innovation

A novel method to quantitate bioprosthetic valve leaflet mechanical stress: a numerical and in vitro study

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KEYWORDS

- clinical research
- innovation
- miscellaneous
- other
- TAVI

Abstract

An original *in vitro*/*in silico* method was developed to estimate the local and global mechanical stress applied on the bioprosthetic valve leaflet, which can be important for better understanding of the valve durability. A non-contact system based on stereophotogammetry and digital image correlation enabled filming and studying the valve leaflet movement frame by frame and performing three-dimensional analysis. The deformation was applied in a finite element model in order to calculate the local mechanical stress applied. High stress regions were primarily observed in the upper leaflet edge and belly and to a lesser extent at the free leaflet edge.

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Abbreviations

3D	three-dimensional
DIC	digital image correlation
FE	finite element
SAVR	surgical aortic valve replacement
SVD	structural valve deterioration
TAVI	transcatheter aortic valve implantation

Introduction

The main limitation of bioprosthetic valves used for surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI) is their limited durability due to structural valve degeneration (SVD), which implies a risk of valve reintervention. The main determinant of SVD is the repetitive mechanical stress imposed on the bioprosthetic valve leaflets[1]. The objective of this *in vitro*/*in silico* study was to propose a novel method to assess the strain and mechanical stress applied on the bioprosthetic valve leaflets during the cardiac cycle.

Methods

Stress computation is based on coupling an experimental method based on non-contact digital image correlation (DIC) and finite element (FE) modelling **(Figure 1)**.

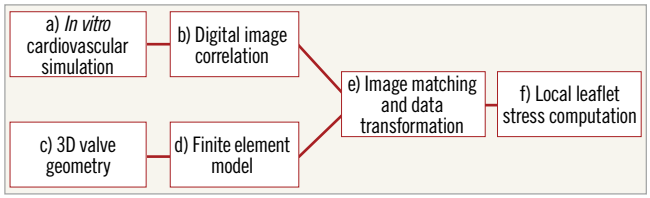

Figure 1. *Implementation of experimental results into the FE model. Schematic diagram of a novel method for calculation and a preliminary evaluation of mechanical stress.*

IN VITRO CARDIOVASCULAR SIMULATION

For the purpose of this study, a double activation left heart duplicator system[2] was used. This system includes anatomically shaped, deformable silicone moulds of left heart cavities and a glass aorta that enables optimal visualisation of valve leaflets **(Supplementary Appendix 1, Supplementary Figure 1-Supplementary Figure 3)**. The aortic valve used in this feasibility study was a surgical stent pericardial bioprosthesis (Trifecta™ 25 mm; St. Jude Medical, St. Paul, MN, USA).

DIGITAL IMAGE CORRELATION

To obtain a high contrast stochastic pattern for the use of DIC, a fine speckle pattern using a black tissue dye (Shandon™ Tissue Marking Dye; Thermo Fisher Scientific, Waltham, MA, USA) was applied to the leaflet surface **(Figure 2)**. The leaflet motion was recorded with two high-speed cameras (2,000 img/sec) (FASTCAM SA3; Photron, Inc., San Diego, CA, USA), equipped with 105 mm lenses (EF 24 Reflex lenses; Sigma Corporation, Kanagawa, Japan) **(Supplementary Figure 4)**.

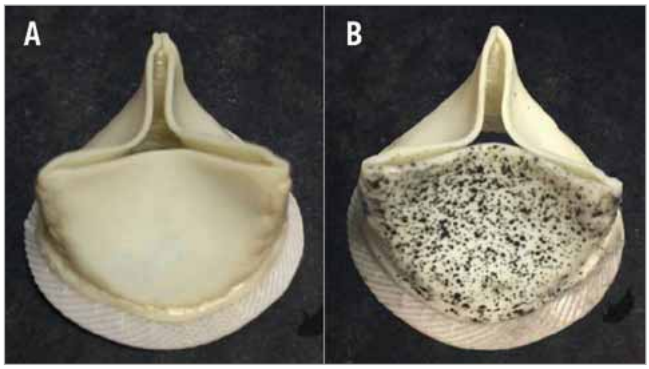

Figure 2. *The surgical bioprosthesis before (A) and after (B) the speckle pattern application. Approximately 1,500 speckle points are applied on the surface of the leaflet.*

Measurement of point displacement was performed using a non-contact optical three-dimensional (3D) DIC method conducted with a commercial system (VIC-3D; Correlated Solutions, Inc., Irmo, SC, USA). This technique allowed direct assessment of the deformation field of the valve leaflet **(Figure 3)**. Local strain was assessed through a section line following the curved surface of the leaflet, and the global strain was computed over the whole surface of the leaflet.

