DESIGN OF SELF-EXPANDING PERCUTANEOUS CAVA VALVE STENT FOR TREATMENT OF TRICUSPID REGURGITATION

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Introduction

Tricuspid regurgitation (TR) is frequently encountered in patients with right heart valvular disease. With an increased volume of TR leakage volume, the patients' cardiac output (CO) will decrease, leading to symptoms of right heart failure. Surgical repair and the replacement of the tricuspid heart valve are the current corrective treatments available. However these interventional treatments carry an operative mortality of up to 22% in high-risk patient population. Transcatheter treatments introduce a minimally invasive approach for treatment of structural disease of the aortic, mitral, and pulmonary heart valves, and this method has expanded the therapeutic options for many high risk patients. At present, there is a lack in the clinical reports on the transcatheter treatment of TR and only limited experimental data have been published so far [Lauten, 2010]. Besides furnishing hemodynamically designed valve leaflets, designing of a structurally sound valve stent is equally important for the success of heart valve. Therefore, in this study we propose a cava valve stent which can withstand cyclic mechanical loads encountered during the life span of a heart valve, with design features that would address the problem of severe tricuspid regurgitation.

Methods

Novel cava valve stent geometries were specifically defined based on the diameter of vena cava. The geometry of the stent was generated using SOLIDWORKS 2012.One of the designs is as shown in Figure 1. The stent design consisted of 9 crowns with square shaped struts with anouter diameter of 25 mm at the stent main body. Two struts join to form a diamond shaped crown structure. The stent design has a strut thickness of 0.5 mm and a height of 12 mm. The material used was nitinol for its superelasiticity and shape memory properties. The design was optimized through a series of crimping and cyclic loading simulations for structural integrity.

Results

Our cava valve stents were designed to be robust and structurally sound during and after percutaneous implantation of the device. Additional unique features of the stent we proposed as shown in the figure include a) Flange arms for self-alignment, b) Rounded tip to prevent atrial perforation and c) Bi-directional hook system to anchor into the vena cavas. Our simulation results showed that the design is capable of withstanding crimping and cyclic loading.

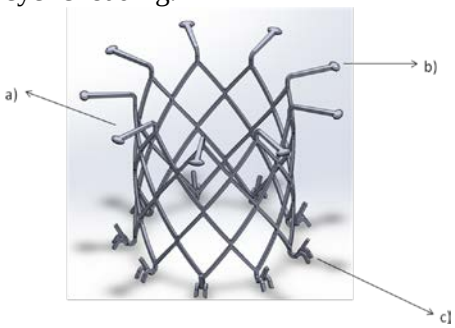

Figure 1: Proposed stent design

Discussion

Our percutaneous stents are specifically designed for cardiac patient population, suffering from moderate to severe tricuspid valve regurgitation. Severe tricuspid regurgitation contributes to sizable proportion of patients seen in most tertiary cardiology or cardiothoracic centres [Boudjemline, 2005]. Many of these patients are unfortunately left untreated due to pre-existing co-morbidities and run a high chance of dying from conventional surgery. Some others may have turned down treatment due to the fear of surgery [Sochman, 2011]. Given the high prevalence of the disease as well as lack of treatment options available, novel devices like the one proposed in this study, is likely to impact on a large number of patients. Most importantly, it would improve these patients' symptoms and longevity.

References

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