The use of balloon-expandable intravascular stents to treat vascular stenoses in children was first described >20 years ago.1,2 With improvements in balloon and stent technology, including the development of premounted stents and lower profile delivery systems, the use of stents to treat areas of resistant stenosis has increased and now facilitates the management of a wide range of anatomic conditions. Redilation of existing stents to account for patient growth and stent restenosis can result in significant increases in stent caliber and is believed to be safe.3–7

Traditionally, stent placement in small infants and children has been limited by the inability of the stent to expand with the somatic growth of the child. Balloon-expandable stents can usually be enlarged beyond the target diameter but have a finite maximum diameter, which may be smaller than the ideal adult size of the treated vessel when the stents are implanted in a small child. The options for treatment of stenosis related to an indwelling stent have traditionally been limited to tolerating residual obstruction or surgical transection/removal of the stent. Ultra–high-pressure (UHP) angioplasty balloons layered with woven high-molecular weight polyethylene have been used to intervene on resistant pulmonary artery (PA) stenoses. In the process of stent dilation, the stress applied to the stent can exceed the ultimate tensile stress limit of the stent and result in an overload stent fracture allowing for further expansion of the vessel lumen.8

There are limited data about the safety of intentional PA stent fracture.9,10 The aim of this study was to characterize the outcomes and complications associated with PA stent fracture in cases of refractory stenosis related to a preexisting stent. The ability to safely and reproducibly fracture and expand stents beyond the maximal diameter may allow us to use stents in small children in whom the maximal diameter of the stent will not accommodate normal growth of the pulmonary arteries.

Background—Treatment with endovascular stents has become increasingly common for the management of vascular stenosis in congenital heart disease. The use of stents in smaller patients has been tempered by concerns about the potential for stent expansion to accommodate somatic growth. One solution to limited stent diameter is the intentional fracture of maximally dilated stents, which can be accomplished using ultra–high-pressure (UHP) balloons.

Methods and Results—This retrospective cohort study compared procedural characteristics and adverse events between a cohort of patients with branch pulmonary artery (PA) stents who underwent stent fracture using UHP balloons and control patients who underwent UHP redilation of previously placed PA stents without stent fracture between 2004 and 2014. Two control patients were selected for every case. Thirty-three PA stents were fractured in 31 patients with a median of 10 years after initial stent placement. The median balloon:waist ratio was 1.17 (1–1.71), and the median inflation pressure was 20 (8–30) atm. There were significant reductions in pressure gradient after angioplasty, with no difference in postangioplasty gradients between cases and controls. There were no major PA complications in the stent fracture group and no difference in the number of adverse events between the 2 groups.

Conclusions—In this small series, PA stent fracture using UHP balloon angioplasty was feasible and did not result in major complications although predictors of successful fracture were not identified. Intentional fracture with UHP balloon angioplasty may be considered when treating stents that have become restrictive despite maximal dilation. (Circ Cardiovasc Interv. 2016;9:e003281. DOI: 10.1161/CIRCINTERVENTIONS.115.003281.)

Key Words: angioplasty, balloon ▪ cardiac catheterization ▪ cohort studies ▪ pulmonary artery ▪ stents

The use of balloon-expandable intravascular stents to treat vascular stenoses in children was first described >20 years ago.1,2 With improvements in balloon and stent technology, including the development of premounted stents and lower profile delivery systems, the use of stents to treat areas of resistant stenosis has increased and now facilitates the management of a wide range of anatomic conditions. Redilation of existing stents to account for patient growth and stent restenosis can result in significant increases in stent caliber and is believed to be safe.3–7

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WHAT IS KNOWN

- Despite excellent acute results using stents for persistent stenotic lesions in children with congenital heart disease, there are still concerns about the ability to expand these stents sufficiently to account for the patient’s somatic growth, especially when these stents reach what is considered to be their maximal diameter.