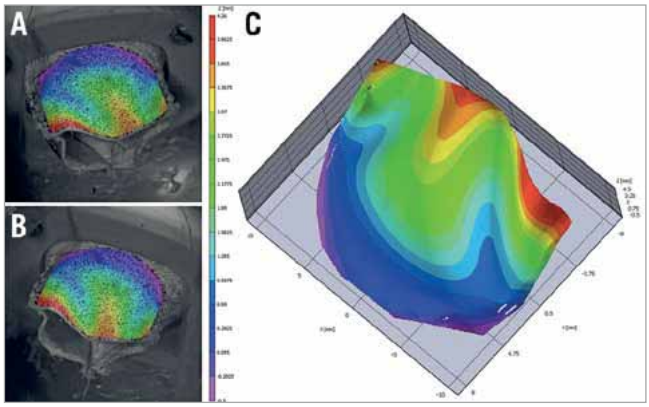

Figure 3. *Creation of three-dimensional surface. A) Left camera view. B) Right camera view. C) 3D surface reconstruction.*

LEAFLET NUMERICAL MODEL

The Trifecta valve was imaged with a desktop micro-computed tomography scanner (microCT-40; Scanco Medical AG, Wangen-Brüttisellen, Switzerland) **(Figure 4A)**. The high-resolution images were imported into a 3D Slicer (open platform for subject-specific image analysis) to create a 3D valve model in stereolithography format **(Figure 4B)**. The finalised surfaces were imported into HyperMesh™ (Altair HyperWorks; Altair Engineering, Troy, MI, USA) to generate a surface mesh **(Figure 4C)** with accurate size *ex vivo*.

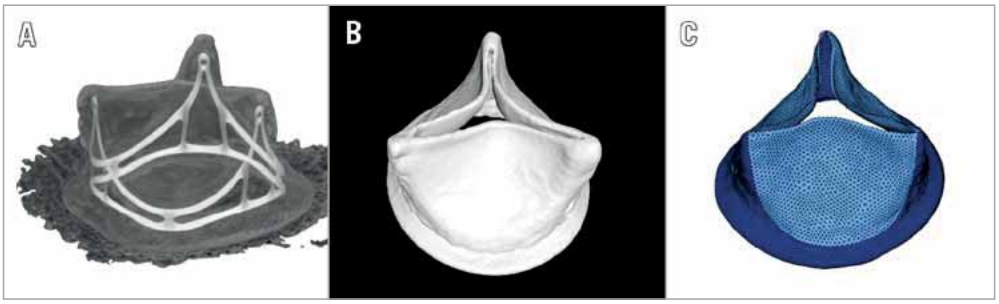

Figure 4. *Creation of finite element model. There are three steps. A) DICOM image. B) Creation of 3D model/.stl file after 3D Slicer reconstruction. C) Final surface mesh created in HyperMesh.*

Stent and skirt geometry were considered a rigid body. Leaflet geometry was modelled using two-dimensional (2D) shell elements. The symmetric impact contact definition was chosen for leaflet-to-leaflet contact to avoid leaflet penetration. FE simulations were performed using RADIOSS™ (Altair Engineering).

A biaxial stretch testing was performed on a homemade rake-based planar biaxial tensile testing device[3] to determine the material properties of the Trifecta valve. Leaflet thickness was measured using SmartScope® MVP (OGP, Rochester, NY, USA) with a resolution <5 µm. The properties data set used in the FE model is shown in **Supplementary Table 1**.

