Modelling and characterization of innovative polymeric mitral valve

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Innovative mitral valve with chordal apparatus – BIOMITRAL

Concept

Valvular Heart Diseases (VHD) rank as the third leading cause of morbidity and mortality in Western industrialized countries, following hypertension and coronary artery disease [1-2].
Mitral regurgitation (MR) is one of the most common conditions affecting the mitral valve(MV) within the spectrum of VHD.

In the USA, MR affects 6% of adults over 65 years old [2]. MR is characterized by a backward blood flow from the left ventricle to the left atrium during systole [3]. Primary MR involves pathological changes of the MV, while secondary MR results as ventricular remodeling [4].

MV repair and replacement are considered the gold standard for treating this pathology. However, these treatments are still affected by significant failure rates due to neglecting important features of the MV such as:
- *chordae tendineae (CT)*
- *3D saddle shape annulus*
- *bileaflet design* typical of the native MV

Scientific approach

This scientific project aims to address the aforementioned challenges neglected by commercial devices employing the in-silico and in-vitro methodologies to developt a biomimetic MV.

The in silico study leverages the Finite Element Methos (FEM) via ABAQUS software to analyze:
- the physiological process of *leaflet coaptation*
- the *optimal number, length, and placement of CT*
- the *mechanics* and the *organ level metrics* (bending deformation index, stress-strain distribution and edge geometric orifice area)
- the *comparative analysis* between flat and saddle-shaped annulus configurations

The in vitro study wants to evaluate the organ-level function metrics of the Stentless-engineered mitral valve with CT using a *custom-made pulse duplicator*.

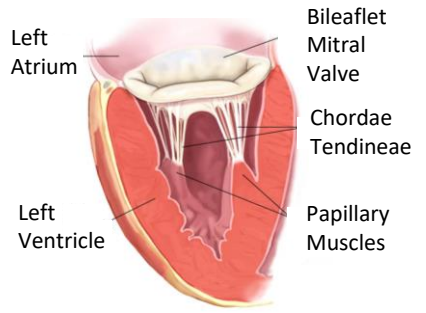
The studies, both in silico and in vitro, will be iterated until the functional metrics of the engineered valve results comparable with those measured for commercially available mitral prostheses.

Research objectives

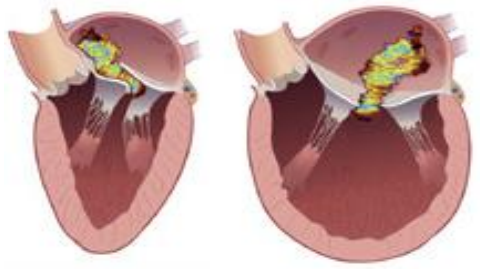
The aim of this research activity is to innovate the field of cardiac valves by developing a *stentless bileaflet MV that incorporates chordal apparatus*, identifying the most effective number, length, and location of the CT.

The evaluation includes a comparative study of a *flat annulus versus a saddle-shaped* one, with the goal of exploring the impact of biomimetic approach.

SCHEMATIC HEALTY AND REGURGITANT MITRAL VALVE

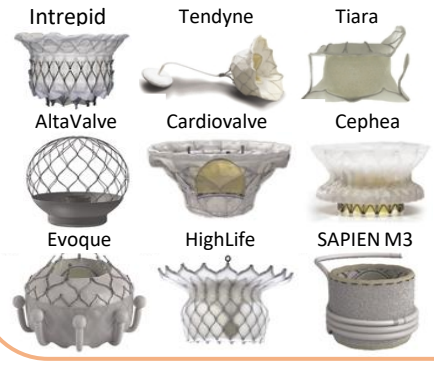


Healthy Mitral Valve (MV)



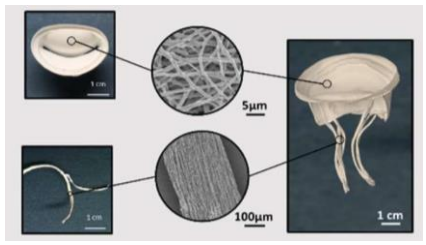
Mitral Regurgitation (MR)

COMMERCIAL AVAILABLE DEVICES



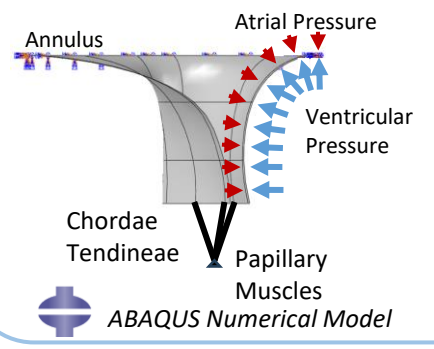
Neglecting crucial native mitral valve features:
- ✖ Natural **mechanical continuum**; chordal *apparatus*
- ✖ *Mitral **dynamism**; 3D saddle shape annulus vs flat annulus*
- ✖ ***Asimmetric blod flow**; bileaflet design*

BIOMITRAL VALVE

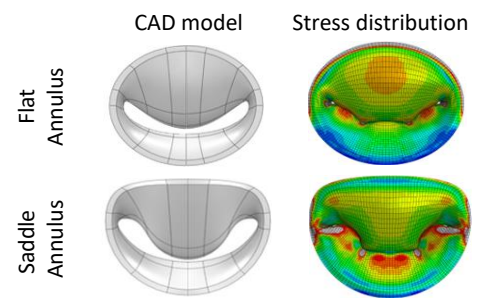


Features of BIOMITRAL valve:
- ✓ Chordal apparatus
- ✓ Saddle shaped annulus
- ✓ Bileaflet design

IN SILICO STUDY

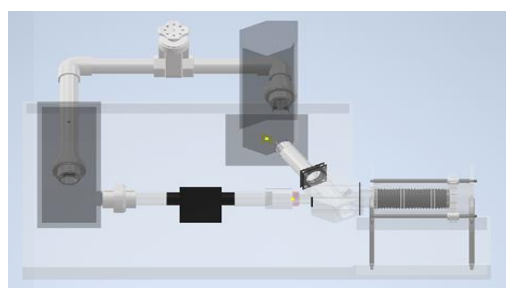


ABAQUS Numerical Model

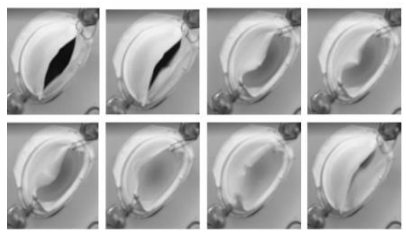


Flat annulus vs. Saddle Annulus

IN VITRO STUDY



Custom-made pulse duplicator



Valve function

[1] K. Maganti, et al., «Valvular Heart Disease: Diagnosis and Management», *Mayo Clin Proc, 2010*
[2] V. T. Nkomo, et a., «Burden of valvular heart diseases: a population-based study», *The Lancet*, 2006
[3] F. Bursi, et al., «Heart failure and death after myocardial infarction in the community: the emerging role of mitral regurgitation», Circulation, 2005
[4] O'Gara PT, et al., «Secondary Mitral Regurgitation». N Engl J Med., 2020