Finite Element Analysis of Stent Deployment: Understanding Stent Fracture in Percutaneous Pulmonary Valve Implantation

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Objectives: To analyze factors responsible for stent fracture in percutaneous pulmonary valve implantation (PPVI) by finite element method.

Background: PPVI is an interventional catheter-based technique for treating significant pulmonary valve disease. Stent fracture is a recognized complication.

Methods: Three different stent models were created: (1) platinum–10% iridium alloy stent – resembles the first-generation PPVI device; (2) same geometry, but with the addition of gold over the strut intersections – models the current stent; (3) same design as 1, but made of thinner wire. For Model 3, a stent-in-stent solution was applied. Numerical analyses of the deployment of these devices were performed to understand the stress distribution and hence stent fracture potential.

Results: Model 1: Highest stresses occurred at the strut intersections, suggesting that this location may be at highest risk of fracture. This concurs with the in vivo stent fracture data. Model 2: Numerical analyses indicate that the stresses are lower at the strut intersections, but redistributed to the end of the gold reinforcements. This suggests that fractures in this device may occur just distal to the gold. This is indeed the clinical experience. Model 3 was weakest at bolstering the implantation site; however, when two stents were coupled (stent-in-stent technique), better strength and lower stresses were seen compared with Model 1 alone.

Conclusions: Using finite element analysis of known stents, we were able to accurately predict stent fractures in the clinical situation. Furthermore, we have demonstrated that a stent-in-stent technique results in better device performance, which suggests a novel clinical strategy. (J Interven Cardiol 2007;20:546–554)

Introduction

Heart valve disease is generally treated with open heart surgery. An innovative nonsurgical technique for heart valve replacement has recently become a reality in the treatment of right ventricular outflow tract dysfunction.1,2 Percutaneous pulmonary valve implantation (PPVI) involves transcatheter placement of a valved stent within the existing degenerated valve or conduit, and provides excellent hemodynamic results.3 The device is made of a valve from a bovine jugular vein, sewed into an expandable stent and mounted on a balloon catheter for delivery (Fig. 1A). Bovine jugular venous valves are available only up to 22 mm of diameter. Therefore, only right ventricular outflow tracts smaller than 22 mm of diameter can be treated with this percutaneous device. However, in borderline cases, with larger or high-compliance outflow tracts, the stent is overdeployed up to 24 mm. The first stent...
used for PPVI was created by a platinum–10% iridium wire (NuMED Inc., Hopkinton, NY, USA). The wire was formed into a zig-shaped pattern and the individual segments were joined together at the crowns to create the full stent, by welding of the platinum. Since the platinum welds were prone to fracture, this device was modified in design by introducing a gold-brazing process to reinforce the crowns of the stent.

Between January 2000 and May 2006, PPVI was successfully performed in 123 patients. The early generation device was implanted in the first 10 patients; the new design prosthesis into the following 113 patients. Stent fracture is a recognized complication following stent implantation for all cardiovascular applications. In our PPVI series, stent fracture was detected in 26 patients: 4/10 (40%) patients treated with the early generation device and 22/113 (19%) patients treated with the gold-reinforced stent. The fractures occurred during crimping of the stent onto the balloon in two cases (both early generation devices), following balloon dilatation in 3 patients, following implantation of a second percutaneous valve in 1, and spontaneously in 21 patients. The exact location of fractures in the PPVI patients was analyzed from both the frontal and lateral chest X rays. The early generation stents fractured at the strut intersections (Fig. 1B). After reinforcing the weld with gold, these fractures were no longer seen. In fact, in the new design stent, fractures occurred more frequently next to the ends of gold-brazed parts (Fig. 1C).

In 6 patients, interventional management of the stent fracture was possible by repeat PPVI (stent-in-stent technique) for stabilization of the fractured parts, with successful hemodynamic results. The feasibility of stent-in-stent implantation has previously been demonstrated with different stents for a variety of indications in congenital heart disease. Repeat PPVI represents the most promising approach to treat stent fracture. Multielement devices can be produced combining stents of diverse material and design to take advantage of their different mechanical properties, reinforce the prosthesis, and avoid fracture.

The purpose of this study was to evaluate stent fracture in PPVI devices, by analyzing the stress distribution during loading conditions and comparing different device designs. Finite element (FE) analyses were used to achieve this. The extra strength provided by a second device in the stent-in-stent technique was evaluated in contrast to the performance of a single prosthesis.