IMAGE MATCHING AND DATA TRANSFORMATION

The 3D data alignment was performed using MeshLab (open-source mesh processing tool, 2008) by matching the point cloud extracted from the first moment of analysed VIC-3D data to numerical surface mesh (HyperMesh). A custom-made Matlab (MATLAB R2015a; The MathWorks, Inc., Natick, MA, USA) program was coded to apply the data transformation **(Supplementary Figure 5)** and create a file to contain all displacements applied on each chosen node in x,y,z direction as a function over time. This 3D data set was then used to perform FE simulations.

Results

DIGITAL IMAGE CORRELATION

The accuracy for the DIC was 0.0011 mm. The maximum major principal strain was observed during leaflet closing near the leaflet commissures (35%) and at the upper part of the belly (27%) **(Figure 5)**. The average value of maximum major principal strain across the leaflet was 4%.

FINITE ELEMENT ANALYSIS

The displacement of the leaflet during opening and closing is displayed in **Figure 6**.

During opening, the higher stress occurs at the commissures and, to a lesser extent, in the upper part of the belly of the leaflet **(Figure 7)**. When the valve is fully open, the maximum stress is observed at the commissures and at the belly of the leaflet and to a lesser extent at the free edge. The maximum principal stress reached 1.97 MPa. During closing, high stress regions were primarily observed at the commissures and in the middle of the belly of the leaflet (1.06 MPa).

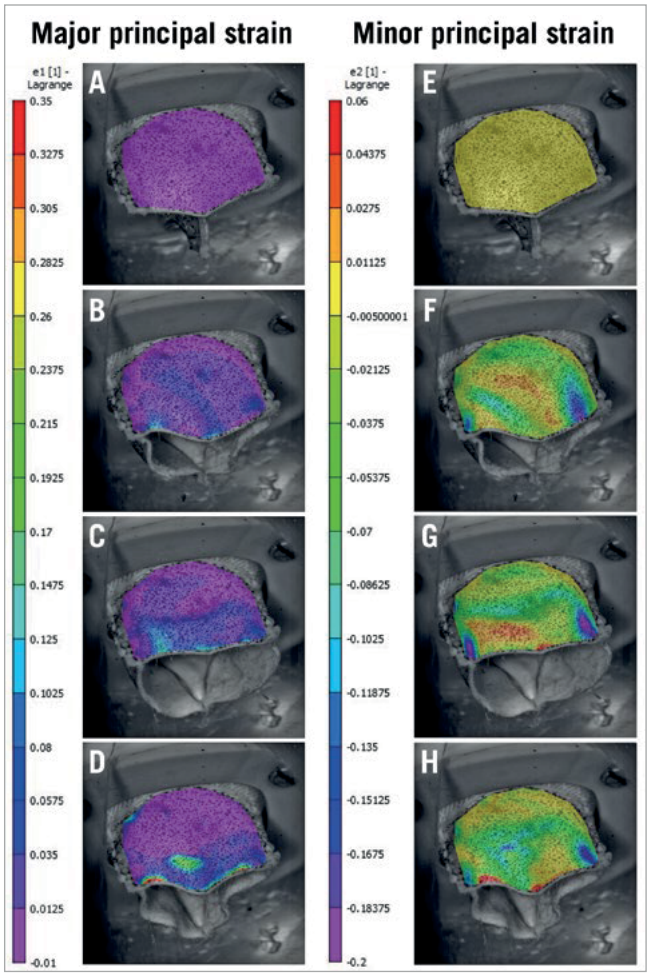

Figure 5. *Development of major and minor principal strain during valve leaflet opening and closing. A) & E) Strain distribution in the initial reference image (closed valve). B) & F) Leaflet opening. C) & G) Leaflet at fully open position. D) & H) Leaflet closing. Positive signs in strain describe tensions and negative signs the compression.*

