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Simulation Based Design and Evaluation of a Transcatheter Mitral Heart Valve Frame

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Abstract

In certain populations, open heart surgery to replace a diseased mitral valve is not an option, leaving percutaneous delivery a viable alternative. However, a surgical transcatheter based delivery of a metallic support frame incorporating a tissue derived valve puts considerable constraints on device specifications. Expansion to a large diameter from the catheter diameter without mechanical fracture involves advanced device design and appropriate material processing and selection. In this study, a new frame concept is presented with a desirable feature that incorporates wings that protrude during expansion to establish adequate fixation. Expansion characteristics of the design in relation to annulus fixation were quantified through finite element analysis predictions of the frame wing span and angles. Computational modeling and simulation was used to identify many favorable design features for the transcatheter mitral valve frame and obtain desired expansion diameters (35–45mm), acceptable radial stiffness (2.7N/mm), and ensure limited risk of failure based on predicted plastic deformations.

Keywords

mitral valve; regurgitation; stenosis; design approach; annulus fixation; computational modeling

Introduction

Heart valve disease most frequently affects the aortic and mitral valves, and the diseased valve may exhibit leakage, i.e., regurgitation, or narrowing, i.e., stenosis. The latter is the most common type of valve disease [1] and is usually the result of rheumatic fever in childhood. It can also be a consequence of plaque obstruction as an adult. The prevalence of moderate to severe mitral valve disease is increasing with population age, where mitral

regurgitation and mitral stenosis have a prevalence of 2.8 and 0.6 for ages 64–74 years, and 7.1 and 1.1 for ages 75 and older, respectively [2].

With patients that are screened and selected appropriately, surgical or percutaneous approaches have been used effectively to treat mitral stenosis by means of balloon valvotomy or commissurotomy. However mitral regurgitation remains a challenge for percutaneous repair, and thus the standard of care for a damaged valve is an artificial heart valve replacement. This requires open heart surgery. Mitral valve repair is specifically recommended for severe mitral regurgitation and heart failure symptoms, pulmonary hypertension, atrial fibrillation, increased left ventricular dimensions, or reduction in left ventricular systolic function [3]. Although surgical repair has been effective, there are a large number of patients that remain untreated. Research studies have reported that approximately 49% of patients with severe mitral regurgitation did not undergo surgery [4]. Patients who are considered high risk for surgery include the elderly, patients with reduced left ventricular systolic function, or other comorbidities [5]. This clearly demonstrates the necessity of a percutaneous valve to meet the demand of this high risk patient population. Additionally, a percutaneous mitral valve approach would be beneficial in situations where re-operative surgeries are required (valve-in-valve) and deployment of the transcatheter heart valve inside a damaged artificial valve would reduce the need for re-interventions. Kempfert *et al* concluded that valve in ring implantation is a promising concept for selected patients after failed mitral valve repair [6]. Similarly, the transcatheter valve could potentially minimize multiple surgeries and procedures, and improve patient recovery time.

Development of new percutaneous devices is necessary to realize percutaneous repair as a viable option to traditional surgical repair. Several indirect annuloplasty techniques address regurgitation by applying tension to the annulus and cinching the valve closed until acceptable coaptation, or leaflet hemodynamics are obtained. Devices such as the CE Mark approved Carillon™ Mitral Contour System (Cardiac Dimensions, Inc., Kirkland, WA) have been tested in animals successfully and clinical trials are underway. Of concern though is the varying coronary sinus location/motion and the reshaping of the mitral valve remains. Other direct annuloplasty techniques such as the AccuCinch™ System (Guided Delivery Systems, Inc., Santa Clara, CA) require a larger access site, which could lead to more surgical complications or longer patient recovery times [7]. Further percutaneous mechanical concepts have been explored to treat mitral valve regurgitation such as clips or even stitching the mitral valve leaflet together, essentially forming a double orifice. Studies have been conducted indicating that the clip was less effective at reducing mitral regurgitation than conventional surgery [8]; routine annuloplasty could be needed [9] and long term results are still unknown.