WHAT THE STUDY ADDS

- We find that it is possible to fracture maximally dilated stents in the pulmonary arteries and that this intervention is not associated with a significant increase in the incidence of major complications compared with similar procedures in which dilatation of previously placed stents did not result in stent fracture.

Methods

Patients and Study Protocol

Patients were identified by searching the clinical databases in the Department of Cardiology at Boston Children’s Hospital. The inception cohort included all patients who underwent angioplasty of existing branch PA or native main PA stents during our first 10 years of experience (2004–2014) using Atlas or Conquest UHP balloons (Bard Peripheral Vascular Inc, Tempe, AZ). Although other angioplasty balloons are capable of generating high pressures and were used for stent re-dilatation during this time period, previous experience and data suggest that angioplasty with UHP balloons is effective in relieving obstructions resistant to high-pressure dilatations. The clinical databases were, therefore, queried specifically for patients undergoing stent re-dilatation with UHP balloons because it was felt that this would yield the largest cohort of patients with intentional attempts at stent fracture. In most cases, UHP balloons were not used with the intention of fracturing the stent and it was not known at the time of the database search which cases resulted in stent fracture. Catheterization records and angiograms were then reviewed for evidence of stent fracture during the balloon dilation procedure or on follow-up PA angiography. Patients were excluded from the study if there were insufficient angiographic or fluoroscopic images to evaluate for evidence of stent fracture or if there was evidence of a pre-existing fracture before balloon angioplasty. Patients undergoing through-cell dilatation and stent strut fracture to relieve obstruction of jailed vessels were not included. The narrowest measurement of the stent was used to select a balloon with a nominal diameter that would result in a balloon:stent narrowest diameter ratio in the range of 1.0 to 1.25, but balloon selection was empirical and depended on the specific circumstances, and larger ratios were used in some circumstances.

Statistical Analysis

The primary outcome variable was a composite selection of adverse events related to the balloon angioplasty procedure and fracture of the stent(s) as defined by the investigators. These included intimal flap resulting in significant vessel obstruction requiring reintervention, complete or partial vessel wall rupture, stent or stent fragment embolization, balloon rupture after balloon rupture, and the inability to remove or difficulty in removing the balloon because of balloon rupture or interference from the fractured stent. Second stent placement to enlarge the vessel post stent fracture with no other evidence of vessel injury was not considered an adverse event.

Demographic and predictor variables included age at intervention, stent location, type of stent, duration of stent placement, the presence of multiple concentric stents across the lesion of interest, maximal balloon pressure achieved during inflation, balloon:waist diameter ratio before the stent fracture, prefracture and postfracture hemodynamic measurements, stent recoil after fracture, and the placement of additional stents. Pressure gradients across the stent were calculated by simultaneously or sequentially taking pressure measurements distal and proximal to the stent both predilation and post-dilatation. Stent recoil was calculated as the percentage difference between the measured diameter of the stent at maximum dilation and the measured diameter of the stent after the fracture and balloon deflation. Continuous variables were expressed as median (minimum–maximum), and categorical variables were expressed as frequency (%). Within-patient data, preangioplasty and postangioplasty, were compared using the paired t test. Between-group comparisons were performed using Fisher exact test for categorical variables or Wilcoxon signed-rank test for continuous data. Scatter plots were generated to demonstrate the different balloon sizes and balloon:waist ratios used for each type of stent in the study.

