Fracture of Cardiovascular Stents in Patients With Congenital Heart Disease

Theoretical and Empirical Considerations

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Stents have become essential tools in the management of various medical conditions, typically as permanent indwelling devices. Implant environments can vary from highly dynamic to quiescent. However, the human body is a dynamic organism, and stents are composed of materials that are intrinsically subject to mechanical fatigue. Thus, as with other implantable medical devices, stent fracture and failure are inevitable concerns. In fact, fracture is an increasingly recognized occurrence affecting stents implanted in many locations, both in the cardiovascular system and in the other organ systems.

In children and adults with congenital heart disease (CHD), stents are used to treat many conditions, including obstruction of systemic and pulmonary arteries and veins, prosthetic conduits, valves, and shunts, and to enlarge, establish, or maintain communications between vessels or chambers of the heart. Most stents placed for CHD are used off-label, to treat conditions for which the stents were not developed, tested, or approved, and they are frequently implanted in previously operated sites with nonuniform material properties, and they may also be exposed to high cyclic mechanical stress. Because patients with CHD who have stents placed are usually children or young adults, the expected lifespan of the stent may be many decades. Stents and other implantable cardiac devices are used with growing frequency in this population, so fracture of such devices, even if relatively rare, is likely to become an increasingly important consideration both in the clinical management of patients and in the evaluation of new technologies.

The purpose of this review is to consider the issue of fracture of balloon-expandable stents in patients with CHD. After a brief discussion of relevant biomechanical considerations, we suggest a descriptive framework for evaluating and discussing stent fracture in this population, then provide a clinical overview and discuss the clinical implications of stent fracture in CHD.

Biomechanics of Stent Fracture

Two types of conditions can cause stent fracture: overloading and fatigue. In the former, fracture occurs when the metal experiences stresses that exceed the ultimate tensile stress limit (ie, the highest stretching force the material can withstand), which is specific for the stent material at the end of the production process (Figure 1). In the normal process of stent deployment, inflation of the balloon on which the stent is mounted results in elastic deformation of the metal, which means that if the balloon is deflated at this point, the stent would recover completely its original shape. Further balloon inflation results in stresses that exceed the yield point of the material, beyond which the stent exhibits plastic deformation, which is permanent and ensures that the stent remains open after the balloon is deflated. However, if the stent is expanded further and overloaded beyond the ultimate tensile stress limit, the material fractures.

The other, more common mechanism of stent fracture is fatigue. When mechanical devices subject to cyclic loading fail, they often do so at stresses less than the ultimate tensile stress limit because cyclic stresses cause fatigue, which gradually alters the ability of the material to resist the external load. When a stent is subjected to a general load, the individual struts or joints of the stent bend. Cyclic bending loads applied to a strut cause a repetitive compressive stress along the inner curvature of the bend and a tensile stress along the outer curvature. These tensile loads result in plastic deformations that may cause surface irregularities at which fatigue cracks can initiate and propagate over time to become full thickness fractures. Intravascular stents are inevitably exposed to cyclic stresses and undergo fatigue although not always to the point of fracture. Empirically, extrinsic cyclic forces seem to be important contributing factors in the fracture of stents implanted for CHD (Figures 2 and 3; Movies I and II in the online-only Data Supplement).

The following section is intended to provide a brief overview of biomechanical considerations relevant to fracture of stents implanted for CHD, which will facilitate the subsequent discussion of clinical stent fracture. More extensive consideration of stent materials and mechanics, stent-vessel interactions, and other biomechanical considerations relevant to this issue is provided elsewhere.
Factors Contributing to Stent Fracture

In general, the fracture resistance of a stent is influenced by multiple factors, including features of the stent, its delivery and deployment, the vessel into which it is implanted, and the implant environment beyond the vessel, per se. In theory, all of these factors likely contribute to the propensity for clinical stent fracture; however, their relative importance and interactions with one another are complex and undefined.

Stent-Related Considerations

Stent-related factors that can affect fatigue-life include the material (eg, stainless steel, platinum-iridium, cobalt chromium), the location and size of intrinsic defects in the metal (eg, grain size, persistent slip bands), the geometry and design (eg, cut tube, welded wire, open versus closed cell, design and thickness of struts, and other elements such as nodes, connecting segments), and the manufacturing process (eg, laser cut tube, welded wire, brazing of welds), which influences the surface quality and residual stresses from cutting, extrusion, welding, etc. Inevitably, stents are left with microscopic defects during fabrication, which, along with other intrinsic elements of metallic alloys, may serve as foci of stress concentration and consequent crack initiation.