The mitral annulus shape is unique and varies from patient to patient depending on the diseased condition. When designing the mitral valve changes in annular geometry were considered because they could drastically alter valvular functional strains in vivo [10]. Although it has been suggested in recent real-time three-dimensional echocardiography (rt-3DE) studies that saddle shape annuloplasty rings may decrease leaflet stress and potentially increase the durability of the repair in patients [11], for a complete transcatheter heart valve replacement device concentricity is equally desirable to provide minimal crimp profile and repeatable uniform deployment. For degenerative mitral valve disease, anterior to posterior diameters were found to be on average at 34 ± 5 mm, and commissure to commissure diameters ranged from 40 ± 4 mm [12]. Further studies have shown that in patients with prolapse of mitral valve and ischemic mitral regurgitation that the mitral annulus dilates while the annulus height remains unchanged or decreases [13]. But, because the anterior annulus is adjacent to the aortic outflow track and valve, it is critical to have a device that can interact with the annulus boundary wall to avoid injury. To date there have

been only a few percutaneous mitral valve designs that have been investigated that attempt to do this. A nitinol self-expanding mitral valve stent housing a glutaraldehyde preserved bioprosthesis was tested in swine and revealed adequate function and effective anchoring for short term animal survival. Unfortunately, the device experienced failure modes ranging from atrial maldeployment with fixation wings caught underneath the anterior leaflet, to stent fracture breakages of the atrial and ventricular fixation systems [14–16]. This technology is evolving illustrated by recent design attempts [17–19]. For example, designs by CardiAQ Valve Technologies, Inc., (Irvine, CA) and Micro Interventional Devices, Inc., (Langhorne, PA; previously Endo valve, Inc., Princeton, NJ) are in early stage development, awaiting for prospective clinical trials.

Multifaceted issues of the percutaneous procedures within the anatomical constraints of mitral space (including blocking the coronary sinus, mitral leaflet geometry, and unique annulus shape) make the engineering involved in developing a percutaneous heart valve very challenging. In order to overcome the limitations of the current mitral regurgitation and stenosis therapies, we took the following design approach for developing the heart valve frame where prioritization was addressed by the following design specifications 1) gross frame expansion (expansion forces, diameters), 2) design features to accommodate annulus fixation, 3) radial stiffness, and 4) plastic strains. Computational analysis provided a means for quantifying and comparing the above listed design specifications relative to different geometrical designs.

Methods

One of the most important design considerations was the gross expansion of the frame because the mitral valve geometry has a unique D-shaped structure compared to other heart valves. Creating a D-shaped structure for the support frame was not ideal because it would require that 1) the device be self orienting once deployed, and 2) the imaging technique used during the procedure show the exact location where the valve is to be placed. Therefore, circular frame designs were compared with finite element analysis (FEA) to establish the expansion characteristics. Because of the frame candidates having semi-axisymmetric geometrical pattern, it was possible to use a representational 1/8 or 1/12 segment to explore full device behavior, which allowed for a quicker simulation. For a gross evaluation of expansion characteristics, multiple designs (examples shown in Figure 1) were simulated through a uniform radial displacement.

For fine-tuning of a favorable geometry a more detailed simulation was performed including an initial expansion to 44 mm diameter and release to a final deployed diameter of 42mm, crimping to 10 mm diameter and release, expansion and release to final deployed size, and a radial stiffness analysis at the deployed state by applying a radial diameter change and calculating radial reaction forces. The crimping utilized rigid planes to compress the stent to the target delivery system size. This process was similar to a mechanical crimper that would be used during valve preparation. To avoid stent buckling or non-uniform compression of the stent, an inner peg was inserted inside the stent, which had a smaller diameter than the delivered size. Utilization of an inner peg was justified by its diameter representative of the delivery system, onto which the device would be crimped. All simulations were conducted using implicit static analysis with Abaqus Standard (versions 6.7–1 or 6.9–1, Simulia, Providence, RI), with nonlinear elastoplastic solution processes.

For modeling purposes a cylindrical coordinate system and boundary conditions were established at angular planes, which represented the semi-axisymmetric behavior and prevented rigid body movement. Several nodes along the stent were constrained in the axial direction to prevent stent migration. The stent was meshed with linear tetrahedral elements

with the goal to provide adequate resolution of small, yet functionally important design features. The computational simulations included loading the stent in a manner that is intended to mimic deployment into the annulus. Each design was tested at the same kinematic conditions. The boundary conditions were modeled with displacement control, which is similar to how a balloon would displace the nodes of the stent in a uniform manner.

