Stent Fracture, Valve Dysfunction, and Right Ventricular Outflow Tract Reintervention After Transcatheter Pulmonary Valve Implantation

Patient-Related and Procedural Risk Factors in the US Melody Valve Trial

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Background—Among patients undergoing transcatheter pulmonary valve (TPV) replacement with the Melody valve, risk factors for Melody stent fracture (MSF) and right ventricular outflow tract (RVOT) reintervention have not been well defined.

Methods and Results—From January 2007 to January 2010, 150 patients (median age, 19 years) underwent TPV implantation in the Melody valve Investigational Device Exemption trial. Existing conduit stents from a prior catheterization were present in 37 patients (25%, fractured in 12); 1 or more new prestents were placed at the TPV implant catheterization in 51 patients. During follow-up (median, 30 months), MSF was diagnosed in 39 patients. Freedom from a diagnosis of MSF was 77±4% at 14 months (after the 1-year evaluation window) and 60±9% at 39 months (3-year window). On multivariable analysis, implant within an existing stent, new prestent, or bioprosthetic valve (combined variable) was associated with longer freedom from MSF (P<0.001), whereas TPV compression (P=0.01) and apposition to the anterior chest wall (P=0.02) were associated with shorter freedom from MSF. Freedom from RVOT reintervention was 86±4% at 27 months. Among patients with a MSF, freedom from RVOT reintervention after MSF diagnosis was 49±10% at 2 years. Factors associated with reintervention were similar to those for MSF.

Conclusions—MSF was common after TPV implant in this multicenter experience and was more likely in patients with severely obstructed RVOT conduits and when the TPV was directly behind the anterior chest wall and/or clearly compressed. A TPV implant site protected by a prestent or bioprosthetic valve was associated with lower risk of MSF and reintervention.


Key Words: stent fracture ▪ percutaneous valve replacement ▪ congenital heart disease ▪ tetralogy of Fallot ▪ valvular regurgitation

Transcatheter pulmonary valve (TPV) placement was first reported in 2000.1 Beginning in January 2007, the Melody TPV (Medtronic Inc, Minneapolis, MN) was implanted in 150 patients at 5 US centers under an Investigational Device Exemption (IDE, No. G050186) protocol for treatment of right ventricular outflow tract (RVOT) dysfunction. In January 2010, enrollment in the IDE trial was completed, and the Melody valve was approved for placement in dysfunctional RVOT conduits as a palliative measure aimed at delaying surgical intervention. One of the clinical and regulatory concerns with the Melody valve has been fracture of the balloon-expandable stent in which the bovine jugular venous valve is housed. In early reports from Europe, survival free from Melody valve stent fracture (MSF) was 85% at 1 year and 75% at 2 years after implant.2 A similar trend was observed in preliminary analyses of the US IDE cohort.3-4 An important incidence of fracture has also been reported in bare metal stents (BMS) placed for RVOT conduit obstruction or central branch pulmonary arterial stenosis.5-7 Risk factors for stent fracture

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WHAT IS KNOWN

- Transcatheter pulmonary valve placement with the Melody valve is effective in the short term for relief of right ventricular outflow tract obstruction and pulmonary regurgitation in patients with surgically implanted right ventricle–to–pulmonary artery conduits.
- Stent fracture with associated right ventricular outflow tract obstruction is the most common indication for reintervention after Melody valve placement, but risk factors for stent fracture and reintervention have not been determined.

WHAT THE STUDY ADDS

- In this series of 150 patients who underwent Melody valve implant as part of the US Investigational Device Exemption trial, we analyzed implant conditions, conduit preparation techniques, and valve-related outcomes and documented an ongoing risk of stent fractures, many of which were not associated with hemodynamic valve dysfunction.
- We found that stent fractures were more likely in patients with severely obstructed right ventricular outflow tract conduits and when the Melody was directly behind the anterior chest wall and/or clearly compressed, whereas a valve implant site protected by a present or bioprosthetic valve was associated with lower risk of fracture and reintervention.

in those series included implantation directly behind the sternum or in direct apposition to the thoracic aorta, and stent compression or recoil after deployment, findings that imply that there are mechanical environments within the mediastinum that may predispose to more extreme loading and consequent fracture of balloon-expandable stents.2,6,7

Computational modeling suggests that multiple concentric stents should have superior radial strength to a single stent.8 However, analytic simulations of stent strength are typically based on idealized conditions.9,10 Using patient-specific modeling, Schievano et al demonstrated that the geometry of the deployed Melody valve in the RVOT may not be ideal; thus, the assumptions used during standard radial strength testing may substantially underestimate in vivo stent loading conditions.9–11 In accordance with the theoretical benefit of implanting multiple stents to increase radial strength, “prestenting” the conduit with BMS or covered stents before TPV placement has become routine at many centers.12–14 Recent data suggest that prestenting may be associated with better gradient relief and protection against MSF,12 but otherwise, little is known about the relationship between prestenting, other patient-related and technical factors, and outcomes after Melody valve implant.

Recurrent RVOT obstruction associated with MSF is the most common indication for reintervention after Melody valve placement.4,15 To deploy TPV technology with optimal clinical benefit and cost-effectiveness, it is critical to understand risk factors for and means to prevent MSF and related TPV dysfunction. In the present study, we assess risk factors for MSF, valve dysfunction, and reintervention after TPV placement in the complete IDE cohort after all patients had reached the 1-year follow-up interval.

Methods

Patients and Study Protocol

The Melody valve IDE trial was a prospective, nonrandomized, multicenter study of TPV placement in dysfunctional RVOT conduits. The original and expanded versions of the protocol and earlier trial outcomes were reported previously.3,4 Patients were categorized according to primary implant indication, based on the hemodynamic inclusion criteria met at the time of enrollment.3,5 If the patient met only the pulmonary regurgitation (PR) or RVOT obstruction criteria, the primary indication was “regurgitation” or “stenosis,” respectively; if the patient met both criteria, the primary indication was “mixed.” For the purposes of analysis, patients meeting the stenosis criterion (stenosis or mixed indication) were considered as a combined group.

Follow-up evaluations were conducted at prespecified intervals (3, 6, and 12 months, then annually) at the implanting center. For the current study, the database was closed for analysis on April 20, 2011, after the full study cohort of 150 implanted patients had completed the 1-year follow-up evaluation or withdrawn from the study for death, valve explant, or loss to follow-up. Patients who were enrolled in the trial and underwent catheterization with intention to treat but did not have a TPV implanted were excluded from this study.

