Biomechanical Outcomes of the Mitraclip® Procedure: A Finite Element Analysis

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***Abstract*—Percutaneous mitral valve (MV) interventions are gaining attention as an alternative to open-chest surgery in reducing mitral regurgitation (MR). Nonetheless, clip implantation can induce biomechanical alterations in the valve functioning, which can be related to sub-optimal outcomes or implant failure. Patient-specific finite element (FE) models, derived from cardiac magnetic resonance (CMR) imaging are herein exploited to quantify MV biomechanics after Mitraclip® implantation and elucidate the determinants of a well-performed procedure as well as the impact of a different level of precision during clip implantation on the MV outcomes.**

***Keywords*—Mitral valve, Mitraclip®, Finite element Analysis.**

I. Introduction

MITRAL regurgitation (MR) is the most prevalent heart valve disease in the Western population [1]. Among possible surgical options, the edge-to-edge repair technique treats MR by suturing the leaflets together and creating a double-orifice valve [2]. The Mitraclip® device has recently emerged as the only available percutaneous strategy able to replace conventional open-chest surgery in high-risk patients [3]. However, despite its conceptual ease, the Mitraclip® implantation still represents a complex procedure, requiring skilled operators and experienced echocardiographists [4]; indeed, a demanding learning curve is necessary to effectively perform the procedure and acquire a high-quality level of implantation. We herein sought to exploit FE patient-specific models to gain further insight into the effects of the Mitraclip® procedure on MV biomechanics, pointing out the biomechanical implications of a suboptimal implantation encompassing clip mispositioning, partial MV leaflets grasping as well as leaflet misapposition.

II. Material and Methods

A male patient (57 years old) was submitted to preoperative *cine* CMR acquisition (TX Achieva 3.0T, Philips Medical System, Eindhoven, Netherlands) before undergoing surgical repair of posterior P2 prolapse due to primary chordal rupture. The end-diastolic MV geometrical model was reconstructed in MATLAB (The MathWorks Inc., Natick, MA, United States), after manual tracing of MV leaflets and inclusion of papillary muscles (PMs) tips and chordae tendineae [5]. MV prolapse defect was reproduced by removing marginal chordae according to intraoperative clinical evidence. Annular and PMs kinematics was reproduced consistently to *cine* CMR data.

All tissues were assumed homogeneous, non-linear and elastic: leaflets mechanical response was described through the transversely isotropic constitutive model proposed by Lee [6]. Also, the hyperelastic response of chordae tendinae was reproduced fitting uniaxial test data from fresh porcine MVs [7]. To simulate the Mitraclip® implantation, the two arms of the clip were modelled as rigid rectangular plates and driven through *ad hoc* kinematic boundary conditions to reproduce the positioning of the device between the MV leaflets on the site of MV defect, and the final device deployment [5]. In particular, an optimal as well as several sub-optimal implantations (Fig. 1) were simulated reproducing a different level of precision in setting: i) Mitraclip® positioning, i.e. exactly on the site of MV defect or at a variable distance from it (1 and 2 arms width); ii) MV leaflets grasping, defined as complete, marginal or asymmetrical, respectively. For each scenario, the post-operative MV biomechanics was assessed throughout a cardiac cycle, prescribing a physiological time-dependent transvalvular pressure drop on the ventricular side of MV leaflets.

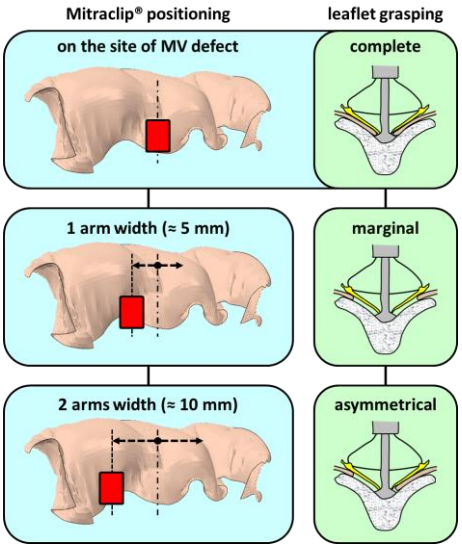

Fig. 1. FE tests on Mitraclip® implantations.

All the simulations were run in the commercial solver ABAQUS/Explicit 6.10 (SIMULIA, Dassault Systèmes, Vélizy-Villacoublay). A general scale-penalty contact algorithm was adopted for MV leaflets while contact slippage and separation were prevented between MV leaflets and the Mitraclip® arms.

III. Numerical Results and Discussion

Regardless of the level of implant precision, MV coaptation area (CoA) improved at peak systole reporting a 30%-40%

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CoA recovery with respect to the prolapse configuration (CoA of 5.55 cm^2), with a complete grasping on the site of defect representing the optimal option.