Results

Patients

The initial search identified 199 patients who underwent 288 catheterizations that included angioplasty of existing PA stents with UHP balloons from 2004 to 2014. During this time period, Palmaz series 4 (referred to as renal stents; Johnson and Johnson, Warren, NJ), Palmaz series 8 (referred to as iliac stents, Johnson and Johnson), Genesis stents (pre-mounted medium, large, and un-mounted extra diameter stents, Johnson and Johnson), and Veriflex coronary stents (Boston Scientific, Natick, MA) were all used and were included in this study (Table 1). Angiograms were reviewed from each catheterization to identify stent fractures directly attributable to balloon angioplasty. This review identified 31 patients who underwent fractures by visualizing a discrete waist in the balloon at the site of a maximally shortened stent, followed by an abrupt resolution of the waist and change in the caliber of the stent, or follow-up angiography demonstrating a longitudinal fracture through the stent struts (Movie in the Data Supplement). Fractures were classified as complete longitudinal fractures if there was clear evidence of disruption of each of the struts along the full length of the stent and partial longitudinal fractures if the struts were disrupted along a portion of the stent but not along its entire length. Circumferential stent fractures, in which the connections between stent rings are fractured but the rings themselves remain circumferentially intact along the length of the stent, do not allow for expansion beyond the maximal diameter of the stent and were not included in this analysis. Patients undergoing through-cell dilation and stent strut fracture to relieve obstruction of jailed vessels were not included. The narrowest measurement of the stent was used to select a balloon with a nominal diameter that would result in a balloon:stent narrowest diameter ratio in the range of 1.0 to 1.25, but balloon selection was empirical and depended on the specific circumstances, and larger ratios were used in some circumstances.
angioplasty with UHP balloons at 33 sites resulting in longitudinal stent fracture; 2 patients each had stents at 2 different sites fractured during the same catheterization. In 5 patients, there were multiple overlapping stents, resulting in a total of 40 stents dilated at 33 sites. Five patients in the stent fracture group were included in a previous study of UHP angioplasty. The nonfracture group was comprised of 62 patients who underwent angioplasty with UHP balloons at 68 sites. Baseline patient characteristics are listed in Table 1.

There was no significant difference between the fracture group and the nonfracture group with regard to sex, diagnosis, or distribution of stent placement. The median age and median duration since stent placement of patients in the stent fracture group were higher relative to the nonfracture group. All of the Genesis stents used in this cohort were premounted and were categorized as Genesis large (balloon sizes, 8–10 mm) or Genesis medium (balloon sizes, <7 mm). The majority of patients had a single stent at the site of fracture. Of the patients with 2 overlapping stents, 1 experienced partial longitudinal fracture of both stents, 1 experienced complete longitudinal fracture of both stents, and 1 experienced complete longitudinal fracture of the outer stent only (the inner stent was not maximally expanded). In both patients with 3 stents, redilation resulted in partial longitudinal fracture of all 3 stents. There was an even distribution of stents between the left and the right PA. The majority of stents were located in the proximal branch pulmonary arteries or main PA.

### Procedural Data

As summarized in Table 2, the nonfracture group was similar to the fracture group with regard to balloon inflation pressure and balloon:waist diameter ratio used in the dilation. Within the stent fracture group, there was only 1 patient with a balloon:waist ratio of >1.32, and in 25 of the stents (76%), the ratio was ≤1.25 (Figure 1). More Atlas balloons were used in the fracture group than in the nonfracture group. Within both groups, there was a significant reduction in gradient postangioplasty. There was no difference between the groups in the degree of gradient reduction after balloon angioplasty. With deflation of the balloon, many of the fractured stents were observed to recoil; the median percentage recoil after stent fracture was 9.2% (0–19.2). Six patients had an additional stent placed across the lesion after the stent was fractured. There were 19 complete longitudinal fractures, and 14 partial longitudinal fractures were observed (Figures 2 and 3). Seven of the 14 partial fractures involved Genesis stents, 3 involved renal stents, and 4 involved iliac stents. Two of the patients with partial renal stent fractures had multiple stents at the site, which may have affected the ability to create a complete longitudinal fracture.