All versions of the protocol were approved by the US Food and Drug Administration, Center for Devices and Radiological Health, as well as the institutional review board at each institution. The trial is registered in ClinicalTrials.gov (Identifier: NCT00740870).

Catheterization and Valve Implantation

In the original catheterization protocol (Figure 1), additional procedures, including prestenting of the conduit, were not permitted. The intent of this policy was to minimize confounding in the assessment of the safety of TPV implantation, particularly given that stents commonly used for prestenting were not approved for implantation in RVOT conduits. However, after the first 35 implants, the protocol was modified to allow prestenting or other concomitant interventions, although no clinical criteria or technical parameters were specified for such procedures. Because patients may have had existing intact or fractured stents in the conduit from a prior catheterization (existing prestent) and/or undergone prestenting with varying types and numbers of stents at the TPV implant catheterization (new prestent), presenting data were reported and analyzed using multiple different designations. For some of these classifications, intact (ie, unfractured) prestents from a prior catheterization were grouped with new prestents (“any intact prestent”). Also, because bioprosthetic valves (BPV) are mounted in a rigid frame, which presumably protects the TPV in a similar manner to a conduit stent, prestented conduits were also grouped with BPV for the purposes of analysis. After the first 70 implants, the protocol was modified explicitly to permit TPV implant in BPV that were not housed within a circumferential conduit.

Fluoroscopic/Angiographic Assessments

Images from the implant catheterization and follow-up radiographic studies were reviewed for predetermined conduit- and stent-related variables. By protocol, MSF was ascertained with chest radiograms at the 3-month, 1-year, and annual follow-up visits and multiplane fluoroscopy at the 6-month visit. MSF were graded by the implanting physician according to the classification proposed by Nordmeyer et al: type I, fracture of ≥1 strut without loss of stent integrity; type II, fracture with loss of stent integrity; and type III, fracture associated with separation of fragments or embolization.2 MSF diagnoses and grades were not confirmed by a core laboratory. There was no systematic assessment or recording of fractures that occurred in conduit prestents independent from MSF. The narrowest preinter-
greater PR or mean Doppler RVOT gradient and freedom from a diagnosis of TPV dysfunction (moderate or excluding conduit explant due to acute procedural complications), freedom from RVOT reintervention related to TPV dysfunction (ie, at the time of explant or death. For analysis of freedom from procedural complications were not included, and patients who did not meet event criteria were censored at the last date they were known to be alive and in follow-up (includes patients later lost to follow-up). For analyses of freedom from a diagnosis of MSF or mixed disease were younger than those with a primary implant indication of PR (19.7 \pm 8.9 versus 23.3 \pm 9.8 years, P = 0.02). Other differences relating to the primary implant indication are detailed in the online-only Data Supplement Materials.

Results

Patients

From January 2007 through January 2010, 150 patients (87 male, 64%) were enrolled and underwent Melody valve implantation at a median age of 19 years (7–53 years). Demographic, historic, and diagnostic data are summarized in Table 1. Patients with a primary implant indication of stenosis or mixed disease were younger than those with a primary indication of PR (19.7 \pm 8.9 versus 23.3 \pm 9.8 years, P = 0.02). Other differences relating to the primary implant indication are detailed in the online-only Data Supplement Materials.

Procedural and Acute Outcomes

Procedural and fluoroscopic data are summarized in Table 2. One or more existing conduit stents from a prior catheriza-
Postimplant fluoroscopic variables

- Bare metal or covered stent (prestent) in the RVOT
- Sizing balloon waist diameter, mm: 17 (14–20)
- Highest predilation balloon pressure, atm: 8 (2–30)
- Shape of the deployed Melody valve, n=148†
  - Cylindrical: 37 (25%)
  - Truncated cone: 4 (3%)
  - Compressed cylinder, eccentricity index >1.1: 17 (11%)
  - Flared cylinder, dogbone
    - Flared at both proximal and distal ends: 65 (44%)
    - Flared at proximal or distal end: 27 (18%)
- Geometry of the deployed Melody valve, quantitative
  - Eccentricity index: 1.03 (1.0–1.31)
  - Proximal flare index: 1.13 (1.0–1.86)
  - Distal flare index: 1.11 (1.0–1.76)
- Motion of the deployed Melody valve during the cardiac cycle, n=146†
  - Minimal/none: 12 (8%)
  - Torsion/rotation around long axis: 55 (37%)
  - Flexion/rotation around short axis: 90 (61%)
  - Compression: 16 (11%)

RVOT indicates right ventricular outflow tract.

Data presented as median (range) or number of patients (percent of total patients); n=150 unless otherwise specified.

*“Intact bare metal stents” refers to stents that were placed before the transcatheter pulmonary valve (TPV) implant catheterization and were not observed to be fractured at the time of TPV implant.
†Multiple patterns were recorded in some patients.

Another variable of interest was the presence of stent fractures. Among the 84 new prestents placed, stent types included 49 Palmaz XL (Palmaz Scientific, Dallas, TX), 27 IntraStent Max LD (eV3 Inc., Plymouth, MN), 4 Palmaz Genesis XD (Cordis Corporation, Miami, FL), and 4 Covered CP Stent (NuMed, Inc, Hopkinton, NY). As depicted in online-only Data Supplement Figure I, there was considerable variation among centers in conduit preparation procedures.

Acute hemodynamic outcomes are summarized in Table 2 and depicted in online-only Data Supplement Figure II. There were no differences in the postimplant peak RVOT gradient obtained in the catheterization laboratory or the discharge mean Doppler RVOT gradient according to conduit preparation techniques (eg, predilation balloon size or pressure, prestenting, postdilation). However, patients with a primary implant indication of stenosis or mixed disease had a modestly higher postimplant peak RVOT gradient (14.2±5.7 versus 12.2±7.0 mm Hg, P=0.05) and discharge mean Doppler RVOT gradient (23.2±9.2 versus 17.5±7.0 mm Hg, P=0.001) than patients with PR as the primary indication. Compression of the implanted TPV was more common in patients with an implant indication of stenosis/mixed disease (OR, 3.3 [1.01–9.1], P=0.04), a peak gradient before intervention ≥40 mm Hg (OR, 3.6 [1.2–10.7], P=0.02), a smaller ratio of angiographic conduit diameter to original diameter (0.50±0.12 versus 0.62±0.17, P=0.005), or substantial ap-
position to the anterior chest wall (OR, 10.8 [3.6–32], \( P < 0.001 \)). Compression of the implanted TPV was not associated with significant differences in postimplant RVOT gradients measured directly in the catheterization laboratory (15.4±7.7 versus 12.8±6.3 mm Hg, \( P = 0.13 \)) or by Doppler echocardiography before discharge (21.8±10.4 versus 19.9±8.4 mm Hg, \( P = 0.4 \)).

