A FE tool to simulate a trans-catheter anchor-based system for mitral valve regurgitation

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***Abstract*—Mitral Regurgitation (MR) is an alteration of normal mitral valve (MV) function that leads to mitral insufficiency. Undersized Mitral Annuloplasty (MA) is the preferred surgical treatment for chronic ischemic mitral regurgitation. However, the preferred shape of undersized MA is unclear. Recently a percutaneous direct annuloplasty capable to reduce the annulus size in real time under echocardiography guidance has been presented.**

The primary objective of this work is to develop a workflow able to provide strain and stress information regarding the novel valvuloplasty transcatheter anchor-based system for the correction of the mitral regurgitation. In this work, the morphological shape of the mitral annulus has been reconstructed by integrating CT and 3D TEE echo images and finite element simulations have been performed. Moreover an integrated environment based on pre-procedural, procedural images and FE simulations is presented. This tool is able to provide additional information on the procedural strategies optimizing the final results.

***Keywords*—Anchorage System, Annuloplasty, Finite element Methods, Mitral Valve.**

I. INTRODUCTION

THE mitral valve (MV) is a complex apparatus with multiple constituents (the annulus, the leaflets, the chordae tendineae, and the papillary muscles) that work cohesively to ensure unidirectional flow between the left atrium and ventricle.

The annulus is a band of connective tissue that encompasses the two leaflets and gives the MV its shape. Defects or disruption to any or all of the MV components can result in incorrect MV closure and, consequently, leading to backflow of blood during systole, into the atrium. This scenario is called mitral regurgitation and it leads to mitral insufficiency, it decreases cardiac efficiency and it effects patient health [1]. In recent years, a novel minimally invasive transcatheter procedure can be adopted in order to define the final MV size. This novel transcatheter surgical system is composed of a delivery system, a prosthesis, and an adjustment catheter. The prosthesis is attached to the posterior annulus, trigone to trigone, via special anchors. A polyester sleeve, which covers the delivery system, is firstly positioned around the mitral annulus and then a series of 12-17 anchors is implanted. Anchors are connected to each other by means of the polyester band together with a metal wire. The annulus size is adjusted by pulling the wire through a specific cinching mechanism: the resulting distance between the implanted anchors is reduced (together with the connection wire and polyester sleeve length) in order to manage the MR issue [2]. Using the size adjustment catheter, the implant can be bidirectionally tuned to reshape the annulus, allowing circumferential annular cinching to eliminate MR after full deployment of the implant.

In this study, Finite Element analyses have been performed in order to evaluate the state of stress and strain of the biological structure under the effects of the anchors pulling phase. Additionally, a novel tool based on an integrated approach able to analyse both pre-procedural, and procedural images in a FE environment is presented. Finally this tool has the capability to predict the final results of the procedure, it could be used also to define the position of the anchors in a planning phase.

II. MATERIALS AND METHODS

A. Valve geometry

Patient specific geometries have been obtained by segmenting the 3D CT pre-procedural dataset (640-slices). The end-diastole valve configuration was chosen as the initial unloaded one, since, at this point in time, the transvalvular pressure drop acting on leaflets is almost zero. The 3D reconstruction of the valve and the annulus curve geometries are depicted in Fig. *1*.

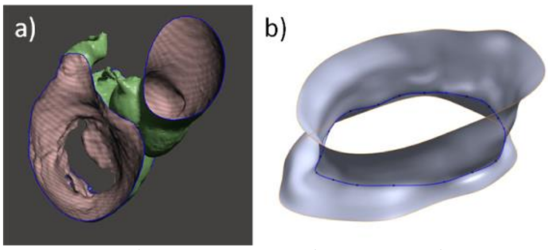

Fig. 1: Example of 3D recostruction of mitral valve from CT scan at the end of the diastolic phase a) and 3D model of the annulus b)

B. Finite Element models

A 2D morphology for the mitral annular has been developed as a projection of 3D annulus curve on a plane. As a justification of this last passage, the distances of each point from the centroid along the three main coordinates have revealed that the mean distance along the *z*-axis is negligible in respect to the one obtained on the other two axes. Moreover, post-operation echografic/fluorosopic images have confirmed the relevance of radial displacement against *z*-axis displacement for this kind of implant. To obtain this geometry the following steps have been performed: firstly, the continuous annular profile has been extracted, then the centroid position has been calculated and a 2D projection of

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the annular profile has been assumed. Finally, a planar surface is obtained from the projection by adding a homothetic transformation in order to better emulate the tissue-anchor system. The geometry has been meshed with 1385 linear triangular elements using Delaunay triangulation method. The material properties have been assumed isotropic, with Young's Module equal to 2.4 MPa and Poisson's ratio equal to 0.49.