**Materials and Methods**

Large deformation analyses were performed using the FE method commercial code ABAQUS/Standard 6.4 (Hibbit, Karlsson & Sorenses, Inc., Pawtucket, RI, USA).

**Geometries and Mesh.** Three stent geometries were created on the basis of data supplied from the company or obtained from measurements by means of caliper and optic microscope. The stent geometries were created to emulate the initial crimped status of the device onto the catheter balloon.

The first model – named PL – was characterized by six wires (wire diameter of 0.33 mm), each formed in eight zigzags. Individual wires were joined together at the crown points to create the full stent (Fig. 2A). This geometry represented the early generation device used in PPVI.

The second model (PL-AU) had the same geometry as the previous one but also included gold-brazed areas in the shape of 0.076 mm thick sleeves around the platinum wire crowns (Fig. 2B). This stent resembled the device currently used.
The third model (PL\textsubscript{1/2}) had the same design as the PL device but with a wire diameter of 0.23 mm (PL\textsubscript{1/2} material mass was half the mass of the PL stent). This model was designed in order to evaluate and quantify the change in mechanical performance of a stent made from a thinner wire.

The biological valve mounted into the clinically used stent was not modeled in this study.

The FE model mesh was automatically generated. All stents were meshed with 10-node tetrahedrons in order to easily fit the complex geometries studied and give an accurate solution. The gold elements of the PL-AU model were tied to the platinum wires to avoid relative movement or separation between the two parts.

Mesh Sensitivity. Before running the analyses, a sensitivity test was performed on the PL model mesh to achieve the best compromise between limited calculation time and no influence of the element number on the results.

Five meshes with an increasing number of elements and nodes were tested (Table 1).

Materials

NuMED supplied platinum–10% iridium alloy engineering stress-strain data for uniaxial tension tests (Young modulus 224 GPa, Poisson ratio 0.37, yield stress 285 MPa). The material was assumed to have isotropic properties. A Von Mises plasticity model, commonly used with metallic alloys, along with an isotropic hardening law, was used in the analyses.\textsuperscript{12-14} Handbook properties were applied for gold mechanical behavior (Young modulus 80 GPa, Poisson ratio 0.42, yield stress 103 MPa).

Analyses. Inflation of balloon-expandable stents is clinically performed by pressurization of a balloon inserted inside the device. Modeling the interaction between the balloon and the stent is expensive in terms of time and power calculation and is only important for analyses in which the transitory configurations are required.\textsuperscript{15} The intention of this study was to look at

Table 1. Mesh Sensitivity Analysis

<table>
<thead>
<tr>
<th>Spacing</th>
<th>Elements</th>
<th>Nodes</th>
<th>$R_{\text{Peripheral}}$ [%]</th>
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<tr>
<td>A</td>
<td>0.17</td>
<td>85393</td>
<td>176424</td>
</tr>
<tr>
<td>B</td>
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<td>95720</td>
<td>195365</td>
</tr>
<tr>
<td>C</td>
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</tr>
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<td>218832</td>
<td>417126</td>
</tr>
<tr>
<td>E</td>
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$R_{\text{Peripheral}}$ — elastic recoil in the stent peripheral sections.
the stent in its final configuration (when the balloon was completely inflated) and after balloon deflation. For these reasons, the balloon was not modeled in the simulations.

Computationally, the inflation of the stent may be performed using either direct pressure applied to the internal surface of the stent or through prescribed boundary conditions. Attempts to expand the device with a pressure applied directly to the internal surface of the stent can prove difficult, due to lack of geometrical symmetry in the design. Indeed the terminal parts of the stent are not constrained by other segments. Therefore, the deployed configuration could result in unrealistic deformations of the device (Fig. 3). Consequently, the stent was inflated using radial expansion displacements up to an internal diameter of 24 mm (maximum diameter reached by the device during actual PPVI). Once the stent had reached the desired diameter, the displacement constraints were removed to simulate the balloon deflation and allow the elastic recoil of the stent.

Lastly, in order to simulate the compression force experienced by the device due to the implantation site wall, a gradual pressure was applied to the external surface of the stent. This enabled evaluation of the stent strength to maintain the patency of the vessel.

To compare the performance of two coupled devices (stent-in-stent technique) against the single prosthesis, the inflation of two stents – one inside the other – was simulated. First, the outer stent was deployed up to 24 mm and released, as previously described. Next, the inner device was inflated up to 24 mm, making contact with the outer stent. The displacement constraints were removed to allow the material to recoil. Finally, a pressure was applied to the external surface of the outer stent to evaluate the strength of the structure.