As described in our previous report, there was 1 conduit rupture during the implant procedure that was treated with conduit replacement, and 1 patient died within 30 days of TPV implant. There were no other procedural complications treated with surgery or leading to death or TPV explant.

Follow-Up

Patients

Among the 148 patients included in the follow-up evaluation, the median duration from implant to database closure or removal from the protocol was 30 months (5–51 months). One patient died of unknown causes 2 years after implant, with no evidence of valve dysfunction or MSF at the most recent evaluation 2 months earlier; no autopsy was performed. Two patients underwent Melody valve explant 5 and 21 months after implant (see below) and thereafter were no longer followed according to the protocol. Three patients were considered lost to follow-up after missing a scheduled follow-visit (1 each after the discharge, 3-month, and 1-year evaluations). Among the remaining 142 patients who were alive and in current follow-up, the most recent follow-up evaluation completed was at 1 year in 47, 2 years in 63, 3 years in 27, and 4 years in 5.

Stent Fracture

MSF was diagnosed in 39 patients, 11 initially at the 3-month evaluation, 15 at 6 months, 6 at 1 year, 6 at 2 years, and 1 at 3 years. In all but 6 of these patients, the MSF was initially classified as type I (online-only Data Supplement Figure III). A total of 17 patients were diagnosed with a type II MSF, either at the time of initial identification \((n=6)\) or after prior diagnosis of a type I MSF \( (n=11) \) (Figure 2). One patient had a type II MSF with embolization to the RV of a single strut segment (type III). Other structural changes associated with type II MSF are depicted in the online-only Data Supplement videos.

As shown in Figure 3, freedom from a diagnosis of MSF was 77±4% at 14 months (after the 1-year evaluation window), 68±5% at 27 months (after the 2-year window), and 60±9% at 39 months (after the 3-year window). Freedom from a diagnosis of type II MSF was 85±4% at 27 months and 74±11% at 39 months.

Variables associated with freedom from MSF to \( P < 0.10 \) on univariable analysis are summarized in Table 3. On multivariable analysis, the combined variable “implant within any intact prestent or BPV” was associated with longer freedom from a diagnosis of MSF and both TPV compression and substantial apposition to the anterior chest wall were associated with shorter freedom from MSF (Table 4 and Figure 4). On multivariable analysis of factors associated with freedom from diagnosis of a type II MSF, the same factors were significant (Table 4). Exploratory analyses did not disclose any marked interactions between factors included in multivariable analysis, indicating that the factors were relatively independent of each other. When the combined variable “implant within any intact prestent or BPV” was replaced with “implant within any intact present,” it remained significant in the model for any MSF, but not for type II MSF. Freedom from a diagnosis of MSF did not differ...
between patients with a single prestent and those with multiple prestents (online-only Data Supplement Figure IV).

Among 39 patients diagnosed with a MSF, the TPV was implanted within a BPV in 1, a new prestent in 3 (1 with a prior fractured prestent), a prior intact prestent without a new prestent in 6, and a prior fractured prestent without a new prestent in 3. Among the 17 patients with a type II MSF, the TPV was implanted within a new prestent (single) in 1, a prior fractured prestent without a new prestent in 2, but none with an intact prior prestent or a BPV. Only 1 patient with a BPV had MSF, which occurred in a portion of the stent that was proximal to the BPV ring and directly retrosternal (online-only Data Supplement Figure III).

Among the 33 patients initially diagnosed with a type I MSF, freedom from diagnosis of a type II MSF was 71\% at 1 year and 56\% at 2 years after the initial MSF diagnosis. TPV compression was associated with shorter freedom from progression to a type II MSF (HR, 4.0 [1.1–14.0], P=0.03).

### Melody Valve Dysfunction

Melody valve dysfunction was documented in 24 patients, all of whom had a mean Doppler RVOT gradient ≥35 mm Hg or underwent reintervention; there were no cases of moderate or severe PR. Four of these patients had hemodynamic dysfunction but did not undergo reintervention. Two other patients reached the echocardiographic threshold for dysfunction (mean RVOT gradient ≥35 mm Hg) at 1 follow-up time point but had a lower gradient at subsequent evaluation; these patients were near the dysfunction threshold on the most recent echocardiogram (mean RVOT gradient 33 and 34 mm Hg, respectively) but were not coded as having dysfunction. As shown in online-only Data Supplement Figure III, patients with a diagnosis of type II MSF had higher RVOT gradients during follow-up than those with no MSF or a type I MSF.

Freedom from Melody valve dysfunction was 88±3\% at 14 months, 87±3\% at 27 months, and 73±7\% at 39 months. Variables associated with freedom from valve dysfunction are summarized in Table 3. In general, these were similar to factors associated with MSF, but the post-TPV RVOT gradient was more important. On multivariable analysis, a higher mean Doppler RVOT gradient early after implant and TPV compression were associated with shorter freedom from TPV dysfunction, and implant within any intact prestent or BPV was associated with longer freedom from dysfunction (Table 4). When “implant within any intact prestent or BPV” was replaced in the model by “implant within any intact present,” it remained significant.

### Melody Valve Reintervention

Twenty patients underwent RVOT reintervention during the follow-up period, initially consisting of Melody valve redilation in 5 patients, implantation of a second TPV within the first16 in 14, and surgical RVOT conduit replacement in 1 (Figures 2 and 5). Two of the 5 patients who underwent TPV redilation subsequently had another catheterization, at which a second TPV was implanted. One of the 16 patients in whom a second TPV was implanted subsequently underwent conduit replacement. All of the patients who underwent a second TPV implant or surgical RVOT reintervention had a MSF, and all but 2 had a type II MSF. None of the patients who underwent Melody valve redilation alone had a documented MSF. Only 1 patient with a BPV underwent reintervention, which consisted of redilation without implant of a second TPV.