Figure 2 shows the FEA mesh model of the favorable design at an undeformed state where boundary and loading conditions are illustrated. A coarse mesh model (25715 nodes, 103081 elements) and a fine mesh model (159009 nodes, 732535 elements) were built and the results were compared for initial expansion characteristics for the entire stent geometry. The coarse mesh model was chosen to work out the crude structural response of the design whereas the fine mesh was utilized to explore worst case scenario plastic strains, which may have been influenced by mesh characteristics. This approach allowed a significant reduction in computational cost, permitting quick assessment of many different design candidates and features.

Once the favorable design was selected based on the gross expansion behavior, the wing anchoring fixation system performance was evaluated. The wing anchoring fixation system encompassed one or more design structures that specifically targeted valve attachment into the surrounding tissue annulus. One key aspect was to design a frame that could be deployed via a catheter that had features that would prevent migration. Computational modeling predictions of wing span, depth, and angle (Figure 3) guided the implementation of design features that were most appropriate for the diseased mitral valve anatomy. The requirements for the frame design were that the wing depth be able to grasp around the minimum leaflet thickness of 2mm because pathological findings of normal formalin-fixed tissue showed a mean thickness of 1 mm, and mean leaflet thickness for patients with mitral valve regurgitation were 2 mm [20]. If the wing depth was greater than 2mm that would be even more beneficial further securing the valve by interlocking around the annulus shelf. The frame design criteria for wing angle was to have it meet an angle greater than 50° due to our preliminary cadaver work. Recent imaging studies with echocardiography and cardiac magnetic resonance have shown that anterior and posterior mitral leaflet angles are 25.41 ± 4.28 and $38.37 \pm 8.89^\circ$ (mean $\pm$ SD) [21], therefore a wing angle of 50° should facilitate pushing the native leaflets out of the way and provide a sufficient clearing for the new transcatheter valve. The wing span distance requirement of 2mm was selected based on 24,380 retrospectively reviewed echocardiograms where the mitral annulus thickness was found to be 1–2mm, 2–5mm, and >5mm for mild, moderate, and severely calcified diseased patients [22].

After an analysis of wing fixation systems, the focus was on the device stiffness. Computational modeling was used to 1) select a desirable material providing adequate structural stiffness, 2) optimize the device thickness and strut width, and 3) quantify the recoil experienced from crimping and expansion. Since the computer simulation was displacement controlled, during the crimping process recoil was calculated based on the difference of the outer crimped device diameter compared to the diameter of the device upon release of the applied displacement. The new shape and size of the device due to the accumulated plastic deformation was considered the recoil phenomenon. Similarly, during the expansion process, recoil was calculated based on the difference of the fully expanded device diameter (due to displacement controlled conditions) compared to the final deployed device diameter upon release of the applied displacement.

One of the biggest technical hurdles was to select a material that would crimp to 10mm diameter in order to fit into the catheter and provide an acceptable crimp profile, while still being able to uniformly expand to a large diameter of 42mm. The material also had to be

biocompatible, corrosion resistant, and have good fatigue performance with a history for surgical heart valve applications. Investigation of both CoCr and 316LSS were considered because of their proven clinical history for heart valve and stent devices, high strength, and chemical stability [23], however CoCr material properties were used during the iterative gross stent expansion evaluations.

Finally, the plastic strains for the crimped and expanded frame design were reviewed after the previous functional performance requirements (expansion, wing depth/span/angle, stiffness) were deemed appropriate. The magnitude of plastic strain was compared against the material limit to indicate suitable fatigue durability.

Results

All designs were expanded to the desired deployed diameter of 42mm and gross expansion characteristics were evaluated. While the frame expanded, geometrical changes to the design were observed. Several designs were rejected because of unacceptable expansion due to overlapping struts, bowed struts, or severely high plastic strains (Figure 4). The ability of the frame design to readily expand upon balloon dilation was assessed by calculating the necessary force it took to open the valve frame from simulation results. For the favorable design, the radial force measured for a 1/12th segment at the expanded diameter was 35.97N, with an effective force area of 2376mm² (for the entire frame). The pressure it would take to open the frame was estimated as 0.1817 MPa (1.793 atm), which is low enough for most off the shelf balloon systems.

