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Design considerations and quantitative assessment for the development of percutaneous mitral valve stent

Gideon Praveen Kumar[a], Fangsen Cui[a,*], Hui Qun Phang[c], Boyang Su[b], Hwa Liang Leo[b], Jimmy Kim Fatt Hon[c]

[a] Institute of High Performance Computing, A*STAR, Singapore 138632, Singapore
[b] Department of Bioengineering, National University of Singapore, Singapore 117576, Singapore
[c] Department of Cardiac, Thoracic and Vascular Surgery, National University Hospital, Singapore 119074, Singapore

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ABSTRACT

Percutaneous heart valve replacement is gaining popularity, as more positive reports of satisfactory early clinical experiences are published. However this technique is mostly used for the replacement of pulmonary and aortic valves and less often for the repair and replacement of atrioventricular valves mainly due to their anatomical complexity. While the challenges posed by the complexity of the mitral annulus anatomy cannot be mitigated, it is possible to design mitral stents that could offer good anchorage and support to the valve prosthesis. This paper describes four new Nitinol based mitral valve designs with specific features intended to address migration and paravalvular leaks associated with mitral valve designs. The paper also describes maximum possible crimpability assessment of these mitral stent designs using a crimpability index formulation based on the various stent design parameters. The actual crimpability of the designs was further evaluated using finite element analysis (FEA). Furthermore, fatigue modeling and analysis was also done on these designs. One of the models was then coated with polytetrafluoroethylene (PTFE) with leaflets sutured and put to: (i) leaflet functional tests to check for proper coaptation of the leaflet and regurgitation leakages on a phantom model and (ii) anchorage test where the stented valve was deployed in an explanted pig heart. Simulations results showed that all the stents designs could be crimped to 18F without mechanical failure. Leaflet functional test results showed that the valve leaflets in the fabricated stented valve coapted properly and the regurgitation leakage being within acceptable limits. Deployment of the stented valve in the explanted heart showed that it anchors well in the mitral annulus. Based on these promising results of the one design tested, the other stent models proposed here were also considered to be promising for percutaneous replacement of mitral valves for the treatment of mitral regurgitation, by virtue of their key features as well as effective crimping. These models will be fabricated and put to all the aforementioned tests before being taken for animal trials.

1. Introduction

For most patients suffering from mitral regurgitation and stenosis, one of the common valvular heart diseases, heart valve repair and replacement remains the only option for the alleviation of symptoms. However, the conventional surgical approach is associated with substantial operative mortality rates in high risk patients [1]. As a result, a less invasive and a safer approach to heart valve replacements hold the promise for less surgical-associated complications, with improved patient's survival rate and shorter recovery time. Though percutaneous heart valve replacement has gained traction amongst cardiology and cardiovascular surgical procedures following reporting of satisfactory early clinical experiences [2], the use of this technique is increasing for the replacement of pulmonary and aortic valves than that of the mitral valves [3]. The reasons why it is not so common in mitral valve replacement are: (a) complexity of the mitral annulus anatomy including chordae tendinae tissue, (b) difficulty for device anchoring, (c) paravalvular leakage, and (d) stent crimpability without undergoing mechanical failure [4]. The earliest percutaneous aortic stent valves were large, stiff devices (24F–26F in diameter, 1F = 0.33 mm), but iterative designs have reduced the system profiles of these devices to 18F for femoral approaches [5]. The similar profile limitations are applied to mitral valves if they are to be implanted through the

* Corresponding author. Tel.: +65 64191334; fax: +65 64674350.
E-mail address: cuifs@ihpc.a-star.edu.sg (F. Cui).

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femoral approach. Thus the designed stents must be able to mitigate the challenges of anchorage but also can be crimped and mounted onto catheters of these sizes.

More than a decade ago, it was felt that the mitral-valve sector would grow much more rapidly, from a transcatheter implantation standpoint, than the aortic-valve sector. However, the opposite has proven to be the case [24]. Although, catheter-based interventions for mitral regurgitation are currently under clinical evaluation, reports on transcatheter aortic and pulmonary valve replacement surgeries still dominate the current research publications on transcatheter heart valve technologies. Two possible reasons may be the complexity involved in the design of a mitral stent, and a general lack of information regarding the design criteria for mitral valve devices. At present, only a handful of percutaneous devices for mitral valve replacement are in the preclinical stage, and they are Endovalve-Herrmann prosthesis, Lutter prosthesis and CardiaQ prosthesis [6,7]. Some of the major limitations of these devices include anchoring challenges, left ventricular outflow obstruction and paravalvular leaks. The MitraClip (Abbott, Abbott Park, IL), on the other hand, is one of the few transcatheter devices on which there is significant clinical-trial data available to substantiate its use. However, this device is used only for valve repair and not replacement [8].

