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IMPACT OF BIOPROSTHETIC VALVE LEAFLET STIFFNESS AND ANISOTROPY ON TAVR STENT FATIGUE LIFE

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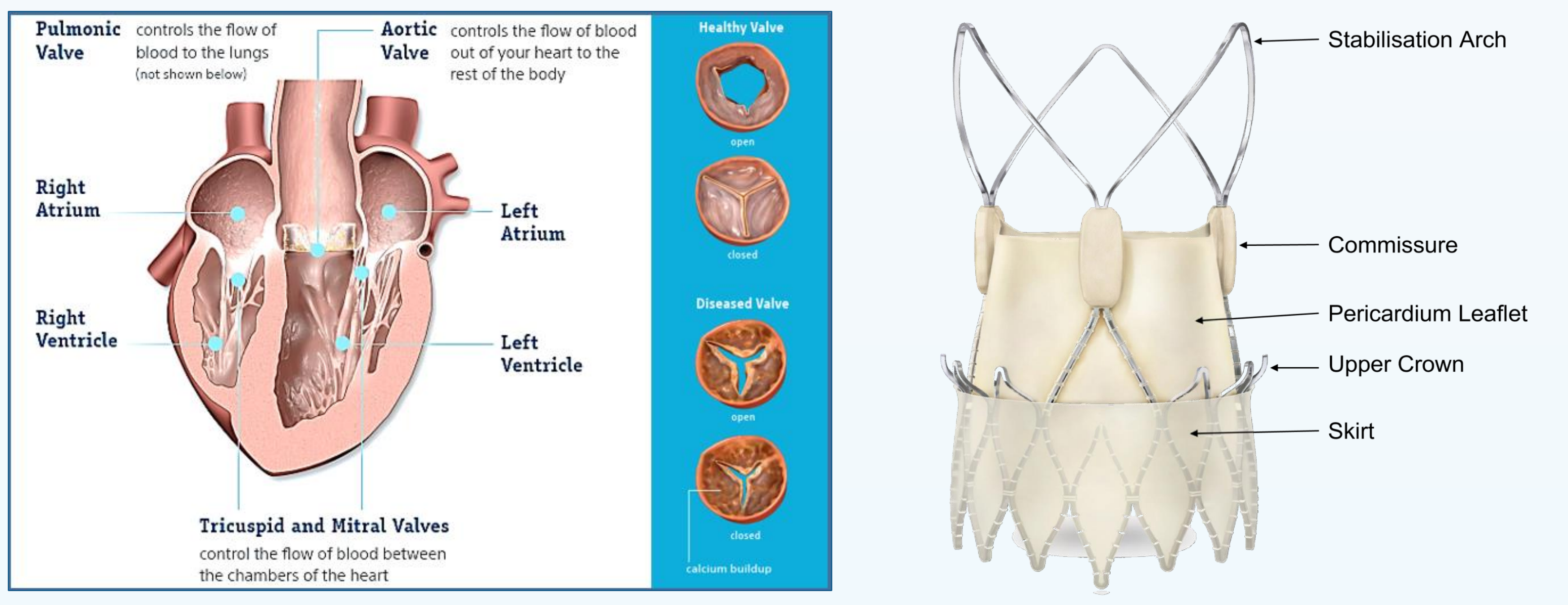
Towards developing a simulation methodology for the design of next-generation Transcatheter Aortic Valve Replacement (TAVR) devices, this numerical study investigates the impact of bioprosthetic valve stiffness and anisotropic behaviour on the fatigue of the nitinol stent frame during a single cardiac cycle.

INTRODUCTION

The aortic valve is the heart valve located between the left ventricle and the aorta. This valve is susceptible to diseases such as aortic stenosis (see Figure 1). Transcatheter Aortic Valve Replacement (TAVR) is an effective, less-invasive treatment for high- and intermediate-risk patients suffering from aortic valve diseases [1].