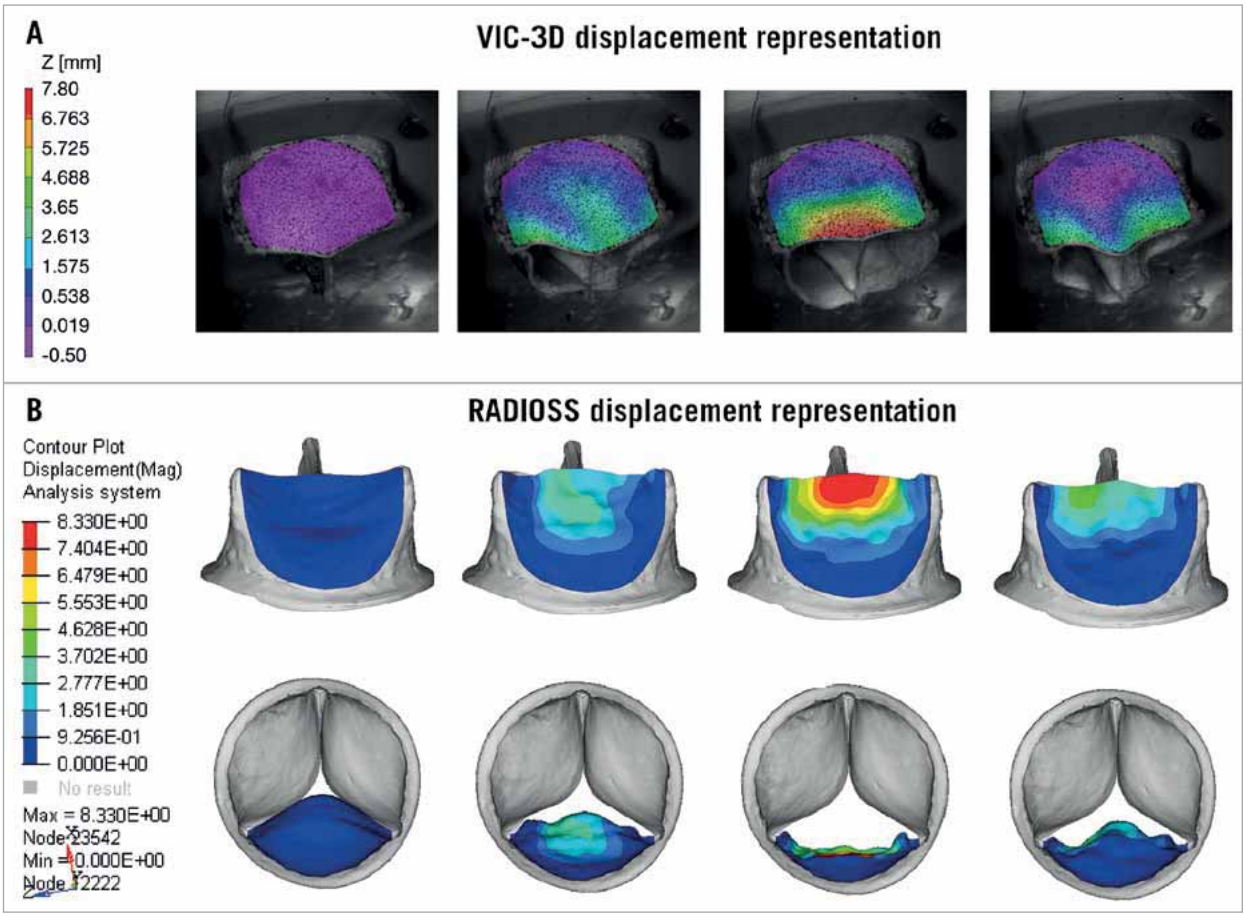

Figure 6. *Displacement representation of opening and closing of the leaflet. A) VIC-3D. B) HyperMesh. The red and orange areas represent high values, whereas the violet and blue areas represent low values.*