In an effort to overcome the challenges faced by developing mitral valve replacement devices for percutaneous implantation, we have proposed several new designs with novel features in this paper. The second objective is to come up with an effective way to study the crimpability which is crucial for implantation through a femoral approach. This has been evaluated through calculations using the crimpability formulation and FEA. Furthermore, one of stent designs was fabricated and on which, leaflet functionality and device anchorage tests were conducted. The results of tests on this design have been reported in the paper. From leaflet functionality tests carried out, it was found that the porcine trileaflet valve used in our prototype device exhibited competence and effectiveness in ensuring unidirectional flow of fluid from the atrium to ventricle during ventricular diastole and the prevention of backflow of fluid during ventricular systole by PIV measurement and dye injection. Besides, the fabricated stent prototype has shown an excellence fit to the mitral annulus in an explanted pig heart and the device has good anchorage in preventing distal migration of our device toward the atrium, without interfering with the chordae tendinae.

2. Materials and methods

2.1. Stent design

The human mitral valve is a very complex, dynamic and highly variable structure [9]. In this study, the mitral valve stent geometries were uniquely defined based on the diameter of the mitral annulus and the extension of the left ventricular outflow tract before arriving at the optimal diameter and the height of the stent, respectively [10]. The 3D geometries of the 4 stent designs were generated using SOLIDWORKS 2012 (Dassault Systemes, MA) software as shown in Fig. 1. The units consisted of several crowns with square shaped struts with an outer diameter of 30 mm at the stent center and a varying diameter along the flanges for different designs. Two struts joined to form a crown which is a diamond shaped structure. The stent design has a strut thickness of 0.5 mm and a height of 20 mm [19]. Table 1 describes the key features of the designed stents.

It seems that a 'D' shaped stent could be more coherent to the saddle shaped annulus. But such a design will have inherent challenges like uniform crimpability, suturing of leaflets, etc. Hence a circular stent design was considered whose diameter was 30 mm. With regard to using a trileaflet valve, studies [25,26] have shown that trileaflet valves have shown excellent results in terms of leaflet coaptation and durability.

2.2. Material model

Annealed Nitinol was selected for the modeling and prototyping of the stents. Nitinol is used in many biomedical applications due to its remarkable superelasticity, shape memory, biocompatibility, corrosion resistance, fatigue resistance and durability [11]. Cooled to less than 5 °C, Nitinol could fully transform into martensite and hence becomes deformable and easily compressed into a small catheter [12]. When the stent is released from the catheter into the mitral annulus aneurysm section, it recovers to its predetermined, considerably larger diameter at the 37 °C body temperature [13]. As a result, it anchors into the mitral annulus and native valve leaflets in the left ventricle. The Nitinol material used in this study was modeled in ABAQUS as a user material (UMAT) which is a thermo mechanical coupled superelastic-plastic model. The model is based on an additive strain decomposition, in which the total strain is taken as the sum of the elastic strain, the transformation strain, and the plastic strain. Plastic strains develop as soon as the material is loaded beyond full transformation. The transformation strain is of the order of 6%, but the elastic strain is much smaller, and should be limited to a maximum of 2%. Since the transformation strains are large compared to typical elastic strains in a metal, the material is said to be superelastic [15]. The mechanical constants used in this model are mainly from the experimental test conducted by our stent manufacturer and with reference to published work [14,18] as listed in Table 2. The uniaxial mechanical behavior of the Nitinol is shown in Fig. 2.

2.3. Crimping formulation

Based on the common geometrical property of our stent designs (see Fig. 1), following crimping Eq. (1) can be derived:

$$W_{total} = (n_{strut}W_{strut} + n_{hook}W_{hook})n_{sector} \quad (1)$$

where W_{total} is the total stent width in the circumferential direction, n_{strut} is the number of struts, n_{hook} is the number of hooks, n_{sector} is the number of sectors (means the design is cyclic), W_{hook} is the hook width and W_{strut} is the strut width.

The basic crimping criteria are as follows:

$$R_{OMC} = \frac{P_{outer}}{W_{total}} > 1 \quad (2)$$

$$R_{IMC} = \frac{P_{inner}}{W_{total}} > 1 \quad (3)$$

where P_{outer} is the stent outer perimeter and P_{inner} is the stent inner perimeter. R_{OMC} is the ratio of outer perimeter of the crimped stent to the total stent width and R_{IMC} is the ratio inner perimeter of the crimped stent to the total stent width. R_{OMC} and R_{IMC} values should be well over unity in order to have adequate crimping of the stent without component entanglement. Eqs. (2) and (3) also set the limit for maximum of crimping for a specific design.

2.4. Finite element modeling

2.4.1. Boundary conditions

The ABAQUS/Standard (v. 6.12-2) finite element analysis package, in combination with user-defined material model for Nitinol as given in Table 2, was employed to calculate the strain fields. A single node was constrained to prevent rigid body translation. For the stent model, rigid-deformable contact constraints were established between the outer surface of the stents and inner surface of