isolated-heart study. After the design of a new rapid-printed reservoir and preliminary proof of concept studies, multiple experiments were performed under pulsatile (n = 10) conditions. A removable sewing ring was fixated to the apex of the left ventricle (LV) and a boroscope for visualization was introduced from the left atrium (LA) through the mitral valve.

**Figure 1: A)** The novel parabolic-tip cannula; and **B)** flow loop setup for the ex vivo assessment (Mr. Olia).
The experimental flow loop was setup similarly to the manner described by Bham et al.\(^4\) (Figure 1B). 40% glycerol in saline, a blood analogue, was utilized within the flow loop and seeded with neutrally buoyant reflective particles (Amberlite IRA-96, Sigma Aldrich, St. Louis, MO). A constant preload into the ventricle was maintained by utilizing a vertically elevated fluid reservoir with an overflow chamber. A Thoratec® PediMAG® was used to generate flow through the heart-cannula assembly and a solenoid pinch-valve proximal to the LA inlet was utilized to induce contraction and free wall movement. The LA, LV, and outlet cannula pressure (CP) values were measured using three pressure transducers (648, PCB Piezotronics Inc., Depew, NY), and a clamp-on flow probe (TS410, Transonic®, Ithaca, NY) was attached at the pump outlet to measure flow rate through the cannula (Q).

The three cannulae were evaluated using two protocol scenarios to mimic the clinical complications of over-pumping and hypovolemia to assess LV unloading ability. Over-pumping was achieved by continually increasing pump speed (PS), starting at an approximate flow rate of 0.3 L/min. The hypovolemia protocol, representing inadequate blood volume, was performed by gradually decreasing LA preload using a tubing clamp placed proximally while maintaining constant PS. Both protocols were executed in normal and misaligned positions to assess positional sensitivity, with malpositioning created by fixing the cannula posteriorly approximately 45 degrees.

Data Analysis

MATLAB\(^\circledR\) was utilized as the main data processing tool in this study. A positional sensitivity index (I\(_{ps}\)) was calculated according Bachman et al.\(^2\) for the maximum flows attained in the over-pumping protocol and flows at certain LA pressures in the hypovolemic protocol.

RESULTS

The average of the individual I\(_{ps}\) values was calculated for the over-pumping protocol (Table 1). These values indicate that the fenestrated and parabolic cannulae were similarly insensitive to misalignment. However, visual analysis showed that the fenestrated-tip was susceptible to partial occlusion (Figure 3) while the parabolic-tip resisted entrapment.

![Figure 3: Boroscopic visualization of the A) bevel, B) fenestrated, and C) parabolic cannulae misaligned within the ventricle under pulsatile conditions.](image)

![Figure 4: Hypovolemia I\(_{ps}\) (n = 10).](image)

![Table 1. Over-pumping I\(_{ps}\) (n = 10).](table)

<table>
<thead>
<tr>
<th>I(_{ps}) (%) ± SEM</th>
<th>Bevel</th>
<th>Fenestrated</th>
<th>Parabolic</th>
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<tr>
<td>61.3 ± 6.8</td>
<td>1.9 ± 2.3</td>
<td>4.3 ± 2.7</td>
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Similar results were found during the hypovolemic scenario (Figure 4), where the fenestrated and parabolic-tip cannulae were similarly insensitive to malpositioning. The bevel-tip showed to be sensitive to positioning under all conditions.

DISCUSSION

Performance of the novel parabolic-tip pediatric inflow cannula in terms of positional sensitivity was qualitatively and quantitatively comparable to the fenestrated-tip cannula while retaining a single entrance path. Testing is ongoing to increase sample size and provide additional
metrics for assessing possible stagnation areas in the ventricle.

REFERENCES

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