Freedom from RVOT reintervention was 92±2\% at 14 months and 86±4\% at 27 months (Figure 3). Variables associated with freedom from reintervention are summarized in Table 3 (also see Figure 6). On multivariable analysis, a higher mean Doppler RVOT gradient post-TPV and TPV compression were associated with shorter freedom from reintervention, and implant within any intact prestent or BPV was associated with longer freedom from reintervention (Table 4). When “implant within any intact prestent or BPV” was replaced by “implant within any intact present,” it remained significant. Among patients in whom the Melody valve was substantially apposed to the anterior chest wall,
Table 3. Results of Univariable Analysis of Freedom From Any Stent Fracture and Freedom From Type II Stent Fracture

<table>
<thead>
<tr>
<th>Variable</th>
<th>Any Fracture HR (95% CI)</th>
<th>Any Fracture P Value</th>
<th>Type II Fracture HR (95% CI)</th>
<th>Type II Fracture P Value</th>
<th>Dysfunction HR (95% CI)</th>
<th>Dysfunction P Value</th>
<th>Reintervention HR (95% CI)</th>
<th>Reintervention P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age at implant, y</td>
<td>0.97 (0.93–1.00)</td>
<td>0.08</td>
<td>0.93 (0.86–0.99)</td>
<td>0.04</td>
<td>0.92 (0.87–0.98)</td>
<td>0.01</td>
<td>0.95 (0.89–1.01)</td>
<td>0.09</td>
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<td>Implant tertile</td>
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<tr>
<td>1st tertile, first 50 cases</td>
<td>Reference</td>
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<tr>
<td>2nd tertile</td>
<td>0.29 (0.12–0.73)</td>
<td>0.008</td>
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<td>3rd tertile</td>
<td>0.86 (0.41–1.82)</td>
<td>0.7</td>
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<td>Implant center, lowest freedom from event vs highest</td>
<td>4.3 (1.3–14.4)</td>
<td>0.02</td>
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<td>Primary cardiac diagnosis</td>
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<td>Tetralogy of Fallot</td>
<td>Reference</td>
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<tr>
<td>Aortic valve disease, Ross procedure</td>
<td>3.0 (1.4–6.5)</td>
<td>0.005</td>
<td></td>
<td></td>
<td>2.92 (1.10–7.8)</td>
<td>0.03</td>
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<tr>
<td>Other</td>
<td>1.7 (0.8–3.8)</td>
<td>0.2</td>
<td></td>
<td></td>
<td>1.4 (0.5–4.0)</td>
<td>0.5</td>
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<tr>
<td>Primary implant indication stenosis or mixed disease</td>
<td>1.9 (0.96–3.6)</td>
<td>0.06</td>
<td>7.1 (2.0–26)</td>
<td>0.003</td>
<td>3.8 (1.5–9.8)</td>
<td>0.006</td>
<td>4.5 (1.6–12.5)</td>
<td>0.005</td>
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<td>Homograft RVOT conduit</td>
<td>7.0 (1.7–29.2)</td>
<td>0.007</td>
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<tr>
<td>Bioprosthetic valve or valved conduit, BPV</td>
<td>0.10 (0.013–0.72)</td>
<td>0.02</td>
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<tr>
<td>Narrowest angiographic diameter of conduit, mm</td>
<td>0.89 (0.81–0.97)</td>
<td>0.01</td>
<td>0.84 (0.73–0.97)</td>
<td>0.02</td>
<td>0.82 (0.73–0.93)</td>
<td>0.002</td>
<td>0.82 (0.72–0.94)</td>
<td>0.004</td>
</tr>
<tr>
<td>Ratio of narrowest angiographic conduit diameter to implanted conduit diameter</td>
<td>0.11 (0.001–0.21)</td>
<td>0.003</td>
<td>0.03 (0.001–0.54)</td>
<td>0.02</td>
<td>0.012 (0.001–0.19)</td>
<td>0.002</td>
<td>0.02 (0.001–0.21)</td>
<td>0.003</td>
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<tr>
<td>Highest predilation balloon pressure, atm</td>
<td>1.08 (1.02–1.13)</td>
<td>0.004</td>
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<tr>
<td>Highest predilation balloon pressure ≥10 atm</td>
<td>2.24 (1.17–4.28)</td>
<td>0.02</td>
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<tr>
<td>Sizing balloon waist diameter, mm</td>
<td>1.22 (1.01–1.49)</td>
<td>0.04</td>
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<tr>
<td>Any new prestent placed at the Melody valve implant catheterization</td>
<td>0.15 (0.05–0.49)</td>
<td>0.002</td>
<td>0.13 (0.02–1.01)</td>
<td>0.05</td>
<td>0.22 (0.05–0.95)</td>
<td>0.04</td>
<td>0.14 (0.02–1.06)</td>
<td>0.06</td>
</tr>
<tr>
<td>Multiple new prestents at the Melody valve implant catheterization</td>
<td>0.12 (0.02–0.91)</td>
<td>0.04</td>
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<tr>
<td>Any present, prior or new</td>
<td>0.37 (0.19–0.73)</td>
<td>0.004</td>
<td>0.18 (0.05–0.63)</td>
<td>0.007</td>
<td>0.30 (0.12–0.76)</td>
<td>0.01</td>
<td>0.35 (0.13–0.91)</td>
<td>0.03</td>
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<tr>
<td>Any intact prestent</td>
<td>0.23 (0.11–0.50)</td>
<td>&lt;0.001</td>
<td>0.06 (0.01–0.46)</td>
<td>0.007</td>
<td>0.20 (0.07–0.60)</td>
<td>0.004</td>
<td>0.17 (0.05–0.59)</td>
<td>0.005</td>
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<tr>
<td>Multiple presents, prior or new</td>
<td>0.36 (0.14–0.91)</td>
<td>0.03</td>
<td>0.17 (0.02–1.26)</td>
<td>0.08</td>
<td>0.16 (0.02–1.19)</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple intact prestents</td>
<td>0.15 (0.04–0.64)</td>
<td>0.01</td>
<td></td>
<td></td>
<td>0.23 (0.08–0.69)</td>
<td>0.009</td>
<td>0.14 (0.03–0.62)</td>
<td>0.009</td>
</tr>
<tr>
<td>New prestent or BPV</td>
<td>0.092 (0.03–0.26)</td>
<td>&lt;0.001</td>
<td>0.061 (0.01–0.46)</td>
<td>0.007</td>
<td>0.32 (0.03–1.07)</td>
<td>0.06</td>
<td>0.12 (0.02–0.89)</td>
<td>0.04</td>
</tr>
<tr>
<td>Multiple new prestents or BPV</td>
<td>0.09 (0.02–0.37)</td>
<td>0.001</td>
<td>0.025 (0.00–1.64)</td>
<td>0.08</td>
<td>0.19 (0.07–0.47)</td>
<td>&lt;0.001</td>
<td>0.14 (0.05–0.42)</td>
<td>0.001</td>
</tr>
<tr>
<td>Any intact prestent or BPV</td>
<td>0.12 (0.06–0.26)</td>
<td>&lt;0.001</td>
<td>0.031 (0.004–0.23)</td>
<td>0.001</td>
<td></td>
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<tr>
<td>Multiple intact prestents or BPV</td>
<td>0.10 (0.03–0.32)</td>
<td>&lt;0.001</td>
<td>0.02 (0.00–1.12)</td>
<td>0.06</td>
<td>0.23 (0.07–0.79)</td>
<td>0.02</td>
<td>0.09 (0.01–0.65)</td>
<td>0.02</td>
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</table>