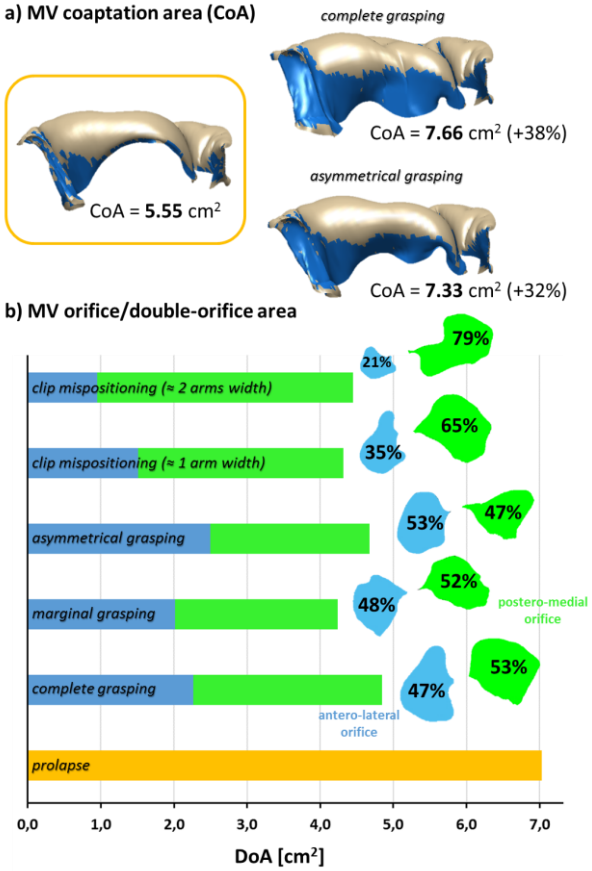

Fig. 2. MV coaptation and double-orifice areas.

During diastole, the Mitraclip® inherently induced a major reduction in the double-orifice area (DoA), which was overall equal to about 60%-70% of the preoperative MV orifice area. Of note, leaflets misapposition due to sub-optimal grasping did not impact on the MV double-orifice configuration, which remained almost symmetrical.

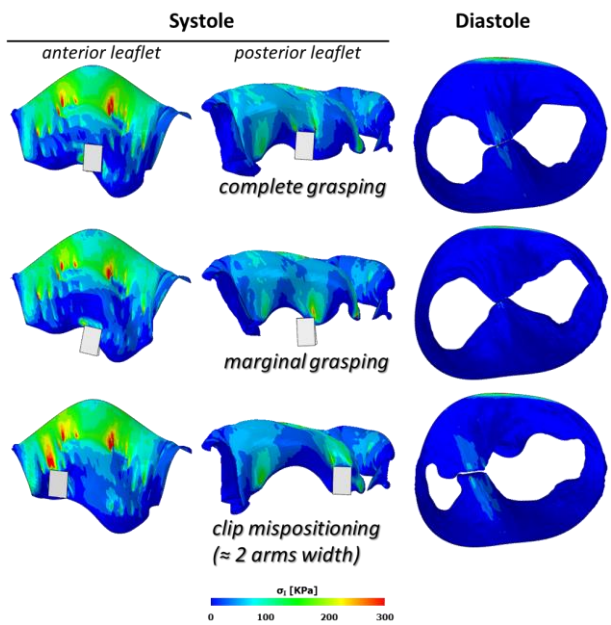

Fig. 3. MV leaflets mechanical stress.

The clip mispositioning, although not significantly altering the DoA entity, resulted in an asymmetrical double-orifice configuration (Fig. 2) and reached a 20%-80% DoA repartition when simulating a 2 arms-width clip mispositioning far from the actual site of MV defect.

As concern MV maximum principal stress, at peak systole (Fig. 3), a common pattern of stress redistribution on MV leaflets was visible with high mechanical leaflet stress localized close to the clip; in this region, an asymmetrical grasping of the leaflets proved to increase mechanical stresses up +15% with respect to a complete grasping, although the stress magnitude remained overall below 400kPa. During diastole, a large extent of MV leaflets was unloaded and exhibited stress values largely below 100 kPa. Clip mispositioning promoted an increase in mechanical stress close to the clip arms.

IV. CONCLUSIONS

FE results confirm that MV biomechanics following the clipping procedure can be dependent on the proper execution of the grasping procedure as well as on the clip positioning, requiring accurate evaluation prior to clip delivery. Thus, echographic or fluoroscopic post-procedural evaluation of the implant is mandatory to confirm the proper positioning of the clip, independently from a good Doppler hemodynamic result. Hence, the biomechanical insight provided by patient-specific FE analysis may play a key role in elucidating the optimal setting of the procedure as well as in tackling current challenges of percutaneous MV repair strategies.

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