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In vitro quantification of mechanical strain in silicon mitral valve

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1. Introduction

Mitral valve regurgitation (MR), defined by a backward flow from the left ventricle to the left atrium in systolic cardiac phase, affects over 10% of the population aged over 70 years (Nkomo et al., 2006). Even though surgical interventions are considered the gold standard, 49% of these patients are denied this intervention due to high surgical risks (Mirabel et al., 2007). To treat these patients, new percutaneous interventions have emerged, but their biomechanical consequences on the mitral apparatus remain unclear. Patient-specific treatment may be the key to quantifying and improving these biomechanical consequences. This study focuses on quantifying the mechanical strain applied on silicon mitral valve (MV) for future patient-specific applications. To validate silicon MVs, mechanical strain will be compared with commercial hydrogel MV used for surgical training and from *in vivo* MV strains described in (El-Tallawi et al., 2021).

2. Methods

2.1 Silicon mitral valve development

Anatomical characteristics of the silicon MVs were based on Lifelike MV (Lifelike BioTissue., CA) that was imaged with desktop micro-CT scanner (NanoScan PET-CT, Mediso). 3DSlicer was used to segment the MV images and create a 3D negative mold on Meshmixer (Autodesk Inc., USA). The mold was then 3D printed (Lulzbot Inc., USA) with an elastic filament (NinjaFlex, NinjaTek 3D, USA) for an eased extraction of the silicon MVs. 18 different combinations of silicon (EcoFlex00-30 (EF30), EcoFlex00-50 (EF50), DragonSkin10 (DS10), DragonSkin20 (DS20), Smooth-On Inc., USA) were then poured layer by layer in the 3D-printed mold. To ensure the biomechanical behavior of silicon MVs, mitral chordae were inserted between the silicon layers using six de-braided polyester strings per valve (Gütterman GmbH, Germany).

2.2 Hemodynamic testing

To validate rheological behavior of silicon MVs, a double activation left heart duplicator system was used (Tanné et al., 2010). Each of the silicon MVs was tested under physiological conditions with a stroke volume of 70 mL, heart rate of 70 bpm and a mean aortic pressure of 100 mmHg. Blood viscosity was reproduced using a saline glycerol solution fixed at 3.8cP at 37°C. Healthy physiological hemodynamical behavior of silicon MVs was defined as: mean pressure gradient (MPG)<2 mmHg and effective orifice area (EOA)>4 cm² (Omran et al., 2011). Hemodynamical responses of each model were analyzed from doppler continuous waves collected by transthoracic echocardiography (Vivid 7, GE Healthcare).

2.3 Biomechanical quantification

MVs' leaflet motion was recorded with two high-speed cameras (FASTCAM Mini AX50, Photron Inc., USA). Measurement of strain was performed using a noncontact optical 3D digital image correlation method conducted with a commercial system (VIC-3D; Correlated

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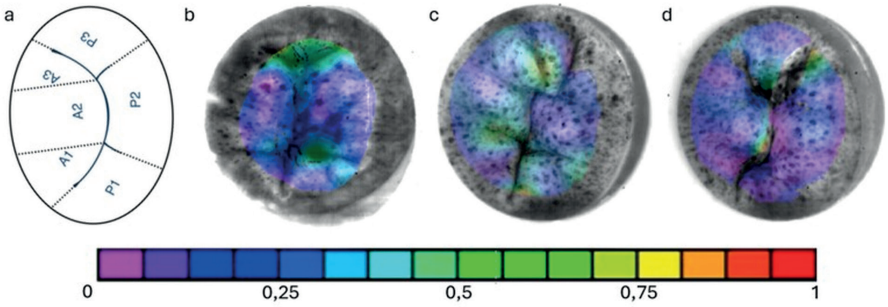

Figure 1. Strain repartition: (a) schematic representation of the leaflet segments (b) Lifelike (c) V1 (d) V2.

Solutions, Inc., USA). To ensure high reliability, a double calibration was realized before each computation. Lagrangian strains were calculated on the whole surface of the leaflet using the 3D dataset. The displacement of each leaflet segment (A1, A2, A3, P1, P2, P3) during systole was used to calculate mitral prolapse.

3. Results and discussion

3.1 Hemodynamical results

Based on the hemodynamical cut-offs chosen to validate physiological behavior of a healthy MV, only two combination of silicon MVs (EF30/DS10/EF30 (V1) and EF50/DS10/EF50 (V2)) had a MPG <2 mmHg (1.81±0.12 mmHg vs 1.67±0.22 mmHg respectively) and a EOA>4cm² (4.81±0.15 cm² vs 5.05±0.35 cm² respectively).

3.2 Biomechanical quantification

The major principal Lagrangian strain (Ɛ1) and average displacement in Z of each segment were analyzed during the systolic phase (*i.e* valve closed) because during this phase, the MV leaflets were subjected to higher strains. The local strain distribution and displacement was analyzed for each anatomical region of MV (Figure 1, Table1).

Higher strain is triggered in the commissural junction of the leaflet (A3-P3) and between the different segment areas in the Lifelike MV (Figure 1). Similar strain repartition seems to be found in V2 but seems to be higher in V1 belly regions. V2 induced lower strains than V1 ($p<0.001$) and LifeLike ($p<0.001$) and was comparable to *in vivo* studies. Highest strains were induced in A3 segment for Lifelike and V1 MVs whereas for V2 MV the highest values were found in P3 segment (0.39±0.23 vs 0.32±0.06 vs 0.16±0.06 respectively). Mitral Valve prolapse defined as mitral valve displacement more than 2 mm above the mitral annulus was found only in A2 region of V2 silicone MV.

4. Conclusions

This study aimed to reproduce the physiological behavior of healthy native mitral valve in regard to hemodynamics and biomechanical properties. Only two silicon combinations out of 18 reproduced the hemodynamical behavior of healthy native mitral valve based on clinical criteria. The strain repartition induced by the V2 MV

Table 1. Major principal strain (Ɛ1) and Z displacement (mm) of each leaflet segment.

Parameters	Ɛ1						Z_{max}					
Segments	A1	A2	A3	P1	P2	P3	A1	A2	A3	P1	P2	P3
Lifelike	0.15	0.15	0.39	0.20	0.17	0.36	0.03	0.19	0.19	0.30	0.36	0.02
V1	0.21	0.26	0.32	0.28	0.19	0.26	1.25	2.32	1.77	1.25	0.89	1.35
V2	0.08	0.13	0.13	0.09	0.10	0.16	0.36	1.33	0.57	0.80	0.30	0.89
In vivo	0.09			0.08			-					

was similar to the strain repartition of the Lifelike and was the closest one to the *in vivo* strain quantification. In addition, V2 mitral valve did not present leaflet prolapse unlike V1 mitral valve and thus we suggest that this silicon combination could be used for future purposes of patient specific applications. Limitation can be found in Lifelike strain quantification which did not match reported *in vivo* strain quantification but can be explained by the rigidification of this hydrogel mitral valve due to a long period of use.

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