(Continued)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Any Fracture HR (95% CI)</th>
<th>Any Fracture P Value</th>
<th>Type II Fracture HR (95% CI)</th>
<th>Type II Fracture P Value</th>
<th>Dysfunction HR (95% CI)</th>
<th>Dysfunction P Value</th>
<th>Reintervention HR (95% CI)</th>
<th>Reintervention P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery system size</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>18 mm</td>
<td>Reference</td>
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<td>Reference</td>
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<td></td>
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<td></td>
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<tr>
<td>20 mm</td>
<td>0.59 (0.26–1.37)</td>
<td>0.2</td>
<td>0.54 (0.18–1.58)</td>
<td>0.26</td>
<td></td>
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<tr>
<td>22 mm</td>
<td>0.46 (0.21–0.98)</td>
<td>0.05</td>
<td>0.38 (0.14–1.04)</td>
<td>0.06</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Melody valve redilated after deployment, postdilated</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Directly measured peak RVOT gradient</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preimplant, mm Hg</td>
<td>1.02 (1.01–1.04)</td>
<td>0.03</td>
<td>1.04 (1.01–1.08)</td>
<td>0.02</td>
<td>1.03 (1.00–1.06)</td>
<td>0.04</td>
<td>1.03 (0.99–1.06)</td>
<td>0.08</td>
</tr>
<tr>
<td>Preimplant gradient ≥40 mm Hg</td>
<td>2.1 (1.1–4.0)</td>
<td>0.03</td>
<td>4.5 (1.47–13.8)</td>
<td>0.009</td>
<td>2.7 (1.1–6.3)</td>
<td>0.03</td>
<td>2.5 (0.99–6.3)</td>
<td>0.05</td>
</tr>
<tr>
<td>Postimplant, mm Hg</td>
<td>1.07 (1.01–1.14)</td>
<td>0.03</td>
<td>1.07 (1.02–1.14)</td>
<td>0.01</td>
<td>1.07 (1.01–1.14)</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postimplant gradient ≥20 mm Hg</td>
<td>2.7 (0.99–7.4)</td>
<td>0.054</td>
<td></td>
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<tr>
<td>Postimplant mean Doppler RVOT gradient, mm Hg</td>
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<tr>
<td>Implantedy Melody valve substantially apposed to chest wall</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Compression of the deployed Melody valve, eccentricity index &gt;1.1</td>
<td>5.0 (2.4–10.3)</td>
<td>&lt;0.001</td>
<td>12.0 (4.3–33)</td>
<td>&lt;0.001</td>
<td>5.4 (2.2–13.0)</td>
<td>&lt;0.001</td>
<td>7.8 (3.0–20.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Eccentricity index of the deployed Melody valve, per 0.1 change</td>
<td>2.4 (1.7–3.3)</td>
<td>&lt;0.001</td>
<td>2.9 (1.8–4.5)</td>
<td>&lt;0.001</td>
<td>2.2 (1.4–3.3)</td>
<td>&lt;0.001</td>
<td>2.2 (1.4–3.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Compression of the deployed Melody valve during the cardiac cycle</td>
<td>5.3 (2.7–10.6)</td>
<td>&lt;0.001</td>
<td>10.6 (4.1–26)</td>
<td>&lt;0.001</td>
<td>4.5 (1.9–10.8)</td>
<td>0.001</td>
<td>6.4 (2.6–15.9)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

HR indicates hazard ratio; CI, confidence interval; RVOT, right ventricular outflow tract; and BPV, bioprosthetic valve.

HRs are only presented for variables with $P<0.10$.

Also see Tables 1 and 2 for definitions.
Table 4. Results of Multivariable Analysis of Freedom From MSF, Reintervention, and TPV Dysfunction

<table>
<thead>
<tr>
<th>Variable</th>
<th>Multivariable Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from any MSF</td>
<td>HR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Melody valve implant within any intact prestent or BPV</td>
<td>0.14 (0.07–0.30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Implanted Melody valve substantially apposed to chest wall</td>
<td>2.5 (1.2–5.0)</td>
<td>0.009</td>
</tr>
<tr>
<td>Compression of the deployed Melody valve, eccentricity index &gt;1.1</td>
<td>2.5 (1.1–5.4)</td>
<td>0.02</td>
</tr>
<tr>
<td>Freedom from type II MSF</td>
<td>HR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Melody valve implant within any intact prestent or BPV</td>
<td>0.04 (0.01–0.33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Compression of the deployed Melody valve, eccentricity index &gt;1.1</td>
<td>3.9 (1.3–11.7)</td>
<td>0.01</td>
</tr>
<tr>
<td>Implanted Melody valve substantially apposed to chest wall</td>
<td>3.5 (1.2–10.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>Freedom from Melody valve dysfunction</td>
<td>HR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Postimplant mean Doppler RVOT gradient, mm Hg</td>
<td>1.12 (1.06–1.17)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Melody valve implant within any intact prestent or BPV</td>
<td>0.20 (0.07–0.53)</td>
<td>0.001</td>
</tr>
<tr>
<td>Compression of the deployed Melody valve, eccentricity index &gt;1.1</td>
<td>5.3 (2.0–14.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Freedom from Melody valve reintervention</td>
<td>HR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Compression of the deployed Melody valve, eccentricity index &gt;1.1</td>
<td>6.1 (2.3–16.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postimplant mean Doppler RVOT gradient, mm Hg</td>
<td>1.07 (1.02–1.30)</td>
<td>0.007</td>
</tr>
<tr>
<td>Melody valve implant within any intact prestent or BPV</td>
<td>0.18 (0.06–0.57)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

MSF indicates Melody stent fracture; TPV, transcatheter pulmonary valve; HR, hazard ratio; CI, confidence interval; BPV, bioprosthetic valve; and RVOT, right ventricular outflow tract.