### Adverse Events

There was no statistically significant difference in the frequency of adverse events between the groups (Table 2). Among the 33 stented lesions in which a stent fracture occurred, there was 1 instance of distal stent fragment embolization, which was nonobstructive. In a second patient, a portion of the fractured stent was felt to be unstable, resulting in placement of an additional stent to prevent potential embolization of that fragment. One patient developed a confined vascular tear after fracture, which required placement of an additional stent. An additional patient with a right PA stent after arterial switch operation for transposition of the great vessels underwent successful stent fracture. There was no evidence of vascular disruption after the stent fracture. After placement of a second stent in the right PA, an angiogram demonstrated

### Table 1. Baseline Demographics

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Stent Fracture</th>
<th>Nonfracture</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetralogy of Fallot</td>
<td>23 (74)</td>
<td>41 (66)</td>
<td>0.42</td>
</tr>
<tr>
<td>Transposition/</td>
<td>5 (16)</td>
<td>3 (5)</td>
<td>0.07</td>
</tr>
<tr>
<td>malposition complexes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truncus arteriosus</td>
<td>3 (10)</td>
<td>6 (10)</td>
<td>1.00</td>
</tr>
<tr>
<td>Peripheral pulmonary stenosis</td>
<td>0</td>
<td>5 (8)</td>
<td>0.10</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>7 (11)</td>
<td>0.06</td>
</tr>
<tr>
<td>Vessel location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main right pulmonary artery</td>
<td>16 (49)</td>
<td>28 (41)</td>
<td>0.48</td>
</tr>
<tr>
<td>Main left pulmonary artery</td>
<td>13 (39)</td>
<td>32 (47)</td>
<td>0.47</td>
</tr>
<tr>
<td>Main pulmonary artery</td>
<td>2 (6)</td>
<td>0</td>
<td>0.04</td>
</tr>
<tr>
<td>Right lower pulmonary artery</td>
<td>2 (6)</td>
<td>4 (6)</td>
<td>0.97</td>
</tr>
<tr>
<td>Left lower pulmonary artery</td>
<td>0</td>
<td>4 (6)</td>
<td>0.15</td>
</tr>
<tr>
<td>Stent type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genesis</td>
<td>15 (38)*</td>
<td>42 (51)†</td>
<td>0.15</td>
</tr>
<tr>
<td>Iliac (P128, P188, and P308)</td>
<td>8 (20)</td>
<td>27 (33)</td>
<td>0.13</td>
</tr>
<tr>
<td>Renal (P104, P154, and P204)</td>
<td>17 (42)</td>
<td>7 (9)</td>
<td>0.001</td>
</tr>
<tr>
<td>Coronary</td>
<td>0</td>
<td>4 (5)</td>
<td>0.15</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>2 (2)</td>
<td>0.32</td>
</tr>
<tr>
<td>No. of stents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>28 (85)</td>
<td>54 (79)</td>
<td>0.51</td>
</tr>
<tr>
<td>2</td>
<td>3 (9)</td>
<td>14 (21)</td>
<td>0.15</td>
</tr>
<tr>
<td>3</td>
<td>2 (6)</td>
<td>0</td>
<td>0.04</td>
</tr>
<tr>
<td>Duration of stent placement, y</td>
<td>10.3 (0.7–21)</td>
<td>4.7 (0.5–16.1)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Data are presented as median (minimum–maximum) or n (%).

*Percentage of total stents (n=40).
†Percentage of total stents (n=82).

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Figure 1: Baseline patient characteristics are listed in Table 1.

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Figure 2: Among the 33 stented lesions in which a stent fracture occurred, there was 1 instance of distal stent fragment embolization, which was nonobstructive. In a second patient, portion of the fractured stent was felt to be unstable, resulting in placement of an additional stent to prevent potential embolization of that fragment. One patient developed a confined vascular tear after fracture, which required placement of an additional stent. An additional patient with a right PA stent after arterial switch operation for transposition of the great vessels underwent successful stent fracture. There was no evidence of vascular disruption after the stent fracture. After placement of a second stent in the right PA, an angiogram demonstrated...
the creation of an aortopulmonary window. This was treated with a covered stent in the right PA. There were no episodes of obstructive flap or aneurysm formation, balloon fragment embolization, or balloon removal or delivery problems related to stent fracture. Two patients had evidence of a nonobstructive intimal tear visible on follow-up PA angiogram. One of these patients underwent placement of a second stent within the fractured stent. Follow-up catheterization 8 months later in this patient demonstrated a residual gradient of 10 mm Hg across the stented segment with no evidence of obstruction, stent embolization, or progressive vascular injury. In the nonfracture group, there were 2 instances of vessel rupture. In 1 patient, balloon rupture during dilation resulted in vessel rupture causing hemoptysis. The damaged vessels were coil occluded. A second patient experienced vessel rupture resulting in a hemothorax, which required chest tube placement.

