FRACTURING THE RING OF SMALL MITROFLOW BIOPROSTHESES BY HIGH-PRESSURE BALLOON PREDILATATION IN TRANSCATHETER AORTIC VALVE-IN-VALVE IMPLANTATION

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Early deterioration of Mitroflow aortic bioprostheses (Sorin Group Inc), particularly small sizes 19 and 21 mm, has been reported. Treatment of failing bioprostheses by transcatheter valve-in-valve (VIV) therapy has become an alternative to repeat surgery. However, VIV treatment is problematic with small surgical bioprostheses because of a further reduction in the effective valve orifice. One way to overcome this challenge may be to fracture the ring of the surgical valve by high-pressure balloon dilatation before implanting a larger size transcatheter valve. The feasibility of this approach was recently reported for an Edwards Perimount bioprosthesis (19 mm) in the pulmonic position. We report the first cases in vitro and in man of high-pressure balloon dilatation to fracture the ring of small dysfunctional Mitroflow aortic bioprostheses followed by transcatheter VIV implantation.

The Mitroflow bioprosthesis is build from a bovine pericardial sheet sutured to the outside of an acetyl stent to form the leaflets. The sewing ring is made from soft radiopaque silicone covered by a Dacron mesh. Mitroflow 19 and 21 mm prostheses have internal stent ring diameters of 15.4 and 17.3 mm, respectively. In vitro, we gradually inflated a 22 mm high-pressure balloon (ATLAS Gold, Bard, Temple) in an unused 21 mm Mitroflow valve. On fluoroscopy, there was a waist in the balloon from the bioprosthesis, and at a pressure of 11 atm, the ring of the Mitroflow valve fractured with an audible click followed by expansion of the balloon to its full diameter (Figure 1). The Dacron ring was intact with no irregularities or sharp edges and only by palpation a fracture line could be recognized in the stent ring. Dissecting the Mitroflow bioprosthesis revealed a single regular thin fracture line in the inner acetyl stent ring of the valve (Figure 1). The experiment was repeated twice giving the same findings. With a 23 mm Z-MED balloon, we subsequently implanted a SAPIEN XT (Edwards Lifesciences, Irvine) transcatheter heart valve in vitro in one of the fractured 21 mm Mitroflow bioprostheses.

After in vitro testing and informed consent, we performed this procedure in 2 patients with small Mitroflow bioprostheses (19 and 21 mm) and high risk to redo surgery (Table). High-pressure balloon predilatation by an ATLAS Gold balloon led to fracturing of the stent ring of the Mitroflow valves with subsequent successfully VIV with an SAPIEN XT valve 20 mm (19 mm Mitroflow) and a SAPIEN III 23 mm valve (21 mm Mitroflow; Table). The procedures were performed in general anesthesia guided by fluoroscopy and TEE. Rapid right ventricular pacing (180 bpm) and cardiopulmonary support (CPS 2 l/min; right atrium to left femoral artery) were used during the high-pressure balloon predilatation and at the time of VIV implantation. The Mitroflow valve ring fractured at a pressure of 16 atm (Mitroflow 19 mm) and 11 atm (Mitroflow 21 mm) evident by a sudden drop in inflation pressure and resolution of the waist in the balloon with expansion to its full diameter (Figure 2; Movies I and II in the Data Supplement). The 2 cases were successful without any complications. There were no signs of damage to the aortic root or paravalvular leaks on follow-up TEE or cardiac CT. In both patients, there was a marked reduction in the pressure gradient across the Mitroflow valve and an increase in the aortic valve area as evaluated by echocardiography. The Mitroflow ring circumference measured by computed tomography was increased 17% to 18% as an indirect proof of stent ring fracture (Table; Figure 3).

The surgical valve ring will normally protect against aortic root rupture or dissection in VIV therapy, but this advantage may not apply after balloon-induced fracturing of the ring. Moreover, coronary ostial compression is a serious complication to VIV therapy, such that only patients with coronary ostia distant to the upper part of the bioprosthesis or those having well-functioning bypass grafts will be suitable. Until
more experience is gained, repeat surgery remains the standard treatment for dysfunctional small bioprostheses, and the described novel technique should only be performed in highly selected patients.

Disclosures
Dr Christiansen is Proctor for Edwards Lifesciences; and Dr Klaaborg is Proctor for Edwards Lifesciences. The other authors report no conflicts.

