Pediatric Heart-Assist System for Congenital Heart Failure in Infants & Children: Silicone Coating and Delivery-System Development

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Abstract:

The ventricular connection is a critical component of an implantable pediatric heart-assist system. This project investigated silicone coating and delivery of a braided Nitinol cannula intended for sutureless left ventricular access. Work included material screening, dip-coating trials, preparation of MED-2014/xylene formulations, and development of an alternative release mechanism. An acute ovine study achieved transapical access, hemostasis, and initial cannula advancement, but incomplete flange deployment revealed limitations of the tear-strip delivery system. A helmet-style tip was subsequently developed, and ex vivo testing demonstrated flange opening while identifying friction-induced premature release. These findings linked coating quality to insertion and deployment behavior and established priorities for the next prototype: reproducible coating, controlled retention, and reliable flange release.

Summary of Research:

PediaFlow is a miniature, magnetically levitated ventricular assist device developed for infants and young children. Its development has combined computational design with experimental evaluation of hydraulic performance and blood compatibility [1,2]. The ventricular connection must also accommodate small anatomy and maintain unobstructed inflow. Prior work by Antaki and colleagues showed that cannula geometry and positioning affect intraventricular flow and susceptibility to obstruction [3].

Cannula Architecture and Fabrication

The cannula consists of a braided, shape-set superelastic Nitinol frame, a silicone membrane, and a deployable distal flange (Figure 1). The frame provides a collapsible structure, while the coating is intended to form a flexible, blood-tight conduit. The distal flange is designed to conform to the endocardial surface and provide sutureless anchoring [3]. Fabrication and delivery must preserve both membrane integrity and flange expansion following release from the compressed configuration.

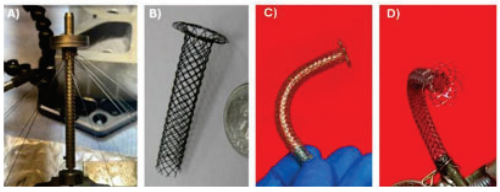

Figure 1: Ventricular cannula fabrication: (A) Nitinol braiding, (B) shape-set frame, (C) silicone dip-coated cannula, and (D) deployed distal flange.

Silicone Material Screening

Material evaluation considered silicone viscosity, tear resistance, elongation, processing time, and intended implant duration. The process comparison included MED10-6400, MED6-6606 RTV silicone, and MED-2014. Additional screening covered MED-6600, MED-6615, MED-2214, and Elast-Eon E2As. MED-2014 became the working formulation for the dip-coating trials. It is a fully compounded silicone dispersion in xylene suitable for heat-cured thin films; the manufacturer excludes human implantation beyond 29 days, so its selection addressed prototype and acute-study needs [4].

Dip-Coating Formulation and Thermal Processing

The initial coating bath contained 40 mL of MED-2014 dispersion and 5 mL of added xylene. Subsequent coats used 30 mL of dispersion and 8 mL of xylene. Both formulations were vacuum-deaired until visible bubbles were eliminated. Increased dilution in subsequent coats was intended to limit film buildup while maintaining coverage of the braided frame. These ratios describe the supplied dispersion and added solvent

The processing schedule recorded for MED-2014 comprised 1h at 50°C, 1h at 150°C, and at least 3 h of ambient stabilization, consistent with the manufacturer's property-conditioning schedule [4]. Consultation with

NuSil addressed bubble removal, mandrel release, withdrawal control, and convection-oven airflow. Shorter drying intervals and MED10-6640, a higher-tear-strength candidate, were identified for further evaluation. Residual-solvent and mechanical testing remain necessary before adopting a shortened process.

Acute In Vivo Evaluation in an Ovine Model

An acute ovine study assessed transapical penetration, hemostasis, cannula advancement, and distal flange deployment in collaboration with the Cornell College of Veterinary Medicine team (Figure 2). Ventricular access and initial advancement were achieved with hemostasis maintained. Tear-strip fracture prevented complete intraventricular flange deployment. Insertion depth and position were difficult to resolve, and echocardiographic assessment did not provide sufficient wall-thickness information for reliable placement. The principal failure mode was incomplete mechanical release, motivating revision of the delivery mechanism and improved control of insertion depth.

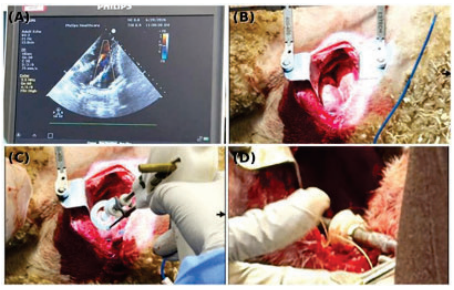

Figure 2: Acute ovine evaluation: (A) echocardiographic assessment, (B) LV apical exposure, (C) positioning of the delivery system, and (D) trigger-actuated deployment attempt. Distal flange deployment remained incomplete.

Delivery Mechanism Redesign

Alternative concepts included tubing-based confinement, telescopic components, and axial pusher mechanisms. The helmet-tip design used a distal cap to retain the compressed cannula during insertion. Relative axial displacement of the tip and cannula releases the flange for expansion (Figure 3). Design objectives were to eliminate the external tear-strip material, minimize the insertion profile, and separate tissue penetration from controlled flange release.

An ex vivo heart connected to a mock circulatory loop supported assessment of cannula placement and alternative delivery (Figure 4). Cap/helmet testing demonstrated flange expansion, although nonuniform silicone coating was associated with increased insertion friction. In one attempt, proximal displacement of the cannula relative to the tip caused premature release. This observation identified an interaction between coating uniformity, axial retention, and deployment timing. Reduced flange-coating thickness and a mechanical retention feature were proposed to limit unintended displacement during insertion.

Figure 3: Delivery-system development, left to right: current prototype, helmet-tip CAD concept, and sleeveless delivery tip.

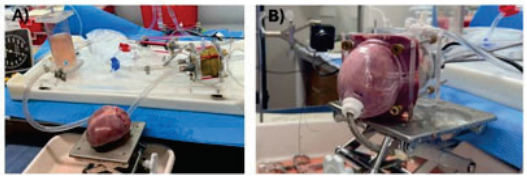

Figure 4: Ex vivo evaluation: (A) mock circulatory loop and (B) ventricular apex cannulation with an alternative delivery system.

Conclusions and Future Steps:

This work established a working MED-2014 dilution approach and identified how coating uniformity affects cannula delivery. Acute testing demonstrated ventricular access and hemostasis, while flange release remained the principal procedural limitation. The helmet-tip concept enabled ex vivo deployment. Next steps are to standardize coating thickness, evaluate a single flange-coating layer, measure insertion and retention forces, and repeat deployment testing with defined success criteria. Solvent removal and coating durability should be verified before further animal studies; long-term support will require an appropriately qualified material.

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