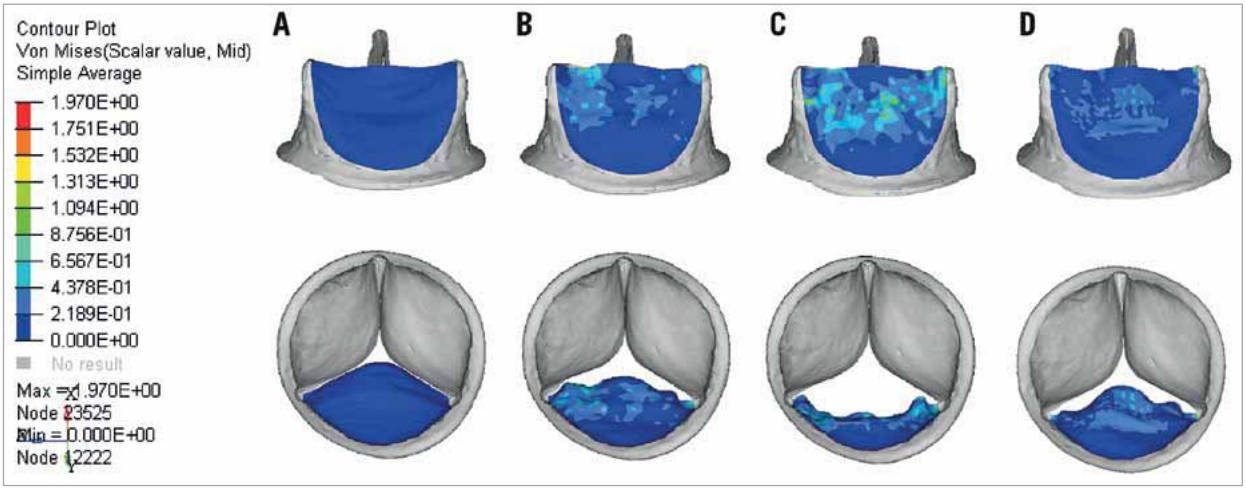

Figure 7. *FE model for leaflet stress distribution. A) Leaflet coaptation. B) Leaflet opening. C) Leaflet at fully open position. D) Leaflet closing. The red and orange areas represent high values, whereas the blue areas represent low values.*

Discussion

The novel method that we proposed by coupling *in vitro* experiments and numerical simulation allows accurate assessment of the magnitude and distribution of the leaflet stress during the different phases of the cardiac cycle. Compared to previously proposed methods, our method measures the real displacement of the leaflet tissue and thus has the potential advantage of being more accurate in estimating the magnitude and distribution of the leaflet mechanical stress. In this

study, we assessed the feasibility of this new method in one leaflet of one model and size of SAVR valve. The results show that the higher leaflet strain and stress are observed at and near the commissures during the opening phase, at the commissures and belly when the valve is fully open, and at the belly during the closing phase.

Limitations

We present the results of only one leaflet (one model and size of surgical valve). The next step is to extend the analysis to the three leaflets to: i) be able to simulate the full leaflet closure during diastole, ii) determine the heterogeneity in the magnitude and distribution of the stress among the three leaflets.

Conclusion

Recent studies using a definition of SVD based on the evidence of valve morphologic and haemodynamic deterioration during echocardiographic follow-up revealed an incidence of SVD >30% at 10 years following SAVR[4]. For TAVI valves, the results of mid-term (five to seven years) durability are encouraging but long-term data are not available. The novel *in vitro*/*in silico* method can provide a useful tool to determine the magnitude and distribution of the leaflet strain and stress during the cardiac cycle.

Impact on daily practice

This method provides useful information that may help to predict the durability of a given model and size of bioprosthetic valve in different conditions relevant to the clinical context. In particular, the measurement of leaflet strain and stress in the context of TAVI oversizing and thus underdeployment or undersizing and overexpansion would inform on which conditions may worsen the leaflet stress and thus impair the long-term valve durability.

Conflict of interest statement

P. Pibarot reports receiving research grants from Edwards Lifesciences and Medtronic. R. Rieu reports receiving research grants from Medtronic. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. Methods.

Supplementary Figure 1. Suboptimal leaflet visualisation through a silicone-made aorta.

Supplementary Figure 2. Schema of glass aortic root and ideal camera position.

Supplementary Figure 3. Leaflet visualisation through a glass aorta.

Supplementary Figure 4. High-speed camera views of the valve leaflet.

Supplementary Figure 5. 3D data alignment.

Supplementary Table 1. Properties data set used in the FE model.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-19-00327

Supplementary data

Supplementary Appendix 1. Methods

In vitro cardiovascular simulation - rationale for using a glass aorta

For this study, it was essential to obtain an optimal visualisation of the bioprosthetic valve leaflets. When the valve was implanted in a silicone-made root, only 65% of the valve leaflets was analysable, as the lower part of the valve was not visible simultaneously by both high-speed cameras **(Supplementary Figure 1)**. Furthermore, high-speed camera imaging was performed through many different refractive interfaces (Air – Glass – Water – Silicone – Water), which is not recommended for DIC. The small diameter of the silicone aorta did not allow calibration within the aorta, which caused a difference in refractive interface between calibration and leaflet motion acquisition. Motion of the wall of the compliant silicone aortic root during the cardiac cycle could interfere with the DIC analysis.

