Annual Report- Slezak Super Center

<u>02/2017</u>

Simulations of Stenotic Bicuspid Aortic Valve Fluid-Structure Interaction Biomechanics Models

Rami Haj-Ali, Ehud Raanani and Sagit Ben Zekry

Brief Summary:

Calcific aortic valve disease (CAVD) is a formation of tissue similar to bone on the leaflets of the aortic valve (AV), which rapidly leads to aortic stenosis (AS). Over 50% of AS patients have Bicuspid Aortic Valve (BAV) abnormality at relatively earlier ages compared to AS patients with Tricuspid Aortic Valve (TAV). Minimally invasive transcatheter aortic valve replacement (TAVR) has emerged as an effective therapy for inoperable patients with severe AS. Still, there are some concerns regarding TAVR implantation in BAV patients, most of them are due to the eccentric morphology of the BAV that could lead to complications such as incomplete anchoring, paravalvular leakage, and annular rupture. Our aim is to expand our methods of retrospectively calcification growth evaluation techniques to BAVs and to assess the deployment of the latest generation TAVR devices, both balloon and self-expandable, with numerical models. The paravalvular leakage (PVL) was compared using hemodynamics models of the diastole in the resulted deployed configurations.

CT scans of pre-TAVR patient with BAV were collected from our existing database of CAVD scans. A severe AS patient was chosen with heavily calcified raphe region. Our Reverse Calcification Technique (RCT) was employed for this BAV patient in a similar manner to our previously suggested RCT for TAVs. This technique is based on using pre-TAVR CT scans of AVs to study the calcification progression that leads to the current state. Idealized geometry of the BAV type 1 anatomy was created for non-fused leaflet angle of 140° and symmetrical fused leaflet. For this purpose, our existing parametric geometry and mesh generation method was modified for asymmetric BAVs. The native leaflets and root are meshed with 3D and shell elements respectively, and have native tissue properties. The calcium deposits are embedded inside the leaflets and have calcium material properties.

Deployment of two TAVR devices, Sapien 3 and Evolut R, are modeled in the CAVD-BAV anatomy. For Sapien 3, the leaflets and stent were drawn based on publicly available figures from Edwards. The stent of the CoreValve was generated based on Bezier curves, resulted in a structured hexahedral mesh. The materials used to model the stents are MP35N alloy and purely superelastic NiTi for the Sapien 3 and Evolut R, respectively. The stents were initially crimped with a cylindrical crimper. The Evolut R deployment is a result of the residual stresses present in the stent after the crimping while gradually pulling the sleeve toward the aorta. The Sapien 3 is deployed by balloon (NovaFlex+) inflation as we previously used for first generation Sapien. The FE solver is SIMULIA Abaqus (Dassault Systèmes, Providence, RI).

The RCT subtraction algorithm was commenced and used to generate various stages of the CAVD disease in BAV. An initiation nodule of the calcification growth appears on the raphe region, a location that is subjected to higher stresses in healthy BAV type 1. The non-fused leaflet has similar arc shaped pattern as in TAVs while the arcs are connected in the fused leaflet. Preliminary deployment of the Evolut R stent in healthy and stenotic BAVs. In the healthy model, a circular deployment was found, which allowed the bioprosthetic leaflets to be centrally closed. In the calcified model, the Evolut R adapted the elliptical shape of the BAV opening ('fish-mouth'), which might prevent proper coaptation between the bioprosthetic leaflets and a full closure, but on the other hand, 'fish mouth' opening of the BAV could be narrow enough to prevent it. The deployment of Sapien 3 inside the calcified BAV was performed and detailed prediction of the leakage locations, including the small gaps between the native leaflets and the cuff. Similar deployment models were solved for previous stages of the disease to estimate the desired occasion for intervention.

Publications as a result of full or partial Shlezak grant:

- Halevi R, Hamdan A, Marom G, Lavon K, Ben-Zekry S, Raanani E, et al. Fluid-structure interaction modeling of calcific aortic valve disease using patient-specific three-dimensional calcification scans. Medical & biological engineering & computing. 2016;54(11):1683-94. doi: 10.1007/s11517-016-1458-0. PubMed PMID: 26906280.
- <u>Abstract submitted:</u> Predicting Calcific Aortic Valve Disease Progression and its Effect on Transcatheter Aortic Valve Deployment in Bicuspid Valves: Marom G, Lavon K, Bianchi M, Halevi R, Hamdan A, Raanani E, Haj-Ali R, Bluestein D.