Digital twin in healthcare: development of an integrated imaging and finite element model of Cardioband® procedure for the treatment of mitral regurgitation

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Introduction - The mitral valve (MV) regurgitation is a disease produced by defects of valve structure such as a dilatation of the mitral annulus ring. In this situation, during systole, the blood flows back towards the left atrium decreasing cardiac efficiency [1]. In recent years new transcatheter techniques have been proposed to correct MV regurgitation. The Cardioband® system (Edwards Lifesciences, Irvine, USA) [2] uses a specific polyester sleeve, fastened on the posterior mitral valve annulus by helicoidal metal anchors, to reshape the mitral annulus and repair the mitral regurgitation disease.

Figure 1

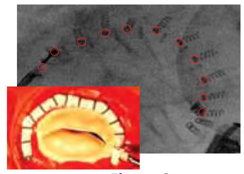

Figure 2

Figure 3

The **procedural phases** of the Cardioband intervention are:

1) Implant deployment phase: the metal anchors are fixed (about 12-17) around the mitral annulus, from trigone to trigone. Each anchor is connected to the other through a polyester sleeve (Fig. 1).
2) Cinching phase: the metal wire, connected to the anchors by sleeve, is pulled by a spool mechanism so its length is reduced as much as the resulting distance between the anchors (Fig. 2).
3) Tuning phase: the annulus size and shape is tuned allowing circumferential annular reduction to eliminate Mitral Valve regurgitation after full deployment of the implant (Fig. 3).

The final shape of the patient's annulus depends on the position and the number of anchors. Currently, these parameters are decided only on the base of the CT/US dataset by analyzing the site of access and the annulus shape and length.

Aim - This study points out the feasibility to develop a pre-planning phase of the intervention based on Finite Element (FE) simulation of the cinching phase of the procedure, able to provide additional information on the procedural strategies of anchors positioning in order to guarantee the best reduction of the mitral regurgitation. The entire workflow (Fig. 4) has been implemented in a specific Matlab code.

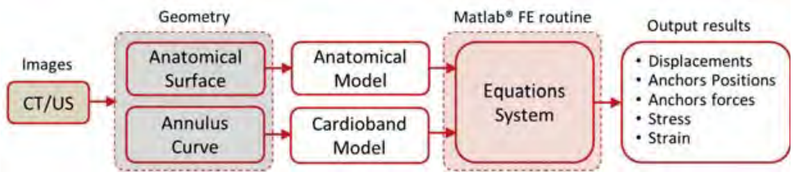

Figure 4

Geometries - The stereolithographic geometries (Fig. 5a), provided by the CT images, have been interpolated by NURBS functions to obtain the anatomical surface (Fig. 5b) and the annulus curve (Fig. 5b. From the annulus curve is possible to define the anchors positions by a manual or an automatic picking.

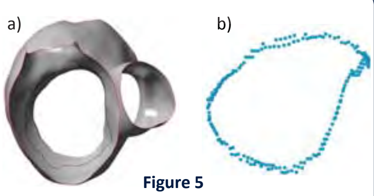

Figure 5

Cardioband model – Reproduce the behaviour of the Cardioband system.
The interactions between the polyester sleeve , the guide wire and the anchors, have been simplified in the Cardioband model (Fig 6a), which is consider as a single 3D ideal cable (inextensibility, no flexural stiffness, point loading, polygonal shape) sliding through the anchors points (Fig 6b).

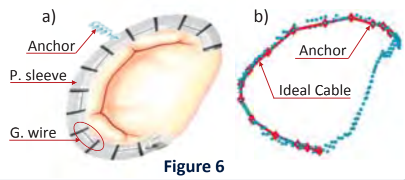

Figure 6

Anatomical Model – Reproduces the 3D behaviour of the left ventricle - left atrium - mitral annulus - aortic root during the procedure.

Mesh element type

Triangular 3-node 18-dof 3D Shell [3]

Material Properties

Different Hyperelastic isotropic zone models

Boundary conditions

Fixed displacement for left atrium and aortic Root (Fig. 7)

External model loads

Distributed forces exchanged with Cardioband model:

- Applied to a spherical area around each anchor position

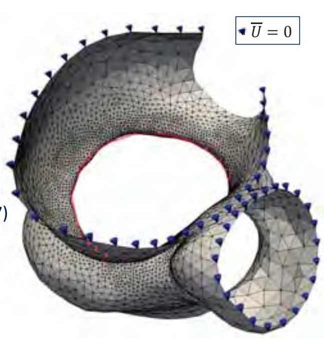

Figure 7

Fe routine – Resolves iteratively an equations system composed by the Cardioband equations, Anatomical FE equations and the Compatibility equations which governing the Cardioband system, the heart structures and their interactions during the cinching phase.
Fig. 8 depicts the entire algorithm where the initial cable length is reduced by a incremental steps. The results of each iterative step have been evaluated starting from the previous one.