**Courtesy of Boston Scientific*

Figure 1: Overview of aorta and aortic stenosis (left) and the Boston Scientific ACURATE neo2^{TM} TAVR (right)

A self-expanding nitinol stent TAVR with attached porcine pericardium (PP) valve leaflets (Figure 1) is considered in this study. Variations in leaflet stiffness can be as large as two orders of magnitude and dependent on various factors, including pericardium source, leaflet chemical preservation treatment and collagen fibre orientation within the leaflets. It is also well-known that PP tissue used for the prosthetic valves exhibits mechanical anisotropy [2].

This study aims to establish the effects that leaflet stiffness and anisotropy have on the nitinol stent frame fatigue.

METHODOLOGY

An explicit dynamics finite element model of the nitinol stent with attached PP leaflets was built in Abaqus 2022. The model was used to evaluate the deflection and corresponding stresses of the stent frame commissures due to the haemodynamic pressure loads acting on the leaflets for a single cardiac cycle. The simulation results were compared to *in vitro* testing of the device in a ViVitro pulse duplicator (Figure 2). A high-speed camera was used to track stent commissure deflections while the valve was loaded in the pulse duplicator.

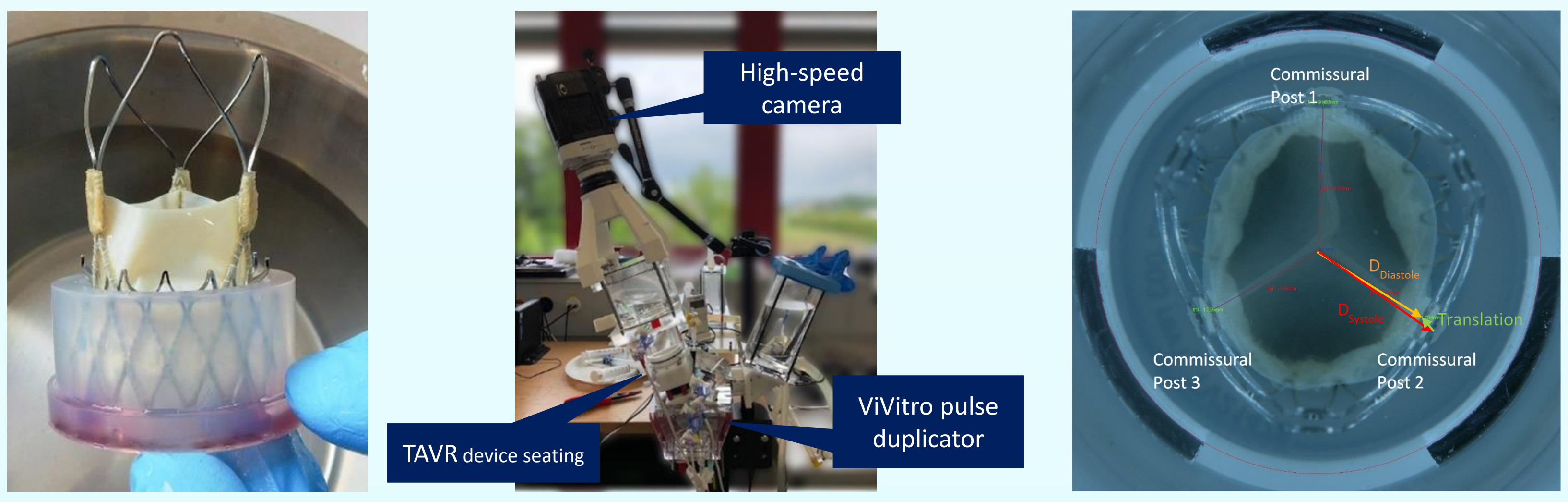
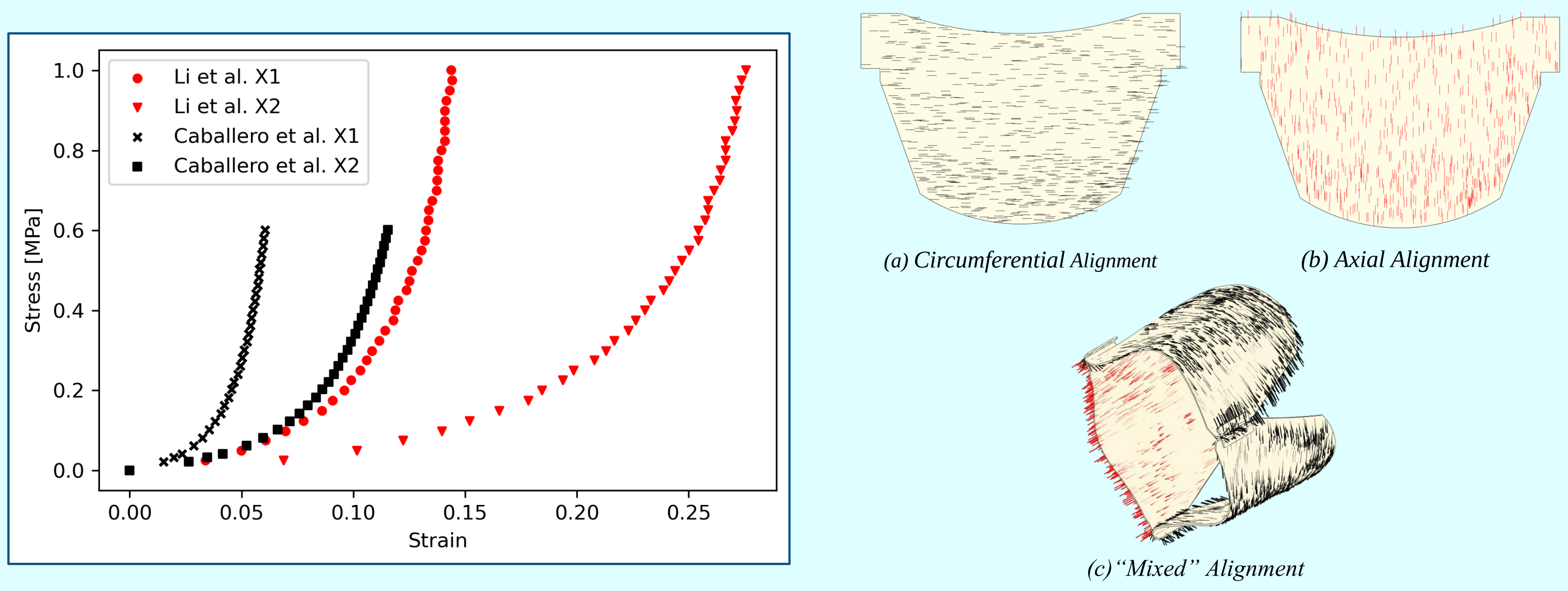