During the pulling phase the resulting distance between the implanted anchors is reduced therefore, the total length of wire decreases. In addition, the wire, anchored at the ends, slides through the intermediate anchors through polyester sleeve. This behaviour in the study has been simplified considering only one cable that can slide through anchors. The model of metal cable has been developed assuming, in accordance with classical cable theory, that has zero flexural rigidity, that the cable is either inextensible and that external loads, applied by anchors on cable, are modelled in the form of point loads. Therefore, the shape of the cable is discontinuous and it is a polygonal chain. An equations system has been implanted and developed in Matlab to simulate the interaction between all the elements (anchors, cable and annulus) during the pulling phase. These implemented equations are:

- equilibrium equations of each portion cable at the intermediate anchor's point;
- equilibrium equations of the portion cable at the ends;
- equation of sliding conditions;
- equation of final cable's length;
- compatibility equations of wire-annulus interactions.

C. *Finite Element simulation*

In order to define the initial polygonal shape of the cable, a series of 17 anchors (according to clinical procedure) has been selected on the annulus geometry. Fig. 2 depicts the FE model with boundary conditions. A parallel solution between the constitutive cable equations and the finite element equations has been performed with MATLAB software, imposing a length cable-decreasing equal to 20 mm.

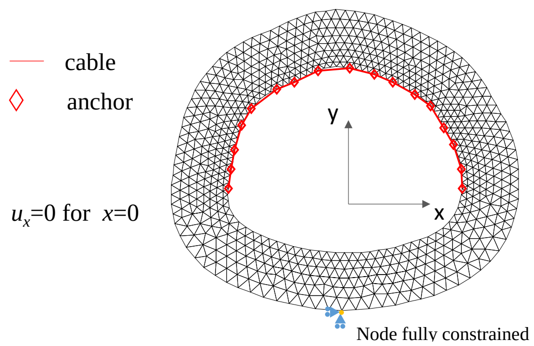

Fig. 2: FE model

III. Results

Fig. 3 depicts, as example, the radial displacements on the projected annulus plane, due to the effects of cable cinching on the internal shape of the annulus. As expected, the maximum value of radial displacement is located in in the middle of the posterior leaflet (at about 90°) and a more elliptical shape has been assumed by the annulus. These results are in good agreements with the clinical results. From our simulations, a reduction of area equal to 26% and a maximum radial displacement of about 5 mm have been obtained. The cable normal stress is equal to 4 N. The equivalent stress map in the annulus shows a peak at the position of the end anchors equal to 3.5 MPa, in these points there is also a peak of equivalent strain equal to 6 mm/mm. The maximum anchor force is equal to 4 N and it is located at the ends. These last results are in accordance with the clinical procedure due to the presence of fixed anchors at both ends.

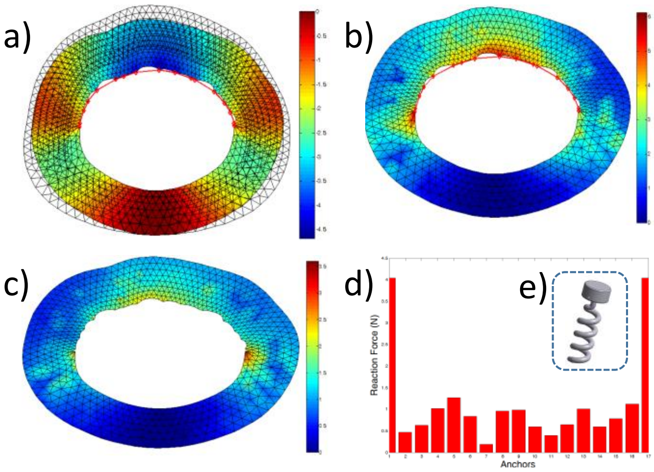

Fig. 3: Example of radial displacements on the projected annulus plane (a), stain map (b), stress map (c) and plot of magnitude of the reaction forces on each anchors (d) with 3D CAD model of an anchor (e).

IV. Conclusions

We presented here a structural FE model of the MV correction that combines a description of valvular geometry and the tissues' mechanical response with the modelling of annular contraction by using specific anchors. The work presented here in is a pilot study aimed at testing a new modelling approach and to the authors' knowledge; this is the first time that this procedure has been investigated in a FE model. By adding features to the model, the annulus shape after implant adjustment could be defined in advance also by taking into account of the hyperelastic nature of the cardiac tissues. With this approach, it will be possible to evaluate the results of the procedure in a pre-planning phase; it will be possible to define the anchors position able to give the desired annulus' deformed shape. This work poses the basis for more complex approaches that might allow the potential to foresee the post-procedure results.

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