We developed a glass aorta to optimise visualisation of the valve leaflets **(Supplementary Figure 2)**. The tubular ascending aorta had the same diameter as the sinuses of Valsalva, thus creating a "tube" with a flat wall surface that permitted a calibration inside the aorta and therefore caused no difference in refractive interface between calibration and leaflet motion acquisition (good precision and accuracy). The number of refractive images went from 5 to 3 (Air – Glass – Water). The VIC-3D 8 option called Variable Ray Origin can be used to make accurate the DIC measurements through glass and glass/water interfaces.

Compliant chambers were added downstream of this non-compliant glass-made aorta to obtain physiologic flow and pressure waveforms similar to those with a compliant aorta.

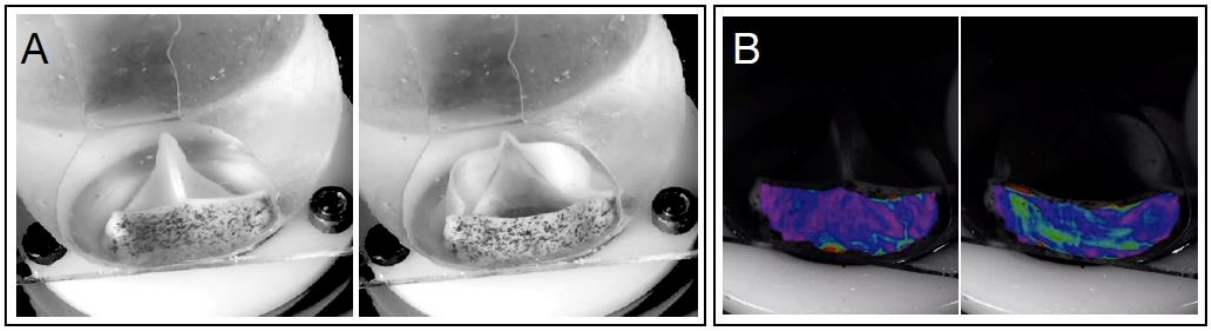
This glass aorta enabled visualisation and analysis of 100% of the leaflet with good accuracy **(Supplementary Figure 3)**.

Image matching and data transformation

The 3D data alignment phase was the first step of the displacement transformation. MeshLab, an open source software, provides a powerful tool for moving the different meshes into a common reference system, able to manage a large set of range maps. The alignment was

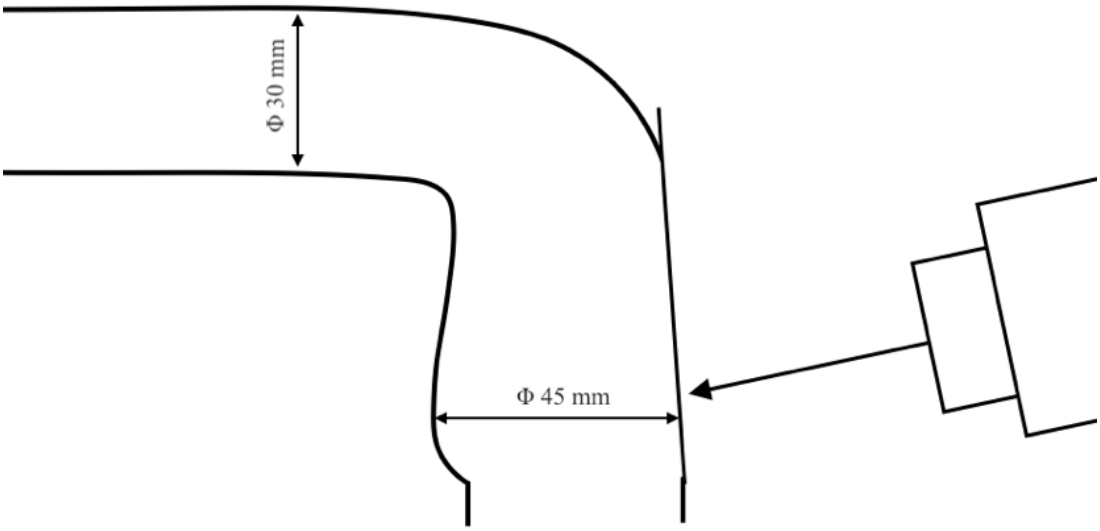
performed by matching the point cloud extracted from the first moment of analysed VIC-3D data (closed leaflets) to numerical surface mesh exported from HyperMesh and then compared using Hausdorff distance. Once the point cloud and surface mesh were successfully aligned, the transformation matrix was saved. A custom-made Matlab (MathWorks) program was then coded and subdivided into four principal functions:

- Reading and importing two STL files containing the 3D coordinates point cloud from VIC-3D analysis and the 3D node coordinates of surface mesh from HyperMesh **(Supplementary Figure 5A)**.
- Collecting the transformation matrix from the MeshLab file and performing the alignment of imported files **(Supplementary Figure 5B)** and a supplementary comparison using the maximum distance of a set to the nearest point in the other set. A sub-function was then applied to transform the three-dimensional displacement field acquired by VIC-3D analysis at each moment of the cycle. A total of 600 files (displacement fields) were transformed.
- Applying the 3D displacement field on the surface mesh nodes. This function was personalised so that the user can either choose to apply it on every node of the surface mesh, or on every second, third, fourth node, etc., which helps to speed up the FE calculation. Several tests were performed to determine the minimal number of nodes on which the displacement could be applied; this number was fixed by choosing every third node (400 nodes) to reduce the time of numerical analysis.
- Creating a file that contains all displacements applied on each chosen node in x, y, z direction as a function over time and including it in the RADIOSS file in order to perform the FE simulation.

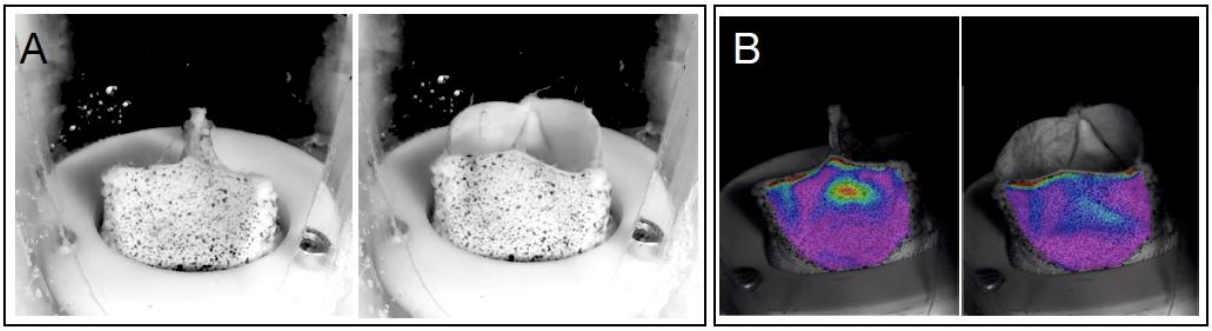


Supplementary Figure 1. Suboptimal leaflet visualisation through a silicone-made aorta.

A) Leaflet visualisation. B) Major principal strain computation with “aliasing”.