Deployment-Related Considerations

Delivery- and deployment-related factors that may have implications for fatigue fracture include whether and how the stent was crimped onto the delivery balloon, the type of balloon used to implant the stent, the size of balloon on which the stent was deployed relative to the lesion and the adjacent vessel, the occurrence of dog-boning or asymmetric shortening of the stent during expansion, the final expanded geometry and diameter of the stent, potential torsion on the stent attributable to balloon unfolding, particularly if a portion of the stent is restricted in its movement by the vessel wall, and possibly others. Malposition or distortion of a stent during removal of the balloon or subsequent crossing may cause focal deformations or otherwise impact fracture resistance as well. Delivery and deployment operations lead to accumulated stresses in the metal that can promote failure.

Environmental Considerations

Environmental factors that may affect the fatigue-life of a stent include not only the vessel or structure into which the stent is implanted, but also the local environment beyond the vessel. Characteristics of the target vessel that may be important include nonuniform or otherwise abnormal compliance of the tissue related to the disease (eg, elastin arteriopathy), the presence of surgical material (eg, patch angioplasty or conduit interposition, anastomoses), other postoperative changes (eg,
calcification or perivascular fibrosis), and potentially more. The main purpose of a stent is to resist the recoil that develops after implantation because of the hoop stress in the vessel. This inward force is typically anisotropic along the length of the stent, which is usually longer than the stenosis, and the magnitude of stress almost certainly differs at the site of stenosis and contiguous sections of normal vessel wall.

More broadly, the implant environment beyond the vessel, including adjacent mediastinal structures and the movement of the heart, may have an impact on fatigue-life through the transmission of mechanical stresses such as flexion, torsion, and tension/compression during the cardiac cycle, all of which may vary in nature, amplitude, and direction. These factors are discussed in relation to specific implant locations below.

Unfortunately, there are limited data about the biomechanical properties of congenitally abnormal and postoperative vessels that are treated with stents, and almost no published information about the in situ mechanics of most implant locations and environments, which limits our ability to understand the stresses to which stents are exposed clinically.

Preclinical Testing of Stent Strength
Numerous studies have been performed to assess methods of evaluating stent mechanics, to identify the strength of specific stents, and to understand the biomechanics of stent delivery, deployment, and fatigue. A central element of preclinical testing of all stents and implantable medical devices is assessment of stress and fatigue-life. The US Food and Drug Administration has published an extensive guidance document summarizing recommended engineering tests for intravascular stents. The recommended analysis of fatigue fracture–resistance is limited primarily to idealized radial strength testing to a predetermined number of cycles. In the heart and great vessels of patients with CHD, stents are used in many different sites, and, in these manifold locations, they may be deployed with irregular geometry and be subject to complex and variable multiaxial forces (Movie III in the online-only Data Supplement). Thus, uniform radial strength testing does not reflect many of the clinical parameters that are germane to the performance of stents in CHD applications and does not seem to anticipate the clinical performance of stents in such circumstances.

Given the complex and compound forces to which stents are exposed, and our limited understanding of these forces, it is not practical to expect that all potential in situ conditions can or will be evaluated in preclinical testing. Most stents used in patients with CHD are not approved for those indications, and the preclinical testing is not designed to simulate conditions to which they will be exposed in off-label applications. Although the types of stents used in CHD applications have changed over time, it is probably fair to say that methods of testing device strength have rarely, if ever, simulated realistically the forces to which they are exposed in many CHD applications. With increasing development of stents and stent-based devices intended for CHD applications, the issue of how best to assess stent fatigue before clinical application may assume greater importance.

An exciting development in this regard is that investigators have begun to use computational methodologies and patient-specific simulations to better understand mechanical stresses that develop in stents under highly specific loading conditions. Computational analyses, such as finite element modeling, can be valuable for evaluating the mechanical response of a device to fatigue during the design process and other stages of stent development and use. Computational simulation is an attractive tool for this purpose because it can account for complex loading conditions that cannot be replicated on the bench, thus facilitating assessment of mechanical performance in more realistic environments. Moreover, computational methods can help reduce the time and cost of design by avoiding the production and in vitro assessment of multiple suboptimal prototypes.