References


Table. Two Patients Treated by Transcatheter Aortic Valve-in-Valve Implantation After Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation

<table>
<thead>
<tr>
<th></th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, sex, BSA</td>
<td>84 y, male, 1.88 m²</td>
<td>80 y, female, 1.43 m²</td>
</tr>
<tr>
<td>Mitroflow, year since implant</td>
<td>21 mm, stenotic, 11 y</td>
<td>19 mm, stenotic, 10 y</td>
</tr>
<tr>
<td>Postsurgical peak gradient</td>
<td>NA</td>
<td>40 mmHg</td>
</tr>
<tr>
<td>ATLAS Gold balloon</td>
<td>22 mm</td>
<td>20 mm</td>
</tr>
<tr>
<td>Threshold for ring fracture</td>
<td>11 atm</td>
<td>16 atm</td>
</tr>
<tr>
<td>Edwards Sapien</td>
<td>III 23 mm, transapical</td>
<td>XT 20 mm, transfemoral</td>
</tr>
<tr>
<td>NYHA class (pre/FU)</td>
<td>II/II</td>
<td>II/II</td>
</tr>
<tr>
<td>LVEF (pre/FU)</td>
<td>35%/35%</td>
<td>60%/60%</td>
</tr>
<tr>
<td>Peak gradient (pre/FU)</td>
<td>65/26 mmHg</td>
<td>127/38 mmHg</td>
</tr>
<tr>
<td>Mean gradient (pre/FU)</td>
<td>41/17 mmHg</td>
<td>81/27 mmHg</td>
</tr>
<tr>
<td>AVA (pre/FU)</td>
<td>0.8/1.0 cm² (25% increase)</td>
<td>0.3/0.9 cm² (200% increase)</td>
</tr>
<tr>
<td>Mitroflow circumference CT (pre/post)</td>
<td>57.5/67.2 mm (17% increase)</td>
<td>49.6/58.7 mm (18% increase)</td>
</tr>
</tbody>
</table>

Clinical and echocardiography parameters were obtained preprocedural and at follow-up (FU) 4 weeks (Case 1) and 6 weeks (Case 2) after the procedure. AVA indicates aortic valve area; BSA, body surface area; LVEF, left ventricular ejection fraction; and NYHA, New York Heart Association.

Key words: aortic valve bioprosthesis dialatation transcatheter aortic valve implantation transcatheter valve-in-valve implantation
Figure 1. An ATLAS Gold 22 mm high-pressure balloon was gradually inflated inside a 21 mm Mitroflow valve. At a balloon pressure of 11 atm, the acetyl stent ring of the valve fractured with a load click. At the same time, the waist in the balloon disappeared, balloon pressure dropped suddenly, and the balloon did fully expand to a diameter of 22 mm. The outer Dacron ring of the bioprosthesis was intact and no sharp elements did protrude (A). A fracture line could be appreciated by palpation and was visualized by dissection of the valve ring (B and C, arrow).
Fracturing the Ring of Mitroflow Bioprostheses

**Figure 2.** A 20 mm ATLAS Gold balloon was used to predilate the 19 mm Mitroflow valve. With gradual inflation, there was a waist in the balloon (waist diameter 8 mm) first from the thickened stenotic valve leaflets (A) and second from the stent ring of the bioprosthesis (waist diameter 15 mm; B). At a balloon pressure of 16 atm, the Mitroflow stent ring fractured and the balloon expanded to its full diameter of 20 mm (C). Subsequently, a SAPIEN XT 20 mm valve was implanted inside the fractured Mitroflow prosthesis at an optimal position (D). Cardiopulmonary support (CPS) was used from balloon dilatation to valve implantation to avoid hemodynamic instability. The CPS outflow cannula was in the right atrium (seen on the images) and the inflow cannula in the left femoral artery.

**Figure 3.** Cardiac computed tomography performed after transcatheter valve-in-valve (VIV) with insertion of a SAPIEN XT 20 mm valve into a Mitroflow 19 mm prosthesis (internal diameter 15.4 mm) preceded by high-pressure balloon predilation to fracture the ring of the surgical bioprosthesis. Note the small indentation in the radiopaque silicone band (arrow), which most likely represents the fracture site in the acetyl stent of the valve.
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Circ Cardiovasc Interv. 2015;8:e002667
doi: 10.1161/CIRCINTERVENTIONS.115.002667

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Video 1
High-pressure balloon dilatation using a 20 mm ATLAS Gold balloon to fracture the acetyl stent valve ring of a deteriorated and stenotic 19 mm Mitroflow bioprosthesis. With gradual inflation of the balloon there was a waist (diameter 8 mm) firstly from the thickened stenotic valve leaflets and secondly from the stent ring of the bioprosthesis (waist diameter 15 mm). At a balloon pressure of 16 atm, the stent ring of the Mitroflow valve fractured and the balloon expanded to its full diameter of 20 mm. Right ventricular rapid pacing (180/min) and CPS (outflow cannula in the right atrium) was used during the high-pressure balloon dilatation.

Video 2
Angiography in the aortic root after implantation of a SAPIEN XT 20 mm transcatheter valve into a 19 mm dysfunctional Mitroflow aortic bioprosthesis. Before implantation the acetyl stent ring of the Mitroflow prosthesis was fractured by high-pressure balloon dilatation with a 20 mm ATLAS Gold balloon.