The selected favorable design had an expandable frame that included an outer circumferential axis with wing fixation members. Each wing includes a flexible middle portion, and is integrally formed within the main frame. When radially collapsed, the outer wing fixation members become flush with the main frame, minimizing the crimp profile for catheter delivery. One unique design of the stent frame is a recessed indentation that ensures the wings to open first during valve deployment (Figure 5). The wing anchoring mechanisms expand circumferentially during deployment to contact the mitral leaflets and the chordae.

The mitral valve has a tight landing zone, and therefore in order to prevent device migration it is essential that the design selected fasten on the annulus shelf. The wing span, depth, and angles were extracted from simulation results, and then the design was iterated based on surgeon description of the diseased anatomical environment. The results displayed in Figure 6 show the predicted wing mechanism trends during expansion for the favorable design. As long as the device was deployed to a minimum diameter of 35mm, the wing angle would open enough to grasp the tissue needed to stay in place. There was also an observed 5° angle loss due to expansion and release (recoil phenomenon). For wing depth a minimum of 2mm was required to endure the performance objective, and the device would have to be deployed to at least a 30mm diameter. The wing span prerequisite was also 2mm, which accounted for mild calcification, and the valve would call for a deployment diameter of about 25mm. For more severe calcification >5mm wing span would be desirable and a final deployed diameter of 35mm is recommended. Since the device was built for diameters >35mm, the wing anchoring fixation system (wing angle, depth, and span) met all the design specification conditions.

The mechanical properties of diseased hearts are very different than that of healthy hearts. For example, leaflet extensibility was reduced by 35%, radially oriented anterior mitral leaflet strips were 61% stiffer, and 23% less viscous on average in failing hearts compared to autopsy control hearts [24]. With stiffness increasing as the valve disease progressed, it

was important for the frame material to be able to withstand these compliance changes. Assessing the device material stiffness was done by comparing 316LSS against CoCr, for which all the previous results were shown. Table 1 includes the FEA information for both materials and models that were analyzed. At the deployed diameter the CoCr material showed a 1.5 times more stiff device (2.7N/mm vs. 1.8N/mm), which was expected based its elastic modulus. Because of the dynamic conditions of the heart, an overall stiffer device will be less likely to deform during heart pulsatility. The benefit of having the stiffer material in the device would be that the calcified tissue rim will more likely have to accommodate to the shape of the implant. Selecting CoCr should not negatively affect the heart because previous chronic surgical mitral valve replacement studies that use similar alloying materials have been successful, for example the Carpentier-Edwards porcine bioprostheses made of an Eligiloy TM wireform showed freedom from valve-related mortality in patients aged 61–70 [25]. And because annulus fixation was so imperative to the device function, the more compression resistant CoCr alloy was selected as the material of choice.

The computational model of the frame was also used for other material considerations including the raw material sourcing and the material recoil. Medical grade CoCr is very expensive and generally has a long lead time, and a more through analysis was conducted with multiple starting tube sizes that are commercially available (8–20mm). Our favorable design, for which the results are illustrated, had an initial tubing diameter size of 15mm. The device recoil observed from the initial crimping onto the delivery system was calculated to be a 2mm increase in crimp diameter. Utilization of a uniquely designed sheath could minimize this affect during device preparation, which would aid to hold the crimped valve at its smallest achievable size. And, a 3mm recoil was observed when going from the fully expanded device size (45mm) to the final deployed size (42mm).

The resulting contour plots of plastic strains are provided in Figures 7 and 8. For the fully deployed device a maximum peak strain of 55% occurred at one of the recessed areas in the fixation wings. But because each symmetric recessed wing had different values of plastic strains, this was attributed to a meshing artifact (mesh at those locations consisted of only one element thickness). To confirm, the fine mesh analysis was run and reviewed. The fine mesh results corroborated with our theory and revealed a maximum peak strain of 30% for the recessed fixation wings, and therefore those areas of peak strain in the coarse mesh could be disregarded. Nonetheless, the coarse mesh was adequate to test the performance of the wings of the anchoring fixation mechanism, which lead the team to select the favorable design for future prototyping and testing.