Ten patients in the fracture group underwent follow-up catheterization with a median of 2 years (0.5–5) after the intentional stent fracture. At the follow-up catheterization, the mean gradient across the stented segment was 14 mm Hg, which was not significantly changed from the postdilation gradient from the previous catheterization (P=0.63). There was no evidence of vessel obstruction or embolization of stent fragments related to the previous stent fracture, and no additional stents were placed at the follow-up procedure. In the nonfracture group, 1 additional patient was found to have an aneurysm distal to the stent at catheterization 4 years after the initial UHP dilation, which was believed to be related to the index UHP dilation.

**Discussion**

**Intentional Fracture of PA Stents Using UHP Balloons**

This study describes a cohort of patients in whom maximally expanded PA stents were fractured using UHP balloon angioplasty. Intentional fracture of PA stents using noncompliant UHP balloon catheters can be accomplished across many
different stent types with relatively low adverse event rates. There were significant reductions in the pressure gradients across the stented segments. Among patients with a follow-up catheterization, the gradients across the stents remained low and there was no evidence of new adverse events related to the stent fracture.

The majority of the fractures were complete, with the fracture extending the entire length of the stent. This may reflect the fact that over half of the stents used in the study population were closed-cell iliac or renal stents, which have a higher observed rate of in situ longitudinal fatigue fractures.8 Half of the partial longitudinal fractures occurred in Genesis stents, which can expand in an irregular fashion, resulting in partial fractures. In addition, 3 of the patients with partial fractures of renal or iliac stents had multiple stents at the site of dilation, which may have affected the way in which the stents expanded or our ability to accurately characterize a full or partial fracture. Patients in the fracture group were older, with a longer duration of stent implantation before dilation. The duration of stent implantation may play a role in the susceptibility of the stent to fracture as chronic stresses may result in weaknesses in portions of the stent that are more likely to fracture with balloon angioplasty.

Stent fracture was achieved without significantly oversizing the balloons relative to the stenosis. The median balloon:waist ratio in the stent fracture group was 1.17, which was within the target ratio of 1 to 1.25. Although the balloons used in the stent fracture groups were larger than those used in the nonfracture group, the balloon:waist ratios were similar between the 2 groups, suggesting that balloon sizing techniques were relatively consistent between the 2 groups. Recoil of the stent was observed after fracture in 22 of the 33 sites.
with a median percentage recoil of 9.2%, which is consistent with previous reports of recoil in PA stent redilation in which stent fracture did not occur.12 Despite the presence of stent recoil after fracture, there was a consistent reduction in pressure gradient that was maintained at follow-up catheterization. For patients in whom postfracture catheterization data were available, there was only 1 instance of a worsening pressure gradient across the stent segment. The remaining patients all demonstrated an improvement in the gradient, which persisted on follow-up catheterization.

**Previous and Related Data**

Stent redilation with high pressure and UHP balloons can be performed with few complications.4,6,10 However, little is known about the safety of intentional stent fracture. Two patients from a previous study of stent implantation in patients with congenital heart disease developed stent fractures after high-pressure balloon angioplasty.9 One patient with a probable fatigue fracture experienced embolization of a stent fragment to a branch PA without obstruction. A second patient developed a fracture without obstruction at the fracture site or without stent fragment embolization.

