Electro-Mechanical Modeling of Transcatheter Aortic Valve Deployment in the Simulia Living Heart Human Model

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1 Abstract

Transcatheter Aortic Valve Replacement (TAVR) is a minimally invasive technique to treat inoperable patients who suffer from end-stage calcific aortic valve disease. Although TAVR patients are prone to atrioventricular (A-V) conduction disturbances and arrhythmias, no previous studies numerically modeled the influence of this procedure on heart block mechanisms. The current study proposes a methodology to simulate this phenomenon using the Simulia Living Heart Human Model (LHHM) and unidirectional coupling between the electric and mechanical models. Two types of TAVR stents will be examined, Medtronic *CoreValve* and Edwards *Sapien*, in a modified version of the LHHM that includes characteristic calcification patterns in the native aortic valve. The proposed methodology is based on the following steps: (a) Electrical model of rapid ventricular pacing that represents the conditions during the procedure. (b) Stent deployment simulations in the rapid paced heart. The two models will include a self-expandable nitinol stent and a balloon-expandable stainless steel stent for the *CoreValve* and *Sapien* valves, respectively. (c) Modifying the electrical models based on the resulted deformations in the A-V node region. (d) Modeling additional cardiac cycles of the heart with the deployed stents and the modified electrical conduction. The suggested methodology, that will model the TAVR conduction interference for the first time, has the potential to predict heart block for various TAVR devices and deployment positions. Such models could be used in the future for minimizing this risk by procedural planning. Moreover, in cases with unavoidable arrhythmia such models could help estimate its severity and longevity.

2 Introduction

Calcific aortic valve disease afflicts approximately 0.9% of the Unites States population and can lead to severe aortic stenosis, which is a narrowing of the aortic valve opening, and to heart failure if untreated. Minimally invasive transcatheter aortic valve replacement (TAVR) is an effective therapy for the inoperable patients with severe aortic stenosis, often as their only life-saving alternative. This procedure includes expansion of a stented tissue valve against the diseased leaflets and the aortic root wall. Follow-up studies of TAVR patients however indicate that this procedure may result in serious adverse events. Conduction abnormalities are commonly agreed to be a result of mechanical pressure on the atrioventricular (A-V) node and the Purkinje fibers in general [1, 2]. In severe cases, a permanent pacemaker is needed to treat the conduction disturbances and arrhythmias [3]. Several factors might affect the conduction disorders including the degree of oversizing of the stent [4], the axial deployment location [5], and the patient anatomy [6]. Another factor is the type of the prosthetic valve: patients implanted with a Medtronic *CoreValve* are around three times more likely to need a permanent pacemaker than Edwards *Sapien* patients [7, 8].

The Simulia Living Heart Human Model (LHHM) is an anatomically and physiologically realistic model of an adult male heart, which includes the four chambers, major vessels, electrophysiology, and fibrous architecture of the myocardium [9, 10]. An electrical analysis is used to compute the spatiotemporal pacing of the heart which is then used in a subsequent mechanical analysis that allows device-heart interactions to be modeled. Therefore, this model has the potential to capture several phenomena that were not modeled before in TAVR simulations such as the influence of the beating in general, and the procedural rapid pacing in particular, on the dynamics and kinematics of the TAVR stent. Additionally, even though the model is of a healthy heart, it is possible to introduce the calcification (and consequent altered aortic valve mechanics) necessary for TAVR stent anchoring. This study proposes a methodology to simulate A-V conduction disturbances in two types of TAVR valves, Medtronic *CoreValve* and Edwards *Sapien*, using LHHM and unidirectional coupling between the electric and mechanical models. A possible advantage of this methodology is the capability to evaluate the mechanical influence of the heart contraction on the TAVR stent.

3 Methods

3.1.1 Stent modeling

The stent of the balloon-expandable Edwards *Sapien* valve with 26 mm diameter was modeled with material properties of stainless steel. Prior to the deployment in the LHHM the stent was crimped and placed on a deflated balloon. The deployment with balloon inflation was modeled by pressurizing the balloon uniformly [11]. The self-expandable stent of the Medtronic *CoreValve* was based on Bezier curves and extruded to three dimensional elements. The stent has material properties of superelastic NiTi (nitinol). The stent was crimped by a surface cylinder, positioned in the aortic valve, and deployed by pulling the cylinder to the aorta and allow graduate expansion of the stent.