Figure 2: The TAVR device in the aortic root seating (left), the ViVitro pulse duplicator with attached high-speed camera for in vitro testing (middle) and the commissure deflection measurements of the device during operation (right)

The nitinol stent frame is modelled as a super-elastic shape memory alloy based on experimental testing performed by Boston Scientific. The PP leaflet behaviour is taken from two sources, namely Li et al. [3] and Caballero et al. [4]. The two sources represent the stark differences in porcine pericardium compliance. Stress-strain curves for the material (Figure 3) have two directions, "X1" representing stiffness parallel to collagen fibres and "X2" representing stiffness perpendicular to the fibres. The anisotropic HGO model [5] was used to fit the experimental X1 and X2 curves with a single set of material parameters.

Since collagen fibre alignment in the leaflets is not explicitly tracked during the construction of the TAVR devices, the sensitivity of the device behaviour to leaflet fibre alignment was studied with the following variations:

- All three leaflets have collagen fibres aligned in the circumferential direction (Figure 3a)
- All three leaflets have collagen fibres aligned in the axial direction (Figure 3b)
- Two leaflets have collagen fibres aligned circumferentially; one leaflet has fibres aligned axially (referred to as "mixed" – see Figure 3c)



(a) Circumferential Alignment
(b) Axial Alignment
(c) "Mixed" Alignment

Figure 3: Two material stress-strain curves for porcine pericardium leaflets (left) and pericardium leaflets with changing collagen fibre orientation (right)

RESULTS AND DISCUSSION

Better agreement between the simulation and experimental results, including the prediction of the leaflet "pin-wheeling", is achieved when the leaflet stiffness parameters from Caballero et al. [4] are used, assuming that the collagen fibres in the leaflets are all circumferentially aligned.