Discussion

Stent Fracture

In the US IDE trial, fracture of the platinum-iridium stent frame of the Melody valve was common after implantation in dysfunctional RVOT conduits, with 68±5% freedom from any MSF at 2 years. Fewer than half of the documented MSF were associated with loss of stent integrity. These outcomes were similar to the initial experience of Bonhoeffer’s group.2 Given that MSF is a function of fatigue stress, we suspect that there will be an ongoing hazard for new MSF and for progression of minor MSF to more substantial MSF, which is supported by the fact that we detected new MSF as late as 3 years after implant and that there was continued progression from type I to type II MSF 2 years after the initial diagnosis of MSF.

A number of factors were associated with MSF on univariable analysis, many of which were interrelated. Variables reflecting more severe conduit obstruction were associated with shorter freedom from a diagnosis of MSF, including a primary implant indication of stenosis or mixed disease, younger age (associated with a primary implant indication of stenosis or mixed disease), a higher RVOT gradient before and after intervention, smaller angiographic diameter of the conduit, and a smaller ratio of the angiographic diameter to the original diameter. Other factors associated with shorter freedom from MSF were related to the environment in which the TPV was implanted, such as substantial apposition to the anterior chest wall, TPV compression, and dynamic compressive deformation of the implanted TPV. In contrast, patient-related or procedural variables reflecting a mechanically protected TPV were associated with longer freedom from MSF, including implant within a BPV rather than a homograft or other conduit, and prestenting of the conduit with 1 or more BMS.

Melody Valve Dysfunction and RVOT Reintervention

Although much attention has been drawn to the issue of MSF in assessment of the safety and efficacy of the Melody valve, it is not MSF per se that is important, but rather the consequences of MSF. The most obvious and common adverse outcomes associated with MSF are TPV dysfunction and consequent RVOT reintervention. Although TPV dysfunction and reintervention in this series were almost always associated with MSF, freedom from diagnosis of a type II MSF after the initial MSF diagnosis was only 56±12% and freedom from reintervention was 49±10%, suggesting that progression of a type I MSF to a hemodynamically important MSF is not universal. Thus, whereas MSF are frequently of obvious and progressive clinical importance, they are not always, and, as such, the dialogue should be refocused from "stent fracture" to "clinically important stent fracture."

Most of the factors associated with TPV dysfunction and RVOT reintervention were the same as those associated with MSF. Once a MSF was diagnosed, the only factor associated with shorter freedom from reintervention was compression of the TPV at the completion of the implant procedure, which is consistent with the conclusion that a MSF in a setting of obvious mechanical stress on the conduit is more likely to be hemodynamically important.

Predilation, Pre-stenting, and Postdilation

Preparation of the Melody valve implant site is an important consideration for optimizing the hemodynamic outcome of Melody valve implantation, particularly relief of RVOT obstruction.
In this series, prestenting was clearly associated with a longer freedom from diagnosis of MSF, TPV dysfunction, and RVOT reintervention, but no difference in acute postimplant RVOT gradient. In the only prior study to evaluate the effect of prestenting before TPV implant, patients who underwent prestenting had lower acute post-implant RVOT gradients and a lower hazard for MSF, but there was no difference in reintervention. Assessing the impact of prestenting on MSF in our cohort is confounded by the fact that prestenting was prohibited during the initial 35 implants, after which it was permitted and performed in 43% of patients. However, there was no defined protocol and prestenting practices varied among investigators. Also, a subset of patients had varying numbers and types of existing RVOT stents from prior catheterizations. Some of these stents were documented to be fractured at the time of TPV implantation, and others had been in place for many years and were likely affected by fatigue-related changes. Thus, simple categorization of prestenting could not account for complexity within this factor. This series was not powered to analyze whether different types of prestents conferred more durable protection against MSF.

Almost half of the patients who underwent prestenting received multiple stents. Although freedom from MSF was not statistically related to the number of prestents, the study was not powered to answer this question, and the Kaplan-Meier curves did begin to diverge when both new and existing prestents were considered. This analysis also may have been confounded by treatment bias, with investigators inclined to implant multiple prestents in patients they assessed to be at higher risk for MSF. Whether there are patients in whom multiple prestents provide important additive protection against MSF deserves further study.

Identification of patients who are more and less likely to benefit from prestenting is important. Although it may be simpler to perform prestenting routinely, there are likely risks to prestenting above and beyond those incurred with TPV implantation alone, and it may be prudent to avoid such risks if there is no incremental benefit of prestenting in a given patient. This study provides only limited insight in this regard, due to limited power and heterogeneity in prestenting practices. Given that patients with a BPV rarely underwent prestenting and did not develop type II MSF or undergo RVOT reintervention associated with MSF, it seems that important MSF is uncommon when a Melody valve is implanted in a BPV even without prestenting. Although this study did not allow discrimination of other groups of patients in whom prestenting offers minimal or no benefit, we identified important risk factors that

**Figure 4.** Kaplan-Meier curves showing freedom from diagnosis of A and B, any Melody stent fracture (MSF), or C and D, a type II MSF, according to important factors associated with outcome. BPV indicates bioprosthetic valve.
can be ascertained before TPV implant, including apposition of the likely TPV implant site to the chest wall, higher conduit gradient, and more severe conduit narrowing. Among patients with apposition of the implanted Melody valve to the chest wall, those with an intact prestent or BPV had significantly longer freedom from RVOT reintervention than those that did not, although the number of patients was small. Taken together, these findings suggest that prestenting is likely to be beneficial and may be indicated when substantial chest wall apposition or conduit obstruction are present.

