Engineering of bioinspired, polymeric, stent-less mitral valve: performance comparison of flat vs. saddle shaped annulus.

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Background: In the USA, mitral regurgitation (MR) affects 6% of adults >65 years old and it represents the most prevalent type of valvular disease. 65% of all MR patients are affected by functional (secondary) regurgitation, which is generally associated with a worse prognosis when compared to primary regurgitation. Rather than a leaflet disease, secondary MR, results from remodeling and malfunction of the left ventricle (LV), producing deficient coaptation of leaflets due to tethering of the papillary muscles (PMs). Current treatments to address this pathology include mitral valve (MV) repair or replacement, however, these patients must follow a life-long anticoagulant treatment and they may require additional surgical procedures due to a compromised harmonization of the LV-leaflet mechanics. MV replacement with currently available technologies alters the interaction with LV, due to the use of trileaflet valves, insertion of stents, flattening of the annulus and absence of the chordal apparatus (CA). To address these limitations, this work aims to evaluate the mechanics of two stent-less valve designs:**(FSA)** flat-shaped and **(SSA)** saddle-shaped annulus. The numerical models are meant to facilitate the design and fabrication of a polymeric mitral valve able to restore the native ventricle–leaflet continuum. In addition to the annular shape, this work assesses the optimal number and locations of chordae tendineae (CT) by evaluating tissue mechanics and organ-level function.

Methods: The biomechanics of the models is assessed in-silico by using Abaqus-explicit, where the two annular shapes are evaluated. The valves were attached to the ventricle by cords varying in insertion points, in quantity (2,4,6,8) and length (80,100,120%, of the native length), for a total of n=48 configurations, 24 FSA and 24 SSA designs. Leaflets and cords were modelled with structural elements, shell (S4) and truss (T3D2), respectively. In both parts, the material was modeled with isotropic behavior (Yeoh) and with mass Rayleigh damping. The annulus and PMs are static, with PMs held in systolic position. The leaflets were loaded with physiological atrial and ventricular timewise pressure. Multiple steps of cyclic pressure were applied over the valve until the cardiac cycle reached the steady state.

Results: MVs with SSA generally showed lower stresses than FSA valves with delta-stress (max-min von Mises equal) equal to 1.7-MPa and 2.7-MPa, respectively. The stress peaks were in the commissural region and chordae insertion points. Bending deformation index was equal to 0.7 while the orifice area was estimated as 2.5-cm^2 for both the geometries. The valve designs that included two cords only presented the highest stresses and leaflet prolapse.

Conclusions: Overall, this work shows that the SSA architecture has lower magnitude and more homogeneous stress maps than the FSA model. The comparative analysis of the CA showed that two cords are not enough to confer mechanical stability to the engineered valve with at least four cords being necessary to provide good function. Also, is estimated that six cords may be the maximum needed for the engineered valve apparatus, as the stress-strain distribution for the configurations with six and eight cords did not significantly differ when compared to the four cord design.

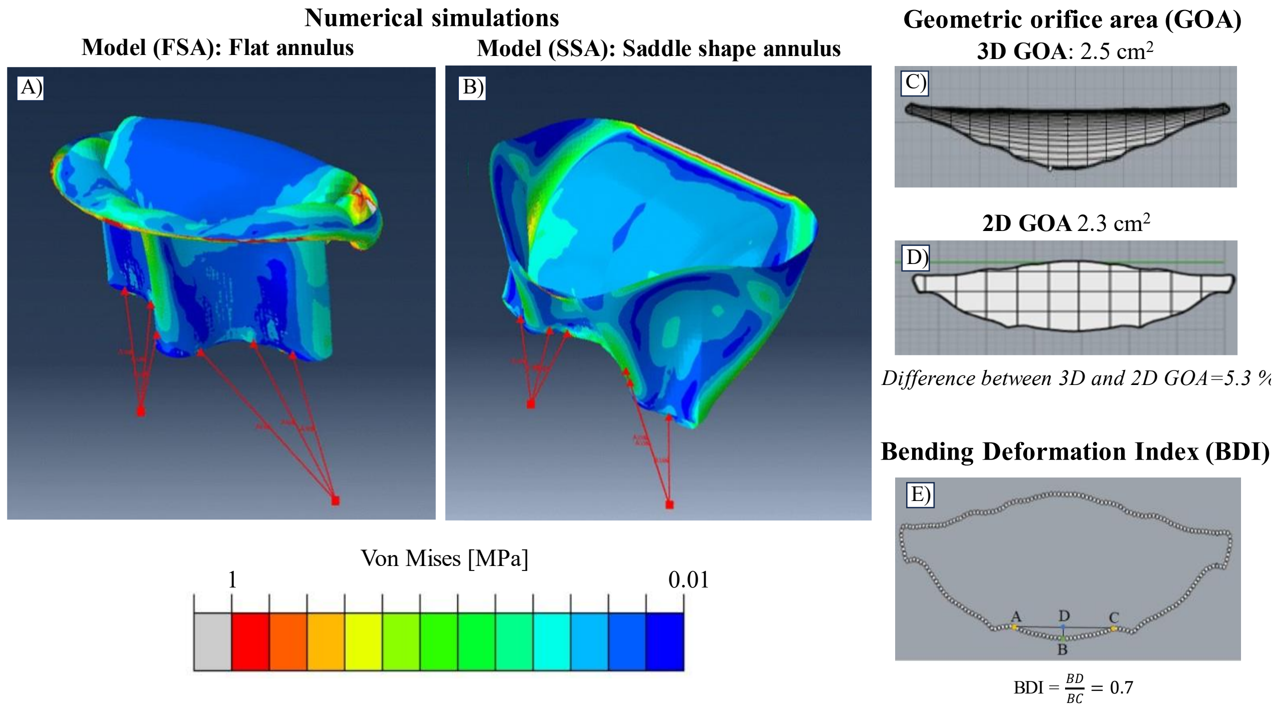

Figure 1 – Example of metrics utilized for the comparative evaluation of the different MV designs. A) *von Mises stress distribution in model FSA with flat annuls, 6 chordae and 100% of the native chordal length.* ***B)*** *von Mises stress distribution in model SS) with physiological-inspired lateral saddle shape.* ***C)*** *geometric orifice area for the FSA configuration.* ***D)*** *geometric orifice area for the FSA configuration.* ***E)*** *Bending deformation index for the FSA configuration.*