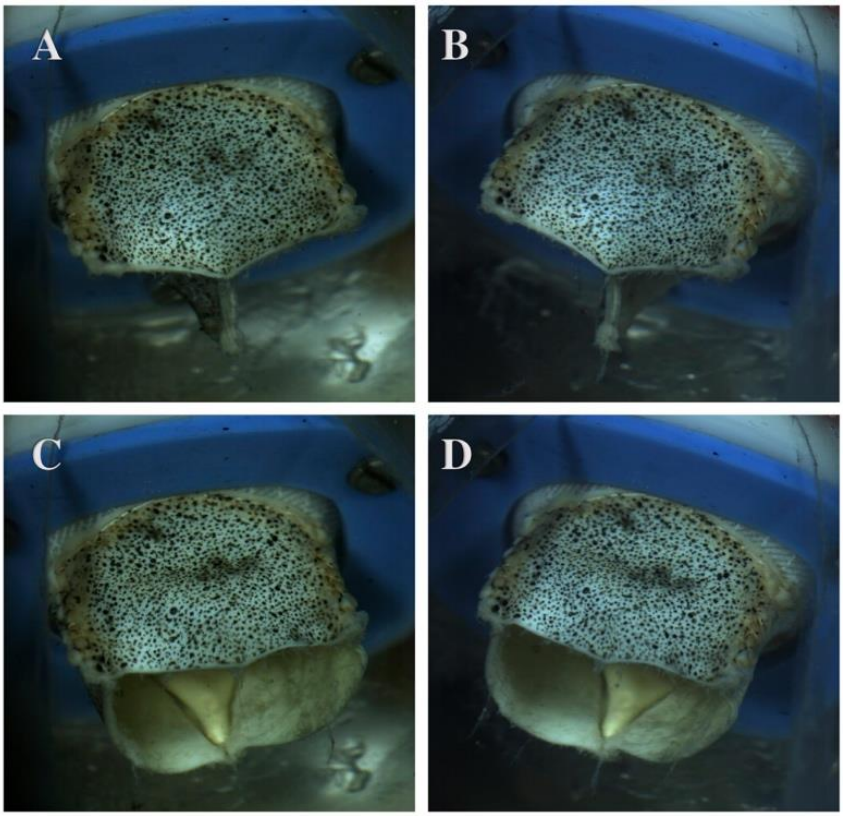


Supplementary Figure 2. Schema of glass aortic root and ideal camera position.



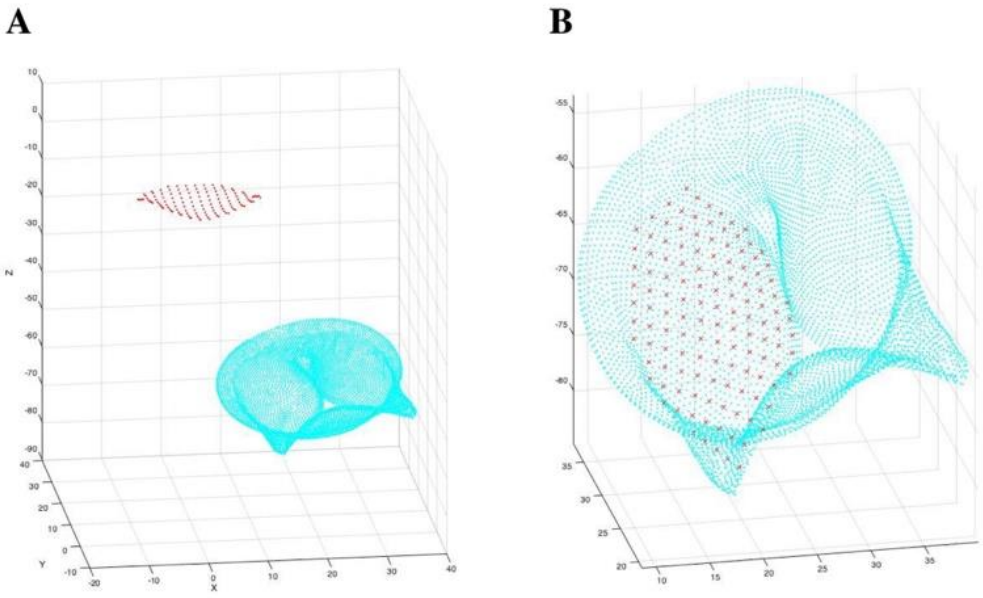
Supplementary Figure 3. Leaflet visualisation through a glass aorta.

A) Optimal leaflet visualisation. B) Major principal strain computation.



Supplementary Figure 4. High-speed camera views of the valve leaflet.

Coated leaflet of the valve seen from the *en face* view; closed position from left (A) and right (B) cameras and opened position from left (C) and right (D) cameras.



Supplementary Figure 5. 3D data alignment.

A) 3D coordinates point cloud from VIC-3D (red) and the surface mesh from HyperMesh (cyan) in their original reference system. B) 3D coordinates point cloud from VIC-3D aligned in the reference system of surface mesh.

Supplementary Table 1. Properties data set used in the FE model.

Property	Value
Thickness	0.15 mm
Young modulus	1.8 MPa
Poisson ratio	0.45
Density	1.100 kg/m^3