

HVBTE 2025, London, Sept 17-19

Bioprocessing and in-vitro assessment of a biomimetic polymeric mitral valve

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Engineering mitral valve (MV) is challenging due to asymmetry, variable thickness, and dynamic motion, making standard electrospinning (ES) methods inadequate. We developed Double Component Deposition (DCD) ES to control scaffold anisotropy, thickness and mechanical properties.

This study combines in-silico modeling and in-vitro validation. Electric field (EF) simulations identified the optimal DCD deposition target, while fluid dynamic analysis defined the mandrel rotation axis to guide fiber alignment and anisotropic scaffold fabrication.

Both eccentric and non-eccentric setups were tested. Leaflet thickness distributions (N=3) were analyzed using heatmaps, showing more uniform deposition in the eccentric configuration for optimal DCD deposition target. Structural and functional anisotropy were quantified by biaxial mechanical testing, scanning electron microscopy, and digital image analysis, using the Orientation Index (OI, where 0.5 = random, 1 = fully aligned). A complete engineered MV (N=1, commissural distance 35 mm) with chordae was tested in a custom pulse duplicator system under physiological human pressure conditions (70 ml/stroke).

The eccentric setup combined with optimal DCD resulted in a more homogeneous EF, leaflet thickness within the desired range (400–600 μm , mean 525 μm), and high fiber alignment (OI = 0.69), closely replicating native MV tissue (OI = 0.68).

Hemodynamic testing showed a geometric orifice area (GOA) of 2.3 cm^2 and a regurgitation fraction (RF) of 7%, aligning with ISO 5840-2:2021 standards.

These results demonstrate that optimized DCD electrospinning enables fabrication of biomimetic MV leaflets with controlled thickness and anisotropy, achieving clinically relevant hemodynamic performance.