The interaction between the two devices was described by a contact algorithm with friction (coefficient of sliding friction equal to 0.25).

The stent-in-stent analysis was performed with two PL (2PL) and two PL1/2 (2PL1/2) devices. Indeed, three different coupling configurations of the two PL stents were analyzed to assess the influence of the relative position between the inner and outer device: perfectly aligned (0 degrees), and 11.25 and 22.5 degrees of relative rotation (Fig. 4). For the PL1/2 stent the perfectly aligned configuration was studied.

Investigated Parameters. The following mechanical properties were measured:

- Elastic recoil (R) following virtual balloon deflation in the stent middle (R_{middle}) and peripheral (R_{peripheral}) sections; the elastic recoil was defined as: \( R = \frac{D_{load} - D_{unload}}{D_{load}} \cdot 100 \), with \( D_{load} \) and \( D_{unload} \) equal to the stent diameter at the end of the loading and unloading step, respectively. The difference in the elastic recoil (\( \Delta R \)) between peripheral and middle section of the stent was defined as: \( \Delta R = R_{peripheral} - R_{middle} \).

Figure 3. Deployed configuration (black) of the PL-AU stent resulting from the application of a pressure directly to the internal surface of the device. The initial configuration of the stent is shown in light gray.

Figure 4. Three relative rotation degrees between the outer (black) and inner (light gray) devices in the 2PL analyses at the end of stent inflation.
• Von Mises stress ($\sigma_{VM}$) map at the end of virtual balloon inflation, deflation, and after application of the external pressure.
• Radial strength, represented by the plot of radial displacement resulting from the applied external pressure. The displacement was evaluated at both the peripheral and central nodes of the device.

Results

Mesh Sensitivity. Von Mises stress color map and elastic recoil of the peripheral nodes of the stent were checked for the different meshes. The stress distribution was similar in all meshes. The difference in elastic recoil between meshes decreased with the increase in element number (Table 1). Mesh C was selected as the mesh that guaranteed a solution independent from the grid without a critical increase in calculation time.

The mesh of the gold parts, built around mesh C of the PT model, resulted in additional 116,602 elements for the PL-AU stent.

The PL$_{1/2}$ mesh was made of 149,703 elements and 304,054 nodes.

Elastic Recoil. Inflation by displacement control resulted in uniform radial expansion in all stent configurations. Upon balloon deflation, the R of the different devices was generally low, especially if compared to the values reported for stents used in different clinical indications.$^{16-18}$

As expected, $R_{PL_{1/2}} > R_{PL}$ because of the larger wire section of the PL stent, and $R_{PL} > R_{PL-AU}$ because of the gold reinforcement in the PL-AU stent (Table 2).

The difference in elastic recoil between the peripheral and middle sections was tiny for all the stents. The highest $\Delta R$ was in the PL$_{1/2}$ stent, where the peripheral sections recovered more than the central part. Pressure applied uniformly to the external surface of the stent revealed that the peripheral sections of the PL$_{1/2}$ device were also weaker than the central part in bolstering the arterial wall (Fig. 5C).

The elastic recoil of the 2PL stent-in-stent analyses was almost the same in the three rotation configurations and $R_{PL} > R_{2PL}$. The coupled system can be imagined as a combination of two parallel springs. The force of recovery in the 2PL is bigger than with one single device.

For the same reason, $R_{middle_{PL_{1/2}}} < R_{middle_{2PL_{1/2}}}$. However, $R_{PL_{1/2}} > R_{2PL_{1/2}}$, the coupling of two PL$_{1/2}$ stents reinforced the peripheral sections of the structure.

Stress Distribution. The Von Mises stress map at the inflated diameter of 24 mm is presented in Fig. 5A for the PL, PL-AU, and PL$_{1/2}$ stents. The highest stresses occurred in localized regions of the devices – at the strut intersections – where a peak of approximately 660 MPa was detected. These stresses were primarily due to the bending of the wires close to the platinum welds as the struts opened during inflation. Stress values throughout the stent were typically lower, diminishing rapidly from the crowns to the straight parts.

After virtual deflation of the balloon, at the end of the elastic recoil (Fig. 5B), $\sigma_{VM}$ were lower everywhere due to the general unloading of the entire structure.

When compared to the PL device, the values of $\sigma_{VM}$ in PT-AU were slightly smaller, both at the end of the inflation step (Fig. 5A) and virtual balloon deflation (Fig. 5B). However, this difference was mostly evident when the external pressure was applied (Fig. 5C), that is, when the stent has to resist to the recovering force of the arterial wall.

