

### 3D CAD Based Conceptual Design of a Novel Aortic Valve Stent

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Vascular support structures are an important tool for treating valve stenosis. A large population of patients are treated for valvular disease and the principal mode of treatment is the use of percutaneous valvuloplasty. Stent devices are proving to be an improved treatment method; these devices now account for 20% of treatments in Europe. This new technology provides highly effective results at minimal cost and short duration of hospitalization. Accurate and reliable structural analysis provides essential information to the design team in an environment where *in vivo* experimentation is extremely expensive, or impossible. This paper describes the design of vascular support structure (stents), to provide designers with estimates of the critical parameters which are essential to restore the functions of the endothelium of the Aorta during and after implantation without injuring it. Stent geometries were uniquely defined using the following parameters. (a) Diameter of the aorta; (b) Distance between the aortic root and the

coronary artery roots; (c) Position of the coronary arteries; (d) Diameter of the coronaries; (e) Stent–Endothelium Mechanics. Keeping these parameters into consideration a novel stent model was designed to suit its requirement for percutaneous replacement. The 3D geometry of the repeatable units of the stent was generated using SOLIDWORKS modeling software. Using the repeating unit geometry of each stent design, solid models were generated. The unit consisted of 8 lips with two non crossing struts making a circular diameter of 16 mm at the center and 18 mm at either ends. The upper and the lower portions of the prosthesis has a high radial force, the upper portion flared to fix the stent firmly in the ascending aorta and the lower portion to expand against the calcified leaflets and to avoid recoil. The middle portion which bears the valve is constrained and narrower to avoid obstruction of the coronary arteries. This varying diameter of different parts of the stent creates the blunt hooks at either end of the stent. The methodology described in this paper is proposed as a method to compare and analyze the existing stents and the ones proposed here. However, further analysis and studies are needed before these stents are fabricated and deployed. Animal experiments are being planned currently for this purpose.

### CT Visualization of Cryoablation in Pulmonary Veins

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Over 2 million adults in the United States are affected by atrial fibrillation (AF), a common cardiac arrhythmia that is associated with decreased survival, increased cardiovascular morbidities, and a decrease in quality of life. AF can be initiated by ectopic beats originating in the myocardial sleeves surrounding the pulmonary veins. Pulmonary vein (PV) isolation via radio frequency ablation is the current gold standard for treating patients with drug-refractory AF. However, cryoablation is emerging as a new minimally-invasive technique to achieve PV isolation. Cryoablation is fast gaining acceptance due to its minimal tissue disruption, decreased thrombogenicity, and reduced complications (RF can lead to low rate of stenosis). One important question in regard to this technology is whether the PV lesion is transmural and circumferential and to what extent adjacent tissues are involved in the freezing process. As ice formation lends itself to image contrast in the body, we hypothesized that intraprocedural CT visualization of the iceball formation would allow us to predict the extent of the cryolesion and provide us with a measure of the adjacent tissue damage. Cryoablation was performed using a prototype balloon catheter cryoablation system (Boston Scientific Corporation). CT visualization of iceball formation was assessed both *in vitro* and *in vivo*. Initial *in vitro* studies were performed in agarose gel phantoms immersed in a 37°C water bath. Subsequently, *in vivo* cryoa-

blations were performed in 5 PV ostia in 3 crossbred farm swine. The catheters were positioned in the ostia under fluoroscopic guidance. CT scans of the thoracic region were obtained every 2.5 minutes. Animals were sacrificed 6 days after the procedures. Gross pathology and histology of tissues in the region of interest were evaluated. Significant metal artifacts from the catheter and edge artifacts from the tissues surrounding the cryoballoon were observed under CT imaging both *in vitro* and *in vivo*. *In vitro*, it was found that the size of the iceball was comparable to that observed visually during freezing of agarose gel phantoms. *In vivo*, contrast change consistent with iceball formation was observed during the ablation in two out of five veins. The most clearly delineated iceball also yielded the clearest morbidity. In this case, esophageal injury on the anterior side proximal to the cryoablation site was noticed during necropsy of the animal in which the iceball was visualized. Transmural and circumferential lesions were obtained in all PVs ablated. We have shown that CT can be used to visualize iceball formation *in vitro* and *in vivo* (with limitations) using our cryoablation system. While the iceball *in vitro* is easily visualized, iceball growth *in vivo* is most evident once the iceball has grown beyond the PV into the adjacent tissues. This suggests that while CT cannot easily visualize iceball growth in the PV wall itself, it may still be an important tool to guide clinicians and reduce potential morbidities in adjacent tissues. The authors acknowledge Dan Busian (Fairview University Medical Center, Minneapolis, MN) and Dr. Erik Cressman for assistance with CT imaging.