**Predilation and Postdilation**

Predilation of the conduit and postdilation of the implanted TPV are other potentially important methods of optimizing the outcome of TPV placement. In the US IDE protocol, predilation of the conduit was required. When performed appropriately, predilation, often using high-pressure balloons, should tear or break the substrate of obstruction. Once this is accomplished, we speculate that residual strain in the conduit wall is reduced relative to its prior state, allowing plastic deformation of the prestent and/or TPV to a larger diameter with less recoil from elastic deformation of the conduit. Thorough predilation should not be seen simply as an alternative to prestenting, although it may be in some cases, but rather as a complement to it. Balloon waists that form during predilation allow identification of the focal point of the lesion and/or the presence of multiple lesions, which should facilitate proper balloon selection,

![Image](image.png)

Figure 5. A and B, Anteroposterior and lateral fluoroscopic images demonstrating compression of the implanted Melody valve stent in a patient with a heavily calcified right ventricular outflow tract homograft conduit that is directly apposed to the anterior chest wall. C, Aortic root angiogram in a caudal left anterior oblique projection demonstrates distortion and compression of the Melody valve from the rightward posterior aspect by a dilated neoaortic root in a patient with conduit obstruction after a Ross procedure. D, After placement of 2 bare metal stents and a second transcatheter pulmonary valve within the fractured Melody valve, the cylindrical valve can be seen to indent the dilated neoaortic root.

![Image](image.png)

Figure 6. Kaplan-Meier curves showing freedom from right ventricular outflow tract reintervention according to A, primary implant indication, and B, the presence of any intact prestent or implant within a bioprosthetic valve.
understanding of conduit compliance, and adequate treatment of unanticipated lesions.

Postdilation after TPV implant was performed in 47% of patients. Although postdilation is not “preparation” for Melody valve implant per se, some of the theoretical benefits of predilation also pertain to postdilation, namely, tearing/cracking the conduit and increasing the final caliber of the implanted TPV. However, postdilation is performed after the TPV is implanted and thus allows less flexibility than predilation: if it results in injury to the conduit wall or is ineffective, it may not be possible to relieve the obstruction or treat the tear without compromising TPV function. In theory, there are other potential drawbacks to postdilation. The absence of significant PR in this series suggests that postdilation does not pose an acute risk to the leaflets, but any impact on long-term valve function remains to be determined. Also, postdilation may impose high focal stress on TPV stent struts. Our data provide no insight into these theoretical considerations, but they may be important.

Because the various conduit preparation techniques were used without strict prescription, and the same heterogeneity that was seen in prestenting also applied to predilation and postdilation practices, we cannot draw conclusions about the independent impact of predilation and/or postdilation from this study.

Limitations
Assessment of MSF in this study was of limited sensitivity and resolution for a combination of reasons. Radiography was performed at predetermined intervals, so the precise timing of MSF could not be defined. Biplane chest radiography, used for evaluation of MSF at all but the 6-month evaluation, may not profile the stent clearly in both views. Multiplane fluoroscopy, which we assumed would be more sensitive for detection of MSF, was only performed routinely at the 6-month evaluation. Additional stents in the RVOT conduit may confound the visualization of fractured TPV stent struts because of radiographic interference and reduction of displacement at fracture points. For all of these reasons, it is possible that subtle MSF may have been missed or ascertainment delayed, although the clinical importance of such MSF is likely to be minimal. The grading scale we used for MSF is imprecise, with the distinction between types I and II hinging on “stent integrity,” which is not defined and may be variably interpreted, and there was no core laboratory assessment to ensure consistency. It is likely that many patients with existing prestents had an underlying obstructive substrate of conduit dysfunction that was not reflected in baseline data due to the prior stent, which may have confounded assessment of risk factors for MSF. Also, there may have been important factors not assessed or included in our analyses, such as TPV “recoil.” Similarly, due to difficulty distinguishing solid body motion from more complex stent motion, our assessment of the dynamic mechanical environment of the implanted TPV was qualitative and simplistic. Two midstudy protocol modifications allowing implantation within a BPV and postdenting after the first 70 and 35 patients, respectively, may have confounded our outcome evaluations. Similarly, institutional practice variation regarding predilation, prestenting, and postdilation confounded assessment of the independent importance of these technical factors.

Conclusions
MSF was common after Melody valve implant in this multicenter experience and was more likely in patients with smaller and more obstructed RVOT conduits, those with homografts rather than BPV, and when the implanted TPV was directly behind the anterior chest wall and/or compressed. Melody valve implant within a protected RVOT, either a BPV with a rigid frame or a prestented conduit, was associated with lower risks of MSF, TPV dysfunction, and reintervention. However, the small number of clinically important outcomes precluded robust multivariable or subgroup analysis. Aside from those with a BPV, it is not yet possible to define patients who will or will not benefit from prestenting, although direct apposition of the conduit to the anterior chest wall and severe conduit obstruction are factors associated with MSF that can be identified a priori and may be reasonable indicators for prestenting. These findings are encouraging because they provide evidence to validate a practice that has become common among cardiologists who perform Melody valve implantation. However, they should not be construed to support universal prestenting.

Sources of Funding
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Disclosures
All authors act as investigators, consultants, and/or proctors roles for Medtronic, Inc, the manufacturer of the Melody valve. Dr Cheatham also acts as a consultant for NuMed, Inc.

References


Stent Fracture, Valve Dysfunction, and Right Ventricular Outflow Tract Reintervention After Transcatheter Pulmonary Valve Implantation: Patient-Related and Procedural Risk Factors in the US Melody Valve Trial

Doff B. McElhinney, John P. Cheatham, Thomas K. Jones, James E. Lock, Julie A. Vincent, Evan M. Zahn and William E. Hellenbrand

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Supplemental Material
Supplemental Methods

Fluoroscopic/Angiographic Assessments

In addition to measurements reported in the main body of the text, the following assessments were performed. Conduit calcification was graded as none to trivial, mild to moderate (incomplete circumference, spotty, variable radioopacity), or severe (densely radioopaque throughout conduit). The qualitative shape of the deployed valve was described according to pre-defined patterns: cylinder, compressed cylinder (compression in any direction), truncated cone, or flared cylinder (proximal, distal, both). To quantify compression/distortion and flaring of the stent, the narrowest, widest proximal, and widest distal portions of the final deployed Melody® valve stent were measured in both fluoroscopic projections in end- or late-diastole and the following ratios were calculated: eccentricity index (defined in main text), and proximal and distal flare indices (ratio of the widest proximal/distal portion to the narrowest portion of the stent). For flare indices, the fluoroscopic projection with the largest ratio was used for analysis. The motion of the deployed TPV during the cardiac cycle was characterized qualitatively as minimal/none, torsion/rotation around the long-axis, flexion/rotation around the short-axis, or compression.
Supplemental Results

Patients

Patients with a primary implant indication of stenosis or mixed disease were less likely to have tetralogy of Fallot (36%) than a Ross procedure (60%) or other primary diagnosis (58%) (p=0.02). Patients with a previously placed conduit stent were less likely to have an implant indication of stenosis/mixed disease than those without an existing stent (OR 0.28 [0.12-0.65], p=0.002).