A recent in vitro study evaluated the stent fracture characteristics of 8 commercially available small-diameter (2.25–6 mm) coronary, biliary, and peripheral stents using UHP balloon catheters.11 They determined that stainless steel stents with a closed-cell design, which shortened minimally during dilation, were most amenable to intentional fracture. Clinical data in this area are limited. In a study of 29 patients with resistant in-stent stenoses >90% (31/34 cases) of obstructions resolved with UHP balloon angioplasty, and there were 5 cases in which UHP angioplasty resulted in overloading fracture of a maximally dilated stent with no associated adverse events.10 These 5 patients were included in this cohort. A retrospective study of 13 patients described attempts at intentional longitudinal (n=6) or through-cell (n=7) stent fracture in a variety of vessels, with no associated complications.9

There have been attempts at developing stents that can be easily fractured or expanded to accommodate patient growth. Breakable stents or growth stents are designed to fracture or open along the long axis of the stent when dilated.14,15 In addition, the development of bioresorbable stents may ultimately provide viable alternatives to the current stent designs and obviate the need to intentionally fracture metallic stents. However, those technologies are not currently available in the management of arterial stenosis in congenital heart disease.

**Limitations**

The cohort of patients with fractures was small, which limits the statistical power and ability to generalize these findings. As such, this is a largely descriptive study designed to illustrate that stent fracture can be achieved without a higher frequency of serious adverse events when compared with stent redilation without fracture. This study cannot provide insight into the frequency of or factors associated with successful or unsuccessful attempts at deliberate stent fracture. Discerning intentionality in a procedure of this nature is challenging. Unless directly specified in the procedure note, it was difficult to determine if the operator was attempting to fracture a stent but was unsuccessful. Understanding factors (technical, stent related, and patient-related) associated with the inability to execute a deliberate stent fracture despite aggressive attempts is an interesting and important issue that will require prospective evaluation.

Under certain circumstances, discerning if a fracture occurred was difficult—in such cases, we typically erred on the side of not diagnosing a fracture. Limitations in imaging quality secondary to era of equipment, fluoroscopy settings, patient body habitus, and angle of interrogation can all have a significant effect on the ability to visualize if a stent has been fractured. In addition, variations in stent geometry or composition may have an effect on our ability to identify stent fractures reliably, particularly in partial fractures or with overlapping stents.

We focused on branch PA stents and did not include patients with stents in systemic or pulmonary veins or systemic arterial vessels. As such, these data cannot be generalized to intentional stent fracture in any of these other vessel types. Many of the stents described in this study are no longer used by operators in the United States and, therefore, may not represent the fracture characteristics of stent types that are currently in use in most congenital catheterization laboratories. There were 2 patients in the control cohort with nonsyndromic peripheral pulmonary stenosis but no patients with systemic arteriopathies (ie, Williams syndrome, Alagille syndrome, and Moyamoya disease). The behavior of stented pulmonary arteries in response to UHP balloon angioplasty in such patients may differ from what we observed in the present cohort of patients who primarily had postsurgical branch PA stenosis requiring intervention.

**Conclusions**

In this preliminary study, there were few adverse events associated with intentional fracture of previously implanted, maximally expanded PA stents. Although the likelihood that PA stents can be fractured using UHP balloons could not be determined, when an intentional fracture was achieved, it seemed to result in hemodynamic benefit and was not associated with a significant increase in the rate of complications when compared with UHP angioplasty without a stent fracture. Factors associated with inability to achieve an intentional fracture deserve further study.

**Acknowledgments**

All the authors were directly involved in the study design, data analysis, interpretation of findings, and article completion. All the authors reviewed the article in detail and have approved it in its submitted form.

**Disclosures**

None.

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Intentional Fracture of Maximally Dilated Balloon-Expandable Pulmonary Artery Stents Using Ultra–High-Pressure Balloon Angioplasty: A Preliminary Analysis
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