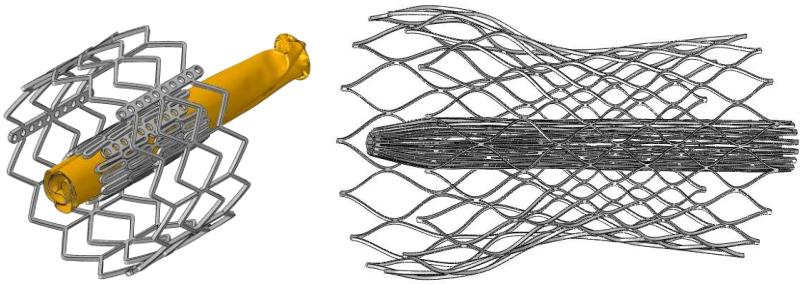

Fig. 1 Edwards *Sapien* (left) and Medtronic *CoreValve* (right) in their initial and crimped positions. The deflated balloon is also shown on the left with cross-section to demonstrate the folding.

3.1.2 Living Heart Human Model

The LHHM consists of both electrical conduction and mechanical models of the heart function but the anatomy is of a healthy heart and it includes the four chambers without the valves. Several modifications were required for accurate modeling of TAVR deployment. The main modification was the inclusion of the aortic valve that is part of the LHHM geometry but not included in the FE model by default. The three leaflets of the valve were modeled with three different hyperelastic material properties while the other parts of the heart were modeled using Holzapfel anisotropic hyperelastic material based on local fiber anatomy [9]. Characteristic calcification patterns [12] in the native aortic valve were introduced by elements sets with linear elastic material properties of calcifications (Fig. 2).

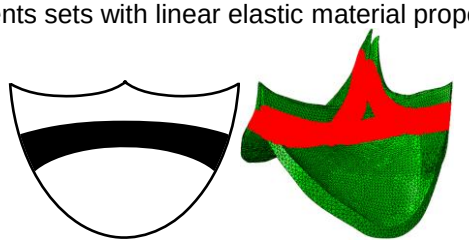

Fig. 2 Characteristic calcification patterns [12] (left) and the elements set, marked in red, on the leaflets of the LHHM (right)

3.1.3 Proposed methodology for conduction disturbances modeling

The first step of the proposed methodology is to model the deployment of TAVR stents in the LHHM with the calcification deposits and to evaluate the influence of the heart contraction on the stents. The native aortic leaflets in the model of the *Sapien* deployment are opened by applying a pressure of 8.2 kPa during the preload phase while the leaflets in the *CoreValve* model were pushed open by the delivery system during the same phase. From the results of these models it is possible to calculate the stress and strain that the A-V node region is exposed to during the deployment. The stretch-activated channels (SACs) in the A-V node are known to be affected by this strain, [13]; however, we are unable to find a published mathematical correlation between the electrical resistance of the A-V node and the mechanical strain experience at that location. Therefore, the next step in our methodology will involve an increase of the A-V node electrical resistance if the strains or stresses in that region exceed a certain threshold, based on results obtained by Bosi et al. [14]. Per these data, a pacemaker is required when the average maximum principal stresses in the aortic annulus exceeds 0.21 MPa.

Finally, the results of the modified electrical model can be used as the input for the mechanical model. In this way, we can achieve a simple unidirectional coupling between the electrical and mechanical models. The results of this model can shed light on the influence of the irregular heart beating on the heart function and help quantify the degree of A-V block that may require a permanent pacemaker.

A future addition to this methodology will be to account for the induced rapid ventricular pacing during TAVR deployment procedure that is done to reduce blood flow from the ventricle [15]. In this proposed methodology the first step will be to model the rapid pacing effect on the LHHM. A gradual increase of the heart rate from 60 bpm in the healthy model to 160 bpm in the paced up model will be tested while keeping the beat and recovery durations as 50% of the cycle each. The pacing will assume similar but faster electrical conduction in the paced heart. The previously described steps will be repeated in the paced model to better capture the contact interaction between the stent and native tissue during the procedure and its effect on the anchorage forces and the possible A-V block.

4 Preliminary Results

Preliminary results of the *CoreValve* deployment in calcified aortic valve and with the normal pacing used in the LHHM are shown in Fig. 3. Panels (b) and (c) of Fig. 3 show the gradual expansion of the stent, starting from the ventricular side and continuing towards the aorta, by pulling the constraining sleeve into the aorta. Later, during the beating (Fig. 3 e and f), the calcification deposits anchor the stent and prevent its motion. In an earlier version of this model of deployment in healthy LHHM, the stent started to migrate into the aorta while the ventricle contracted. These results confirm the assumption that the calcium deposits that provide anchoring to the stent. The axial position of the stent also plays a major role in the probability of migration. However, this positioning has a direct influence on A-V conduction disturbances because a more ventricular position should prevent migration but the stent will be anatomically closer to the A-V node and it may apply larger contact pressures in that region. The stress contours in the leaflets (Fig. 3) also demonstrate the higher stresses in the calcification deposit region where the material is stiffer.

