Pioneering a Novel Synthetic Heart Valve

M.M. Kerr[1], C. McCormick[1], S. Reid[1], I. Stewart[2], S. McKee[2], H. Oliveiria[3], D.J.Wheatley[2]

[1] Department of Biomedical Engineering, University of Strathclyde, 106 Rottenrow East, Glasgow, G4 0NW.
[2] Department of Mathematics and Statistics, University of Glasgow, 26 Richmond Street, Glasgow G1 1XH
[3] Instituto de Ciências Matemáticas e de Computação - ICMC, Universidade de São Paulo - Campus de São Carlos, Caixa Postal 668, 13560-970 São Carlos-SP, Brasil.

Introduction

Cardiac valve disease results in a disruption to haemodynamics, with frequent progression to end stage heart failure if left untreated. Valve replacement restores function to the heart and thus represents a lifesaving procedure [1]. Synthetic heart valves combine the durability of mechanical valves with the haemocompatibility of bioprosthetic valves. However, challenges including calcification, leaflet tearing and poor surface morphology mean that they have yet to reach clinical translation. The design of the Wheatley Heart Valve (WHV, Figure 1a) differs considerably from existing polymeric heart valves as it can be mathematically defined through a series of contiguous circles [2]. This permits changes to the design to be parametrically investigated (by changing the radius of the free edge and leaflet height) and facilitates a sinus washout through helical flow as blood exists the aorta. Computational mathematical modelling, in vitro testing and advanced surface characterisation technologies are investigated to advance the WHV closer towards clinical translation.

Methods

The leaflets were fabricated from solvent cast films of Carbothane™, an aliphatic polyurethane elastomer, which are then laser cut into leaflets. Sintered titanium stents were produced through additive manufacturing and the leaflets attached at the base and commissures via mechanical fixtures to form a tri-leaflet valve having both a concave and convex free edge. Flow performance through the valve was investigated through both steady (Ansys Fluent) and time-dependent (LS-Dyna) computational fluid modelling. Experimental tests were conducted through use of an in-house built pulse duplicator, based on a 3-element Windkessel model and a durability tester (ViVitro HiCycle). Pressure readings were taken using a Biopac MP36 System.

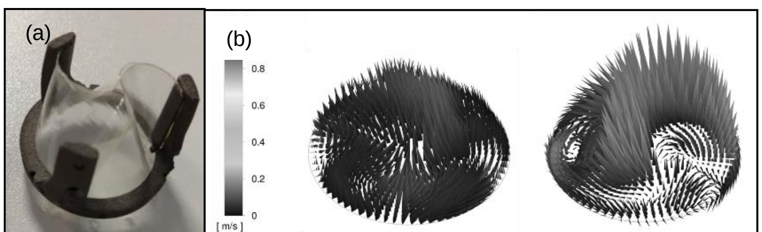

Figure 1 (a) Wheatley Heart Valve and (b) Velocity vectors downstream of forward nozzle according to Annex I of ISO 5840-1 (left) and the WHV demonstrating helical flow during steady state analysis (right).

Results & Discussion

Our steady state computational analysis confirmed that that the unique curvature of the WHV facilitates helical blood flow downstream of the valve (Figure 1(b)). Work is ongoing to optimise the leaflet properties of the WHV by conducting an iterative process between our mathematical models and our in vitro bench tests. Investigations are also underway to enhancing the surface properties with Diamond Like Carbon (DLC) coatings using an ECR (electron cyclotron resonance) ion beam deposition facility. DLC are a class of amorphous carbons having similar properties to diamond, containing a mixture of both sp^2 and sp^3 carbon-carbon interatomic bonds. They have gained interest in medical applications due to their chemical inertness, and similar platelet absorption to LTI carbon (currently used as coatings in mechanical valves). Early investigations have demonstrated good adhesion of DLC films having a thickness of approximately 100 nm on our polymer leaflets. Further work will explore their biocompatibility and mechanical characteristics to enhance the performance of the WHV.

Conclusion

The WHV is a novel synthetic heart valve with the potential to facilitate a washout of blood flow as the leaflets close. Testing is ongoing in accordance with ISO 5840-1 and -2 to advance the WHV towards clinical translation.

Acknowledgments

We are grateful to TENOVUS SCOTLAND for supporting this project. There are no conflicts of interest.

References

[1] A. Vahanian et al., Eur Heart J, vol. 43, no. 7, pp. 561–632, Feb. 2022
[2] S. McKee, et al, J Biomech Eng, vol. 143, no. 8, Aug. 2021