Procedural and Acute Outcomes

Pre-stenting was performed more often in patients with an implant indication of stenosis or mixed disease (OR 2.2 [1.1-4.4], p=0.03), and less often in patients with a BPV than those with other conduit types (OR 0.11 [0.03-0.48], p<0.001).
Supplemental Figure Legends

Supplemental Figure 1. Column graph showing the percentage of cases at each center with a primary implant indication of stenosis/mixed disease, and in which pre-stenting, pre-stenting with multiple stents, high-pressure pre-dilation, and post-dilation were performed. Center numbers were assigned randomly. P values are for comparison between the highest and lowest centers. The percentage of patients in whom the highest pressure pre-dilation balloon inflated to 10atm or higher: p<0.001; the percentage of patients in which pre-stenting was performed prior to TPV implant: p=0.002; the percentage of patients in which multiple pre-TPV was performed: p=0.001.

Supplemental Figure 2. Box plot depicting the median Doppler RVOT gradient over time in patients who were not diagnosed with any SF, those diagnosed with a type I SF only, and those diagnosed with a type II SF. Data at each time point are grouped according to the most severe grade of SF diagnosed at any point, regardless of the presence or type of SF at the particular time point. Patients were excluded after RVOT reintervention.

Supplemental Figure 3. Four examples of type I SF that did not progress and were not associated with progressive RVOT obstruction. The stent in A) was first noted to be fractured at the 3-year follow-up evaluation. In B), there are 2 individual strut fractures in a patient with multiple intact pre-stents in the conduit. The stent in C) was in a patient with a primary implant indication of regurgitation, who had no compression or RVOT obstruction but a dynamic RVOT. The image in D) shows distortion and fracture of the proximal portion of the Melody® valve stent, where it is apposed to the anterior chest wall, in a patient with a BPV in the pulmonary position. This was the only SF of a TPV implanted within a BPV.

Supplemental Figure 4. Kaplan-Meier curves showing freedom from a diagnosis of SF according to A) the number of new pre-stents placed at the TPV implant catheterization, or B) the total number of pre-stents (prior intact or new).
**Supplemental Video Legends**

Supplemental Video 1. This patient developed a type II MSF and underwent reintervention, with implant of a second TPV. At the reintervention catheterization, A) anteroposterior and B) lateral fluoroscopic images demonstrated a type II MSF that allowed a segment of the proximal stent to hinge on the vein wall and prolapse into the conduit lumen during systole, potentially contributing to recurrent obstruction.

Supplemental Video 2. This patient developed a type II MSF and underwent reintervention, with implant of a second TPV. At the reintervention catheterization, it was found that there was systolic flow between the proximal segment of conduit and prolapsing of the vein wall into the lumen, also potentially contributing to luminal narrowing.

Supplemental Video 3. This patient developed a type II MSF and underwent reintervention, with implant of a second TPV. At the reintervention catheterization, A) anteroposterior and B) lateral fluoroscopic projections demonstrated the posterior wall of the TPV prolapsing into the lumen, allowing passage of contrast between the posterior wall of the conduit and the TPV. There was also a disarticulated segment of the proximal stent that prolapsed into the lumen during systole.

Supplemental Video 4. These fluoroscopic images demonstrate different patterns of dynamic compression and displacement of the fractured TPV stent. A) In this patient, a caudal fluoroscopic projection allows an "up-the-barrel" view that demonstrates anteroposterior collapse of and compression along the entire length the stent. B) In this patient, there is fracture and dynamic displacement of the anterior/proximal portion of the device, shown clearly on the lateral projection; C) after implantation of 2 bare metal stents and a second TPV within the fractured initial TPV, the device is well expanded with no evidence of dynamic compression.
Supplemental Figure 1. Column graph showing the percentage of cases at each center with a primary implant indication of stenosis/mixed disease, and in which pre-stenting, pre-stenting with multiple stents, high-pressure pre-dilation, and post-dilation were performed. Center numbers were assigned randomly. The percentage of patients in which the highest pressure pre-dilation balloon was inflated to 10atm or higher ranged from 20-81% across centers (p<0.001), the percentage of patients in which pre-stenting was performed prior to Melody® valve implant ranged from 18-64% (p=0.002), the percentage of patients in which multiple pre-stents were placed ranged from 7-28% (p=0.26), and the percentage of patients in which post-dilation of the implanted Melody® valve was performed ranged from 12-71% (p=0.001).
Supplemental Figure 2. Box plot depicted median Doppler RVOT gradient over time in patients who were not diagnosed with any stent fracture, those diagnosed with a type I stent fracture only, and those diagnosed with a type II stent fracture. Data at each time point are grouped according to the most severe grade of stent fracture diagnosed at any point, regardless of the presence of type of stent fracture at the particular time point. Patients were excluded after RVOT reintervention.
Supplemental Figure 3. Four examples of type I stent fractures that did not progress or develop associated RVOT obstruction. In B), there are 2 individual strut fractures in a patient with multiple unfractured pre-stents in the conduit. The image in D) shows distortion and fracture of the proximal portion of the Melody® valve stent, where it is apposed to the anterior chest wall, in a patient with a BPV in the pulmonary position. This was the only stent fracture in a patient with a BPV, and was not associated with progressive RVOT obstruction.
Supplemental Figure 4a. Kaplan-Meier curve showing freedom from a diagnosis of stent fracture according to the number of new pre-stents placed at the TPV implant catheterization.
Supplemental Figure 4b. Kaplan-Meier curve showing freedom from a diagnosis of stent fracture according to the number of prior intact or new pre-stents.