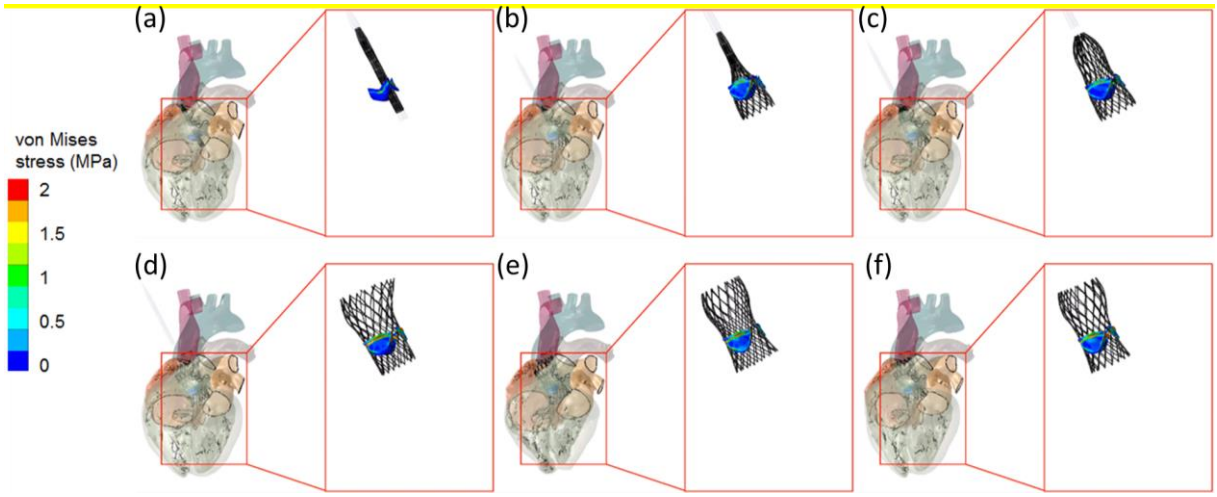

Fig. 3 Medtronic *CoreValve* stent expansion in the LHHM with calcified aortic valve: (a) pushing of the leaflets to open position with the stent and the crimper, (b, c) self-expansion of the ventricular and aortic parts of the stent, respectively, (d) fully deployed stent, (e) beating phase, and (f) recovery phase.

The first step toward the modeling of the paced heart was a comparison between two solutions of the LHHM with normal and paced up heart rates of 60 and 160 bpm, respectively (Fig. 4). Initial results seem to indicate that the paced heart may not achieve a periodic solution (as might be expected from physiological considerations) and that additional model modifications may be needed in order to achieve it. The different amplitudes of the even and odd cycles may be due to the fact that we are applying the default (normal) hemodynamic boundary conditions to a heart that is paced. Clinical data will be used to understand the physiological hemodynamics of paced hearts and to determine appropriate flow boundary conditions to model TAVR deployment in a paced LHHM.

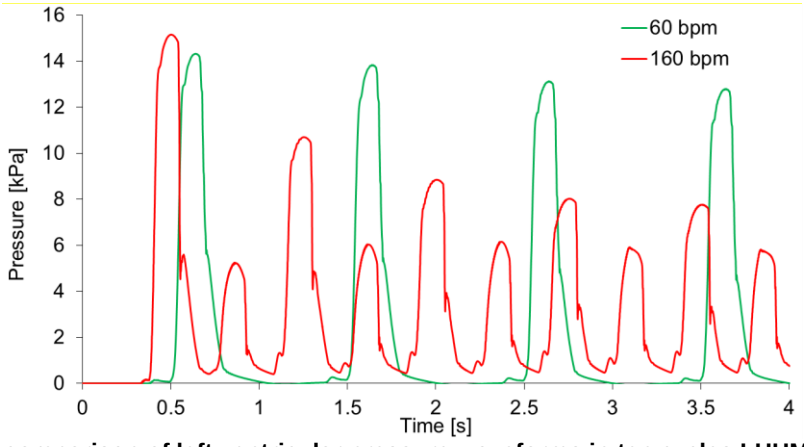

Fig. 4 Preliminary comparison of left ventricular pressure waveforms in ten cycles LHHM model with heart rated of 60 and 160 bpm. Ten cycles are presented for the 160 bpm case while only the first four cycles are presented for the 60 bpm case.

5 References

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