The 2PL model gave analogous results in terms of $\sigma_{VM}$ between the three different relative rotation couplings (Figs. 6A, 6B). The stress distribution in the inner 2PL stent was similar to that of the PL stent. However, the outer 2PL stent presented lower stress values than the PL device during the entire loading history. The same results were found for the 2PL$_{1/2}$ inner and outer stents (Fig. 6C) when compared to the PL$_{1/2}$ model.

Device Strength. The charts in Figure 7 show the radial displacement of the peripheral and middle section nodes of the stents subject to the external pressure. The trend lines were similar in the two sections for all devices: at low pressure levels, high increases in pressure corresponded to low displacements, as the devices possessed adequate strength. However, as the

<table>
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<th>Table 2. Elastic Recoil Values</th>
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<td>Model</td>
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<td>PL</td>
</tr>
<tr>
<td>PL-AU</td>
</tr>
<tr>
<td>PL$_{1/2}$</td>
</tr>
<tr>
<td>2PL – 0 degrees</td>
</tr>
<tr>
<td>2PL – 11.25 degrees</td>
</tr>
<tr>
<td>2PL – 22.5 degrees</td>
</tr>
<tr>
<td>2PL$_{1/2}$ – 0 degrees</td>
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$R_{peripheral}$—elastic recoil in the stent peripheral sections; $R_{middle}$—elastic recoil in the stent middle section; $\Delta R$—difference in elastic recoil between peripheral and middle section of the stent.
Figure 5. Von Mises stress ($\sigma_{VM}$) map in the PL, PL-AU (the gold elements were removed to visualize the stress distribution in the platinum elements), and PL$_{1/2}$ stents at (A) end of the inflation, (B) elastic recoil, and (C) after application of a 0.2 MPa pressure to the external surface of the devices.

Pressure increased past a threshold, all structures lost their strength, and displacement increased disproportionately to pressure. The threshold pressure for each type of stent was different depending on its design.

As expected, the weaker device was the PL$_{1/2}$ stent, because of the thinner wire used to form it. The gold brazing reinforced the PL stent providing it with extra strength. The relative rotation between the inner and...
SCHIEVANO, ET AL.

Figure 6. Von Mises stress ($\sigma_{VM}$) map of the inner and outer stents of the 2PL models for (A) 0 degrees and (B) 22.5 degrees configuration, and (C) of the 2PL$_{1/2}$ model, at 0.2 MPa of pressure.

outer stent in the 2PL devices did not influence the displacement response to the applied pressure. The 2PL model presented a higher strength than the single PL device and even than the PL-AU stent, especially in the peripheral sections. The 2PL$_{1/2}$ device was stronger than the single PL$_{1/2}$ and its strength was comparable to the PL stent.

Discussion

The targets involved in the design of a PPVI stent require a careful compromise between interrelated and sometimes contradictory material and geometrical properties. The PPVI stent must be loaded onto the delivery system and manually crimped on the balloon. Upon insertion into the vascular environment, the delivery system must be manipulated within the tortuous anatomical pathways leading to the implantation site. The delivery of the device to the optimal position requires good visibility under fluoroscopy. Stent deployment is gained by gradual inflation of the balloon. Upon acquiring the final diameter, the balloon deflation causes recoil of the stent to a smaller diameter, which is also influenced by the pressure exerted by the implantation site wall. High stent recoil rate can cause stent dislodgment. Stent structural integrity must be guaranteed in the long term. The major concerns related to fracture are the maintenance of radial strength, integrity of the sutures between valve and stent, and the risk of late embolization in view of the lack of tissue ingrowth that we have seen with the PPVI stent. A high biocompatibility is also necessary to prevent thromboses or restenoses. During follow-up, standard X-ray-based imaging investigation has to be used to assess the performance of the device.

Although platinum and iridium are mechanically rather weak materials, they also present some important characteristics that make them the materials of choice for the PPVI stent. Platinum–10% iridium alloy is biocompatible and has an exceptional radio-opacity due to its high density (21.55 g/cm$^3$ against 7.95 g/cm$^3$ of stainless steel). The resulting high radio-visibility permits the use of thin wires, thus improving flexibility and deliverability. Indeed, the stent wire diameter has to be as small as possible to have the minimum overall profile to negotiate the vascular pathways. The use of this material and the unique wire-based design facilitates crimping onto the balloon and allows stent expansion at acceptable balloon pressures. The reasonably small elastic recoil ($<2\%$) guarantees a safe anchoring of the device in the implantation site. The breakage of the platinum welds at the crown junctions has been solved by gold brazing. However, the resistance to fracture of the new PPVI device remains the major concern of this stent material and design.

