A NOVEL POLYMERIC HEART VALVE: MANUFACTURING AND HYDRODYNAMIC ASSESSMENT

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Introduction

The prevalence of valvular heart disease is increasing worldwide and is a major cause of morbidity and mortality [1]. Valve replacement, with mechanical or biological prosthetic valves, is a well-established treatment option for patients with significant valvulopathy. Polymeric heart valves (PHV) have been suggested as having the potential to replace mechanical and biological valves in the future [2]. Existing PHV manufacturing methods are varied and may result in inconsistent results.

Methods

We present a novel dip-casting approach for creating trileaflet PHV. We describe the preparation of a multi-solvent polyurethane solution that optimises the casting process. We evaluated the hydrodynamic performance of the crafted 25-mm polyurethane valve in a pulse duplicator according to ISO standards [3] and compared the results to a 25-mm St Jude Masters aortic mechanical valve and a 26-mm Medtronic Evolut bioprosthetic valve. Valves were tested at 70 bpm and at cardiac output of 3, 5 and 7 L/min. Effective orifice area (EOA), mean transvalvular pressure gradient (TPG) and regurgitant fraction (RF) were assessed compared between valves.

Results

The polyurethane valve (see Figure 1) markedly exceeded the minimum performance requirements for bioprosthetic aortic heart valves. The polyurethane valve had significantly higher EOA (ranging from 4.2 ± 0.1 cm^2 to 5.0 ± 0.1 cm^2) across the cardiac output range, compared to the Mechanical and Evolut valves (2.1 ± 0.1 cm^2 to 2.8 ± 0.1 cm^2 and 2.0 ± 0.1 cm^2 to 2.4 ± 0.1 cm^2, respectively; p <0.001). For all tested cardiac outputs, mean TPG was significantly lower in the polyurethane valve (ranging from 1.7 ± 0.1 mmHg to 2.8 ± 0.1 mmHg) compared to the Mechanical and Evolut valves (4.4 ± 0.1 mmHg to 7.4 ± 0.1 mmHg and 5.2 ± 0.1 mmHg to 11.6 ± 0.1 mmHg, respectively; p <0.001). Measures of RF were markedly lower in the polyurethane valve (ranging from 2.0 ± 0.8% to 3.0 ± 1.1%) compared to the Mechanical and Evolut valves (5.3 ± 0.6% to 10.9 ± 0.7% and 8.3 ± 0.9% to 12.7 ± 1.0%, respectively; p <0.001).

Figure 1: Final dip-casted 25-mm polyurethane valve.

Discussion

This study presents a novel dip-casting approach for the manufacture of prosthetic polyurethane heart valves. The hydrodynamic performance was very promising, demonstrating superior EOA, TPG, and RF compared to existing clinically approved mechanical and bioprosthetic valves. Thus, this innovative method of dip-casting offers considerable promise as a viable approach for manufacturing prosthetic heart valves.

References

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