Discussion

We analyzed more than twenty frame designs, and came up with a final design that had desirable expansion characteristics, wing fixation performance, radial stiffness, and acceptable plastic strain levels. Computational modeling provided a means to compare these multiple concepts and identify the factors that were significant for a successful mitral heart valve frame. This engineering approach proved to be time efficient and overall cost effective, where each design implementation solution and documentation took less than a day. Having an available transcatheter mitral valve replacement is very important to provide a treatment alternative for high risk surgical patients. Those patients that are not surgical candidates could be offered an option that could extend and improve the quality of their life.

The favorable frame design is unique in its small crimp size, expansion diameter size, fatigue resistant material, and wing fixation expansion features which make it appealing for a transcatheter mitral valve replacement. A large diameter frame is required for a mitral

valve replacement device because the diseased annulus is larger than the healthy annulus. The engineered frame could be manufactured into a large diameter, yet still be delivered through a small catheter size and have acceptable plastic strains accumulated upon deployment. Uniform deployment of the stent and wings was an influential factor for the overall fatigue performance because in order to accurately predict the fatigue of the stent/valve through predictive finite element modeling, the structures of the device need to be expanded homogeneously. The mitral valve design comprises of a prosthetic valve secured within an expandable CoCr frame, knowing that CoCr material has been used successfully previously for heart valve applications. And lastly, because the annulus not only moves but also changes shape during the cardiac cycle [26], the distinctive wing fixation features act as a lock to secure the valve to the position on the tissue shelf, which is important for prevention of dislodgement.

It was important to reflect on the complex issues of the percutaneous procedure in mitral anatomy space when designing the frame, such as measuring the left outflow track dimension, complex mitral leaflet geometry, and unique annulus shape. The mitral anatomy makes it difficult to place the device due to a tight landing zone. Placement is critical for hydrodynamic valve performance and long term valve durability to ensure good leaflet coaptation and minimize peri/paravalvular leakage, thus reiterating the necessity for a design that has wing fixation anchoring features. Since the mitral valve is a trileaflet valve, having a frame design divisible by three helped to provide uniform distribution of areas for suture and leaflet attachment. Mechanical studies on bovine pericardium found that suturing weakens the tissue by being more extensible and lowering the stress at rupture [27], and therefore a uniform distribution could potentially increase valve durability. A circumferentially uniform design also avoids the need to orient the device during placement. Regardless of where the surgeon deploys the valve within the annulus, it is desirable to have it perform similarly. We tried to account for the distance between the anterior leaflet of the mitral valve and the coronary sinus, while accommodating the necessary wing fixation assembly. In the favorable design the valve height was 19.6mm, which is comparable to the highly variable measurements of that distance for patients (up to 19mm) [28]. The valve's intricate anatomy comprises of the annulus, the leaflets, the tendinous cords, and the papillary muscles. The valve is adjacent to the aortic valve and coronary sinus, while superior to the tendinous cords and papillary muscles. An illustration of the device deployed in the mitral valve anatomy is shown clearly in Figure 9.

The computational analysis provided a means for design comparison, but as with any modeling it inherently had some limitations. The device was designed to be deployed into a diseased anatomical environment which has varied geometry, contact interactions, and mechanical properties; yet our simulations provided only a simplified analysis of the boundary conditions. Additionally, device deployment occurs with a balloon, and the simulation does not attempt to model the balloon or represent the interactions of a balloon on the frame. Due to the intricate frame geometries explored, even further refinement of meshing densities would be desirable to obtain more accurate plastic strain predictions. Nonetheless, the simplification significantly reduced cost of virtual prototyping of a large set of design candidates.

One limitation to our study is that the annulus and stent interactions were not modeled, which would have provided a better understanding of the device performance in situ. The 1/8 or 1/12 model simplification was appropriate for assessing gross expansion characteristics and provided a feasible pathway to investigate design characteristics. However, the model simplifications did not account for the D-shape of the annulus, nor the changes in annular height due to the annulus saddle shape. A half of full model may be

necessary in order to investigate the device performance more accurately with integration of annulus and stent interactions.

