

VALIDATION OF A COMPUTATIONAL MODEL FOR A COMPOSITE BIOINSPIRED POLYMER VALVE LEAFLET

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Paper ID: 537

[Symposium S1: Mechanical behavior of polymers and biopolymers: theory, simulations and testing](#)

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Abstract

Introduction 12.4% of the elderly population suffer from Aortic Stenosis (AS), which carries a 50% mortality rate after two years for symptomatic patients if left untreated [1,2]. Treatments for AS, mechanical or bioprosthetic heart valves, both present significant drawbacks such as life-long anticoagulant treatment and low durability, respectively. Thus, biomimetic polymer heart valves have been proposed to deliver optimum valve haemodynamics and durability. This would allow for an anti-calcific, anti-thrombotic, durable, and minimally invasive device which has the potential to surpass all standard treatments. This leaves a wide range of potential designs and materials, for which finite element (FE) computational models can be utilised as a guide. This work proposes a computational-experimental pipeline for the systematic optimisation of 3D-printed polymer valve leaflets, providing an industrially relevant pathway for translation of polymer biomimetic valve concepts. Materials and methods A modelling framework has been developed to determine an optimal structure for fibre-embedded polymer valve leaflets [3]. This encompasses a paired FE modelling and design of experiments (DOE) approach which enables identification of potential optimal configurations of a polycaprolactone (PCL) fibre reinforcement structure embedded within polydimethylsiloxane (PDMS), which includes the number of layers, pore size, and angle of fibres. A combination

of additive manufacturing methods was used to fabricate a novel composite material. The valve leaflet matrix is composed of PDMS with a 16:1 base to curing agent ratio. A Hyrel printer (Hyrel3D, Atlanta, GA, USA) is used to print two layers of PDMS, between which a melt electrowriting (MEW) printer deposits a layered PCL fibre structure (20 μm -thick filaments). The deposited MEW fibres are laid according to the DOE defined configurations. These samples are mechanically tested in uniaxial tension and bulge inflation using an in-house bidirectional inflation rig [4]. The results are then compared to a uniaxial and bulge FE model. Results Based on the modelling framework, MEW fibre-reinforced PDMS samples of varying reinforcement structures have been successfully manufactured and tested at the target thickness of 0.3mm. [MEW v PDMS] Discussion Having shown the feasibility of manufacturing materials informed by the computational framework [3], the next step remains to fully calibrate the model through manufacturing and testing samples with remaining configurations. Additional configurations will then be used to validate the accuracy of the calibrated model. Ultimately, this work will yield a pipeline for the development of next generation polymer valves that can outperform the current commercial devices. Using the established computational model, an optimised bioinspired fibre structure will be determined [3]. Full valve leaflets will then be manufactured with the establish technique and optimised fibre configuration and tested using an industry-grade in-house pulse duplicator and accelerated wear tester. References 1. Osnabrugge (et al.), JACC, 2013. 2. Otto (et al.), NEJM, 2014. 3. Hughes (et al.), Biorxiv preprint, 2025. 4. Whelan (et al.), JMBBM, 2021.

Keywords:

Polymer Heart Valves Finite Element Analysis Melt Electrowriting (MEW)