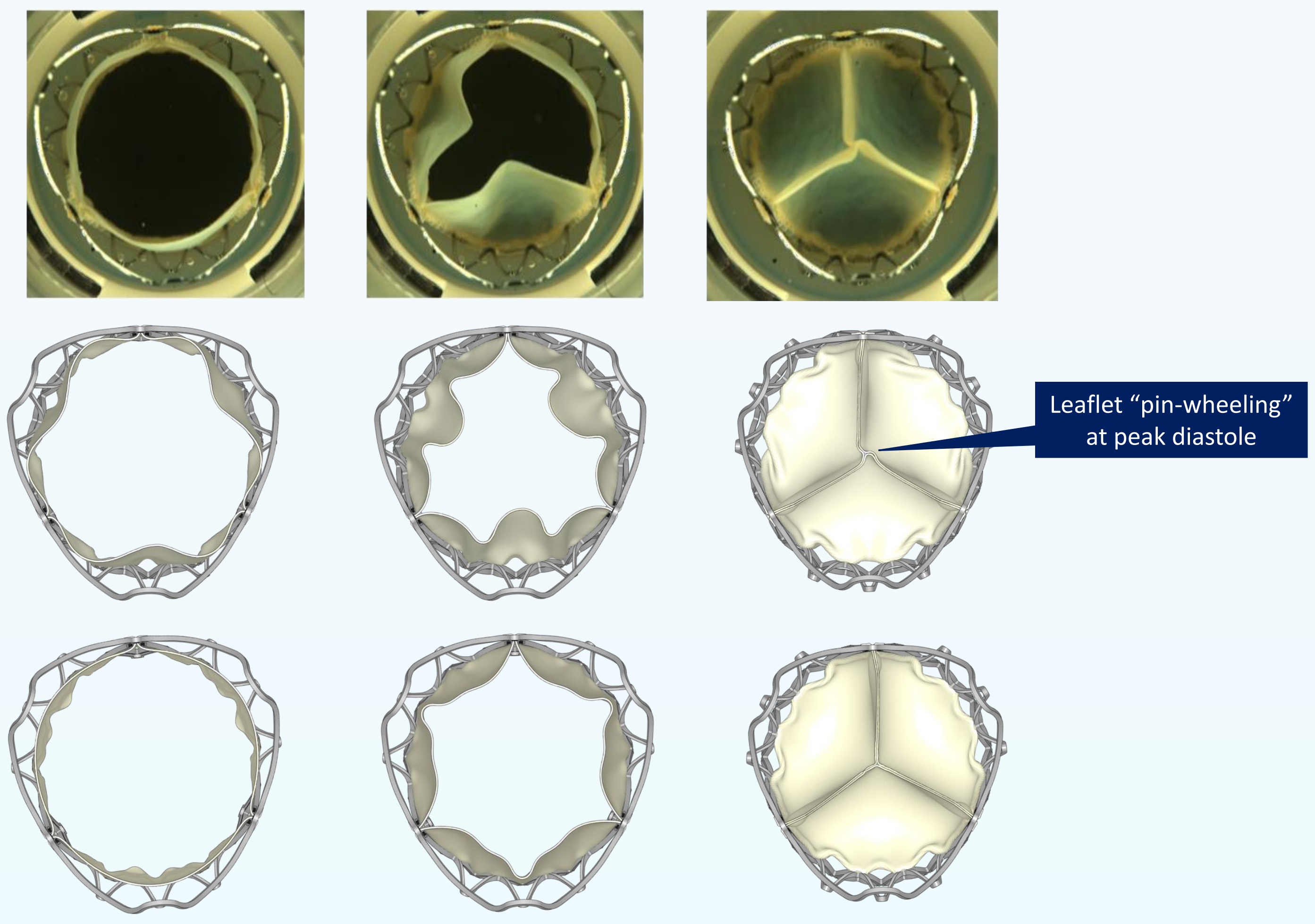


Figure 4: TAVR high-speed images at peak systole, mid-way through closing and peak diastole compared to simulation using leaflet stiffness and circumferential fibre alignment from Caballero et al. [4] (middle) and Li et al. [3] (bottom)

Stiffer leaflet mechanical behaviour (Caballero et al. [4]) results in greater commissure deflection. Similarly, aligning the stiffer collagen fibres in the circumferential direction results in greater commissure deflection compared to when all leaflets have axially aligned fibres (Figure 5). When all leaflets have the same collagen fibre alignment, the deflections are similar for each of the three commissures.