This FE study has proved that the maximum stresses reached in the device during inflation remain
STENT FRACTURE IN PERCUTANEOUS VALVE IMPLANTATION

Figure 7. Radial displacement of the stent peripheral and middle nodes in response to the external pressure applied to emulate the compression force of the implantation site.

acceptable (platinum–10% iridium ultimate tensile strength of 875 MPa, data supplied by the manufacturer). However, it is clearly visible from the computational analyses that the stress increases according to the expansion diameter; the safety of the device, therefore, is highly dependent on the magnitude of deployment.

The comparison between the PL and PL-AU models after external pressure application showed much lower stress in the PL-AU stent at the strut intersections. This is because in these points the resistant section of the PL-AU device is larger. The relatively weak gold actually reinforces the weld sections of the stent. However, it is possible to note a redistribution of $\sigma_{VM}$ in the straight platinum sections, at the end of the gold reinforcements: the structure is loaded at these points more than when there is no reinforcement, because of the reinforcement itself. Indeed, the gold reinforcement creates geometrical and material discontinuities. This suggests that fractures in the PL-AU device may occur just distal to the gold-brazed elements, as proven from patient X-ray investigation (Fig. 1C).

The limited recent experience with the stent-in-stent technique demonstrates not only that repeat PPVI is safe and feasible, but also that the implantation of a previous device before the valved one may act functionally to bolster the vessel and ensure the integrity of the valved stent. The 2PL1/2 device compared to the PL stent showed the same ability to withstand external pressure, the same stress distribution in the inner stent, but favorable, lower stress values in the outer device. Because of its wire diameter, the two PL1/2 stents employed in the 2PL1/2 model present the same material mass as the PL stent, but the thinner wire allows easier crimping, better deliverability, and greater flexibility. The recoil is higher in the 2PL1/2 device than the PL stent. However, the FE study showed that as gold brazing reinforces the platinum wires, the elastic recoil is reduced. Therefore, it is reasonable to conclude that a coupling of two PL-AU devices made of a thinner wire would result in better performance. In clinical practice, the stent-in-stent technique could be performed either sequentially or as a single-step approach. In our experience, sequential stenting can be performed safely (6 patients – no embolization). For the single-step approach (not performed to date), the delivery system would be of similar size, as the two stents are half the size of the previous single device, and thus additional complications of a higher French delivery system would be avoided. Therefore, the multielement stent with gold reinforcement is a possible solution to reduce the chance of device fracture in PPVI and increase the success of this procedure, without theoretically compromising its technical ease. The FE analysis of this device was not carried out, because of the large number of nodes and elements required by the mesh of this model, which exceeds the performance of the computer used in this study.

The pressure to compress the stents modeled in this study to a smaller diameter (Fig. 7) is high if compared to data reported from mechanical tests in endovascular stents, where, however, the device is subject to punctual loads. The pressure in the FE model is uniformly applied along the stent circumference. Therefore, higher pressure values are guaranteed to be on the safe side in the computational analysis.

In vivo, the stent conforms its shape to the implantation site. Some stent dimensions were assessed from angiographic pictures in the PPVI patients. The measurements showed that the shape of the in vivo stent differs from the theoretical cylindrical profile. Therefore, the forces that the stent may be subjected to by the implantation site and the surrounding tissues are not uniform around the circumference. This can cause high-stress concentrations in some parts of the stents.
and increase the risk of fracture. Clearly, the main limitation of this study is the absence of the implantation site model. The next step will be the development of FE models of realistic right ventricular outflow tract geometries, which can be obtained from intravascular ultrasound or magnetic resonance imaging. By simulating the interaction between the stent and the real implantation site model, it may be possible to evaluate the deformed shape of the device and the real distribution of stresses to which the prosthesis is subjected.

Conclusions

PPVI is a successful alternative to open heart surgery for pulmonary valve disease treatment. Stent fracture is the major complication related to this procedure. Few in vivo and experimental data about the factors responsible for PPVI stent fracture have been available until now. In this paper, the FE method is proposed as a technique to analyze and compare existing stents in order to understand the mechanical reasons for their fracture and to optimize their design. The multielement stent presented in this study is a new concept that could solve the problem of fracture in PPVI devices. The coupling of two stents, made from thin wires, results in high strength and low stresses, which guarantees better resistance to fracture, without affecting other fundamental device properties such as easy crimping and low elastic recoil.

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References