Identifying the favorable design was only the initial phase for this project. The engineering approach taken can be improved by applying more realistic *in vivo* conditions in the model. To do this, it may be essential to study different imaging data such as CT (computed tomography), IVUS (intravascular ultrasound), and MRI (magnetic resonance imaging) to reveal details about the diseased environment [29]. This type of work could lead to knowledge about effects due to patient geometry, valve-tissue interfaces, boundary conditions, cardiac pressures and other interactions. Tissue mechanical testing on the diseased valve would provide a better representation of compliance for the tissue shelf, which could further aid in wing fixation design improvements.

A further evaluation procedure is to provide physical prototyping and test the design on cadaver specimens. For this purpose, a preliminary study was conducted to verify anchoring of the fixation system. Figure 9 shows that the wings on the favorable design did attach to the annulus shelf, which would securely place the valve in the correct location. Moving forward it would be useful to build a pressurized *in vitro* test chamber that represents the diseased environment in order to test prospective frame candidates.

There is future work planned relating to the frame durability as well. As required by the FDA guidance, the heart valve frame will need to demonstrate that it can withstand a minimum of 600 million cycles to failure [30]. This may entail making small adjustments to the frame processing and/or manufacturing methods to enhance the life performance. Such modifications could include adjusting the heat treatment parameters and or surface finishing steps. Also, building the frame out of nitinol, a nickel-titanium shape memory alloy material, may be beneficial to the performance and could be investigated in future work. The frame's complex geometry could be fabricated out of nitinol, and certain aspects of the design such as the wing angles would be accurately controlled by shapsetting of the superelastic material. Other advantages such as scaling the device to various patient sizes may be more easily accomplished by using nitinol flat sheet and wrapping around a mandrel to obtain the desired dimensions. And, perhaps the final design would have more conformability to the native geometry, with a constant outward force and radial resistive force that would help to keep the device in place. The disadvantage and main reason nitinol was not investigated during this study was that at the time of the design work only preliminary clinical trial results for a nitinol bioprosthetic heart valve device were available, and compared to other metallic alloys currently used in implant applications nitinol was found to have the lowest fatigue-crack growth resistance [31, 32]. But recently, the aortic transcatheter heart valve Medtronic Corevalve® system made of nitinol has confirmed early and sustained clinical benefits for patients having high rates of procedural success (98%), low rates of adverse events (2.1%), and substantial improvements of cardiac function [33]. The computational model developed could be easily adapted to evaluate manufacturing the device out of Nitinol by replacing Nitinol material properties with the current 316LSS model material properties, and evaluating the strains generated.

A preliminary prototyping and gross testing of the favorable design established the benefit of simulation-based identification of a working candidate. For example, it was possible to crimp and expand the device, as predicted by the model and anchor it to the tissue shelf (Figure 10). However, in order to demonstrate that the expansion/axial fixation can support the loads caused by the high left ventricular (LV) pressures and dynamic annular forces our future work will involve *in silico* testing and animal studies to discover if fractures would occur. Our ongoing work incorporates more acute and chronic animal studies already and is focused on acute sheep testing with initial results indicating no frame dislodgement. Other

small design changes may be investigated, for instance the possibility of introducing an additional support ring to maintain the expanded larger diameter of the frame (45mm). But these design changes would require further structural analysis and testing before prototyping and evaluating.

Conclusion

Through implementation of modeling and simulation, we were able to demonstrate the performance of a stent design prior to production and testing. The computational model provided a means to compare unique stent geometries and concepts for wing anchoring fixation mechanisms. The computational modeling analysis technique accessed other production considerations as well, such as material selection and tubing diameter size by optimization of plastic strains to improve fatigue performance. Virtual prototyping helped identify a favorable design for physical prototyping and testing. This process shortened the design cycle time when considering multiple designs or concepts, allowing for safe and rapid innovation.

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Figure 1.

Several design geometries were tested through computational simulation. Only the periodic circumferential segments (representative of semi-axisymmetry) are shown. All the designs incorporated some form of a wing type structure. Many possibilities including but not limited to overall design size, e.g. diameter, shape of individual components, i.e. of the wings, strut thickness, were considered. The highlighted design, on the far right side, shows the favorable geometry which has a starting tube diameter of 15mm.

Figure 2.