Notably, however, when collagen fibre alignment is "mixed", the load distribution to the stent commissures becomes unsymmetric. Commissure 1 (located between two circumferentially aligned leaflets) has a greater deflection compared to the other two commissures.

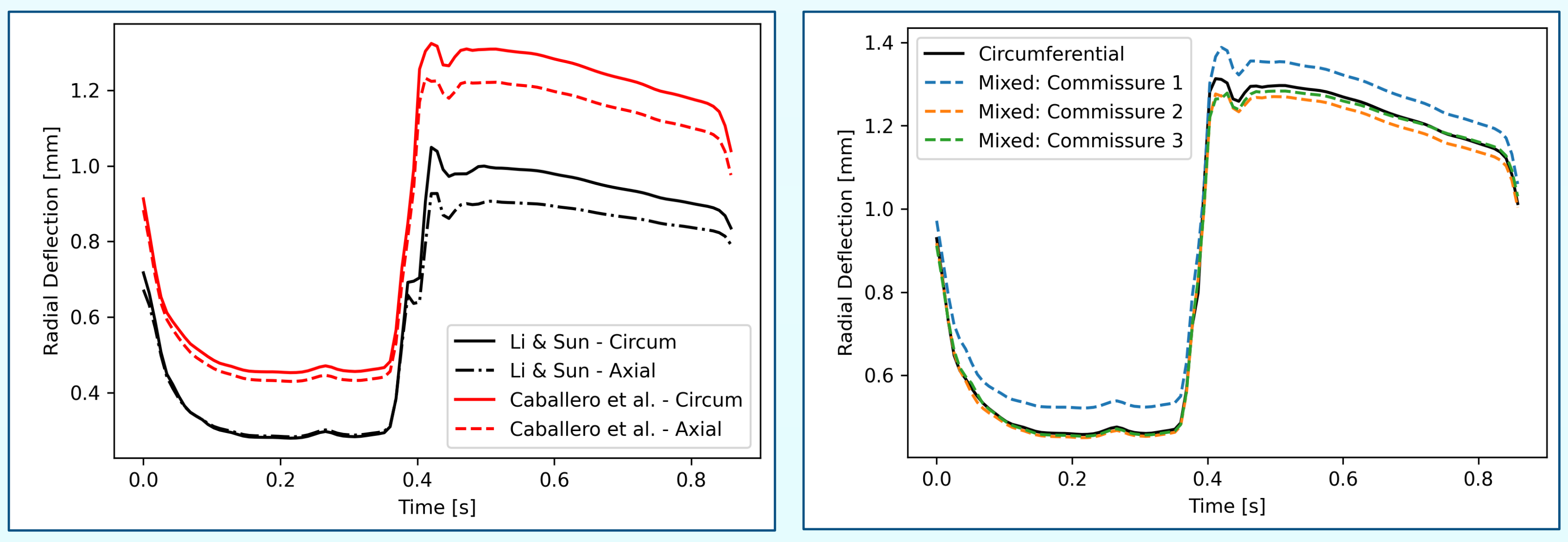


Figure 5:Commissure radial deflections with varied leaflet stiffness and the same fibre orientation for all three leaflets – either circumferentially or axially aligned (left), and radial deflections for Caballero et al. [4] leaflet when fibre alignment is "mixed" compared to all circumferentially aligned (right)

