World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:9, No:11, 2015

Computational Simulations and Assessment of the Application of Non-Circular TAVI Devices

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Abstract : Transcatheter Aortic Valve Implantation (TAVI) devices are stent-like frames with prosthetic leaflets on the inside, which are percutaneously implanted. The device in a crimped state is fed through the arteries to the aortic root, where the device frame is opened through either self-expansion or balloon expansion, which reveals the prosthetic valve within. The frequency at which TAVI is being used to treat aortic stenosis is rapidly increasing. In time, TAVI is likely to become the favoured treatment over Surgical Valve Replacement (SVR). Mortality after TAVI has been associated with severe Paravalvular Aortic Regurgitation (PAR). PAR occurs when the frame of the TAVI device does not make an effective seal against the internal surface of the aortic root, allowing blood to flow backwards about the valve. PAR is common in patients and has been reported to some degree in as much as 76% of cases. Severe PAR (grade 3 or 4) has been reported in approximately 17% of TAVI patients resulting in post-procedural mortality increases from 6.7% to 16.5%. TAVI devices, like SVR devices, are circular in cross-section as the aortic root is often considered to be approximately circular in shape. In reality, however, the aortic root is often non-circular. The ascending aorta, aortic sino tubular junction, aortic annulus and left ventricular outflow tract have an average ellipticity ratio of 1.07, 1.09, 1.29, and 1.49 respectively. An elliptical aortic root does not severely affect SVR, as the leaflets are completely removed during the surgical procedure. However, an elliptical aortic root can inhibit the ability of the circular Balloon-Expandable (BE) TAVI devices to conform to the interior of the aortic root wall, which increases the risk of PAR. Self-Expanding (SE) TAVI devices are considered better at conforming to elliptical aortic roots, however the valve leaflets were not designed for elliptical function, furthermore the incidence of PAR is greater in SE devices than BE devices (19.8% vs. 12.2% respectively). If a patient's aortic root is too severely elliptical, they will not be suitable for TAVI, narrowing the treatment options to SVR. It therefore follows that in order to increase the population who can undergo TAVI, and reduce the risk associated with TAVI, non-circular devices should be developed. Computational simulations were employed to further advance our understanding of non-circular TAVI devices. Radial stiffness of the TAVI devices in multiple directions, frame bending stiffness and resistance to balloon induced expansion are all computationally simulated. Finally, a simulation has been developed that demonstrates the expansion of TAVI devices into a non-circular patient specific aortic root model in order to assess the alterations in deployment dynamics, PAR and the stresses induced in the aortic root.

Keywords : tavi, tavr, fea, par, fem
Conference Title : ICBE 2015 : International Conference on Biomedical Engineering
Conference Location : Kyoto, Japan
Conference Dates : November 12-13, 2015