A tetrahedral mesh was utilized to discretize frame geometries. The undeformed mesh of the favorable design (also see highlighted design in Figure 1) was shown here along with a local coordinate system and boundary conditions. A cylindrical local coordinate system helped implement semi-axisymmetric deformation of the mitral valve frame. Arrows indicate the location and direction of displacement boundary conditions. Prescription of the translational degrees of freedom at these locations provided the simulation of the expansion of the device to a desired diameter.

Figure 3. The wing span, depth, and angle measurement locations were acquired from predicted expansion of the favorable design. A cross-section of the device at the circumferential plane is shown.

Figure 4. Expanded geometry of a failed (on the left) and the working (favorable, on the right) design. Finite element analysis provided the prediction of the designs at expanded states as well as the stress-strain distributions within. Red regions denote plastic strain magnitudes higher than 50%. The failed design had significant plastic deformation even before it expanded to the desired diameter.

Figure 5.

a) Deployed three-dimensional geometry of the favorable percutaneous mitral valve stent frame as predicted by finite element analysis. The predictions utilized a simplified expansion scenario of the frame, prescribed by radial translation of various device regions to a desired diameter (also see Figure 2). Full geometry was generated through circumferential stacking of the semi-axisymmetric model. b) A close-up view of recessed indentation that provided the capacity for wing opening upon valve deployment.

Figure 6.

Wing span, depth, and angle of the favorable design (see highlighted design in Figure 1) as a function of inner diameter dictated during initial expansion. These variables were predicted by finite element analysis, prescribed by incremental radial translation of the design to the desired diameter (in this case 44 mm). See Figure 3 for more detailed description of these expansion variables.

Figure 7.

The plastic strain magnitudes of the favorable design (see highlighted design in Figure 1) at the fully deployed diameter (~44 mm) were found to be less than 30%. Plastic strain magnitude distribution in the device is shown from a top view of the expanded frame. Predictive strains of 55% did occur with the coarse mesh analysis due to a meshing artifact, and this was confirmed by a fine mesh analysis (outermost right subcells).

Figure 8. Predicted plastic strain magnitude distribution for the crimped frame (~10 mm). Results for the favorable design (see highlighted design in Figure 1) are shown, where the observed plastic strains were 15%. Provided analysis results were obtained using the coarse mesh (also see Figure 7).

Figure 9.

An illustration of the transcatheter valve deployed in its final configuration anterior to the fossa ovalis and papillary muscles, and adjacent to the coronary sinus. The device is crimped on the catheter system and positioned across the native mitral valve. Balloon expansion of the device triggers the anchoring fixation wings to secure around the tissue annulus.

Figure 10.
Transcatheter mitral heart valve frame with wing fixation system securely deployed and secured in a cadaver sheep annulus. An axial view is shown.

Table 1

FEA model information for favorable design tested with different materials. Geometry of the favorable design can be seen in Figure 1. Mesh and loading and boundary conditions can be viewed in Figure 2.

Model Parameters		
Model Description	*CoCr Design	316LSS
Number of Nodes	25715	25715
Number of Deformable Elements	103081 linear tetrahedral elements of type C3D4	103081 linear tetrahedral elements of type C3D4
Material Properties	$E = 240 \times 10^3 \text{MPa}$, $\nu = 0.29$	$E = 195 \times 10^3 \text{MPa}$, $\nu = 0.29$
Plastic Kinematic Hardening	Yield Stress 500 MPa -Plastic Strain 0 Yield Stress 1000 MPa-Plastic Strain 0.498	Yield Stress 320 MPa – Plastic Strain 0 Yield Stress 630 MPa - Plastic Strain 0.448
Simulation Information		
Operating System	Linux (CentOS 5.0), KERNEL: Linux version 2.6.18–53.1.4.el5, CPUS: 2 × Intel(R) Xeon(TM) CPU 3.40GHz, MEMORY: 6GB	Linux (CentOS 5.0), KERNEL: Linux version 2.6.18–53.1.4.el5, CPUS: 2 × Intel(R) Xeon(TM) CPU 3.40GHz, MEMORY: 6GB
Software	ABAQUS Standard version 6.7–1	ABAQUS Standard version 6.9–1
Simulation	80855 s (CPU), 167536 s (wallclock) (on single CPU)	46903 s (CPU) 27668 s (wallclock) (on dual CPU)

* Model used for iterative stent computational analysis.