The fatigue life of a material is commonly represented by the alternating strain (ε_a). Leaflet anisotropy affects commissure deflections, and further has an impact on the stent alternating strains (Figure 6). When all leaflets have a circumferential fibre alignment, alternating strain is 10% higher compared to the axial scenario. However, in the "mixed" fibre alignment scenario, the alternating strain is up to 25% greater for commissure 1 when compared to the alternating strain for the other two commissures.

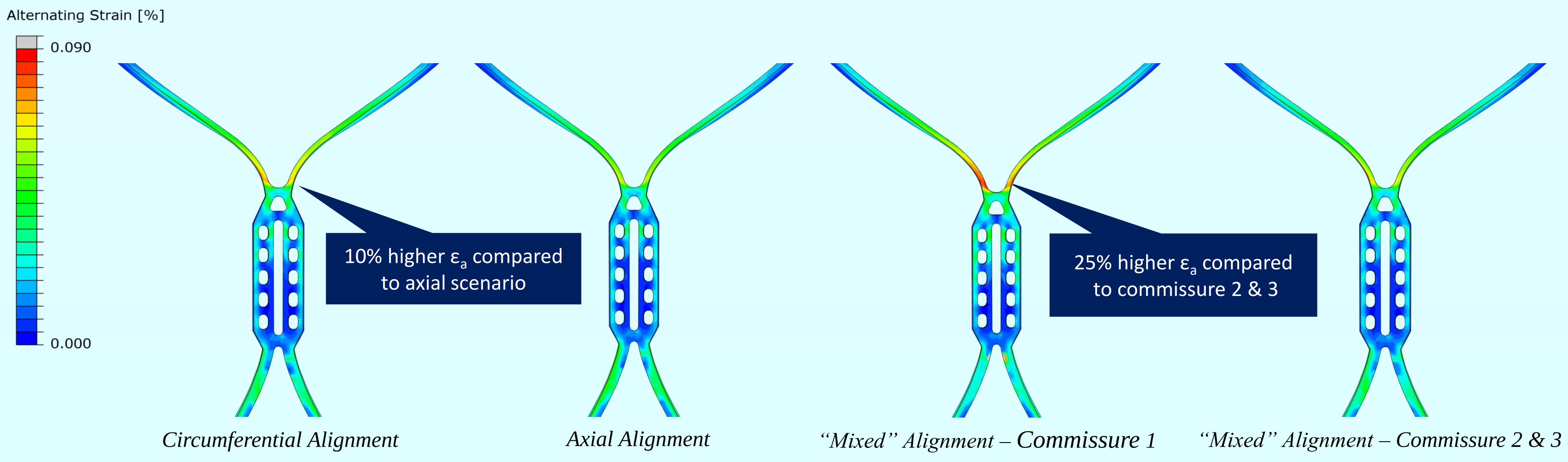


Figure 6: Predicted alternating strains over a cardiac cycle considering leaflet stiffness from Li et al. [3]

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CONCLUSION

While the bioprosthetic leaflet stiffness can be between three to five orders of magnitude less than the nitinol stent stiffness, the pericardium behaviour appears to be a more dominant mechanism for dictating stent frame dynamics during loading. Particularly, the leaflet anisotropy can have a significant impact on how well the valve closes during the diastole phase, as well as whether the stent frame is symmetrically loaded, which may impact the overall fatigue life of the nitinol stent.

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