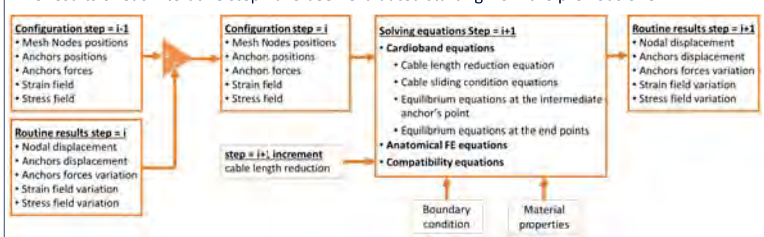

Figure 8

Method accuracy – In order to evaluate the accuracy of FE Routine the standard clinical procedure, with prescribed equi-spaced anchors, has been simulated. The pre cinching X-ray Angiographic (XA) 2D images (Fig. 9a) have been fused with the 3D model projected annulus, so the initial anchors positions have been obtained (Fig. 10a). The cable length has been reduced on the model. The simulated final anchors positions (Fig. 10b) have been compared with the corresponding ones found in the post procedure XA 2D images (Fig. 9b).
Fig. 11 depicts there is a good overlapping between the standard clinical procedure and results of the simulation corresponding routine.

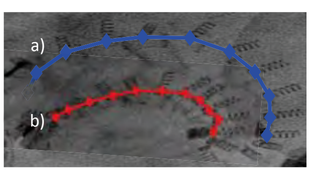

Figure 9

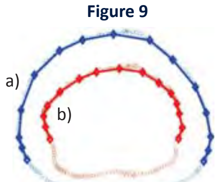

Figure 10

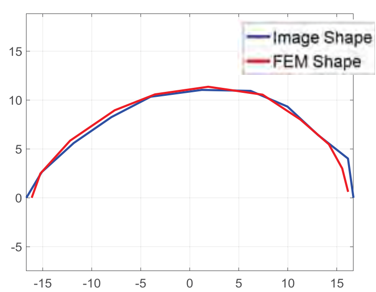

Figure 11

Different anchor positions comparison – In order to understand how the anchor positions are able to influence the final annuls shape, three different configurations have been considered, concentrating the anchors respectively in the trigonal (Fig. 12a), the posterior (Fig. 12b), and the anterior regions (Fig. 12c). The configurations have been compared with the standard clinical procedure simulation in terms of geometric parameters, anchors forces and stress values. Fig. 12 depicts the final annulus simulated shapes, the anterior configurations shows an healthy physiological shape.

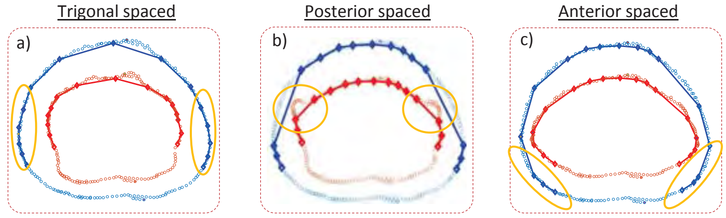

Figure 12

Parameters		Pre-cinch	Clinical	Trigonal	Posterior	Anterior
eccentricity		0.51	+17%	-1%	+26%	+34%
Area (mm^2)		2.7x10^3	-50%	-52%	-50%	-42%
Anchor Reaction Forces (N)	max	-	16	+5%	-19%	-36%
	mean	-	6	+10%	-28%	-32%
	min	-	1.6	+30%	-10%	-4%
σeq_{max} (MPa)		-	3.4	3.3	3.3	3.3

Table 1

Table 1 depicts the results of the simulations, in particular the anterior configuration shows the highest eccentricity value, the lower area reduction and anchor forces values with the same cable length reduction. In the anterior configuration, the Cardioband implant is able to reduce the annulus exploiting the arc effect of the trigone zones which have the maximum of the curvature value. The stress/strain values are the same for all configurations.

Conclusions – The work presented here shows the capability to evaluate the results for this novel adjustable annuloplasty procedure in a the pre-planning phase. Moreover from our simulations, the better results, in term of physiological annulus shape with respect of area and of anchors force reductions, have been obtained with no-equispaced configurations, positioning the anchors in the anterior region.

[1] Roger, V., et al., Circulation (2014).
[2] Maisano, F., et al., Eur. Heart J. (2016).
[3] Felippa, C., et al., Finite Elements in Analysis and Design (1992).

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