Clinical Stent Fracture: Description, Categorization, and Analysis
Despite limited information about the biomechanical and clinical factors leading to stent fracture in patients with CHD, this issue is likely to become increasingly important with the expanded use of stents, stent-based valves, and other intracardiac devices in this patient population. Therefore, we think that it is important to develop a working nomenclature and framework that can be used to approach investigations of stent fracture in a systematic, relevant, and practical manner. In this section, we attempt to provide such a framework, as we review the range of fracture severity and patterns, and important considerations in evaluating stent fractures. Little is known about the stresses to which stents are exposed in patients with CHD, therefore much of the discussion that follows is necessarily observational and speculative.

Description and Categorization of Stent Fracture
Stent fractures can be categorized in several different ways. One characteristic that can vary is the degree of a stent fracture, which may depend on the specifics of the stent construction and composition. A fracture may be partial, affecting ≥1 struts, joints, or connectors, without running the entire length or circumference of the stent (Figures 4 and 5), or a fracture may be complete, with fractured elements along the entire length or circumference of the device (Figures 2, 3 and 6). The orientation of a fracture may be in the long axis (longitudinal, Figures 2 and 3), the short axis (circumferential or transverse, Figure 4), or both axes (complex or spiral, Figures 5 and 7). For any of these types or patterns of fracture, there may be more or less displacement or distortion of the stent segments (Figures 2–7). All of these features may affect the function of the device and carry other implications, such as whether fragments of the stent embolize (Figures 3 and 7).

In addition to describing the pattern or type of fracture, it is important to develop a standard vocabulary for discussing the significance of fractures. To this end, we propose that stent fractures should be classified according to 3 separate and often related elements, recognizing that these features can occur in different combinations, with clearly defined distinctions: (1) severity/extent of the fracture (eg, 1 or 2 struts, multiple struts, complete), (2) hemodynamic consequences, and (3) functional integrity. The specifics of such classification may vary according to the implant site because different types of
fracture may occur and the hemodynamic implications may be more or less obvious.

To our knowledge, the only systematic categorization of stent fractures in CHD was proposed by Nordmeyer et al.\textsuperscript{73} in an effort to understand the prevalence and significance of stent fractures after transcatheter pulmonary valve (TPV) replacement (Table 1). As with systems for classifying stent fractures in other locations,\textsuperscript{14,20} this was an important step in efforts to standardize accounting and assessment of this problem. However, it has since become clear that their classification system is suboptimal although prestenting before Melody valve implant seems to reduce the risk of stent fracture significantly.\textsuperscript{41,74,75}

The issue of stent fracture in TPV stents is described in more detail below. However, for the present discussion, it is important to note that the limitations of the classification system relate to ambiguous terminology and a lack of distinction between aspects of the fracture and its hemodynamic or other consequences. The most important limitations of the system are (1) that the distinction between type I and type II fractures is not clearly defined, and hinges on the subjective assessment of stent integrity, and (2) there is no accounting for the clinical importance of the fracture. There are cases in which a fractured stent seems quite distorted with what might seem to be loss of integrity, but with no regurgitation and only minimal obstruction; on the other hand, there are cases in which distortion related to the fracture seems relatively modest, but there is an increase in obstruction compared with prefracture evaluation. How these fit into the classification system of Nordmeyer et al.\textsuperscript{73} is debatable. When prestenting of the conduit is not used in patients undergoing Melody valve implant, type I stent fractures are relatively common but vary considerably in their appearance and extent (Figure 5).\textsuperscript{41,73} In the US Investigational Device Exemption (IDE) trial, in which investigators reported TPV fractures according to this scale,
Fracture Types Definition

Table 1. Classification of Transcatheter Pulmonary Valve Stent Fractures Proposed by Nordmeyer et al

<table>
<thead>
<tr>
<th>Fracture Types</th>
<th>Definition</th>
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<tr>
<td>I</td>
<td>Fracture of ≥1 struts without loss of stent integrity</td>
</tr>
<tr>
<td>II</td>
<td>Fracture with loss of stent integrity</td>
</tr>
<tr>
<td>III</td>
<td>Fracture associated with separation of fragments or embolization</td>
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with no core lab adjudication, type II fractures were almost always associated with recurrent obstruction, suggesting that the investigators’ interpretation of stent integrity was closely related to hemodynamic dysfunction.41

For these reasons, and because TPV stent fracture has been a prominent regulatory and clinical concern, a modified system for describing and classifying stent fractures in TPVs and other right ventricular outflow tract (RVOT) conduits based on the aforementioned principles may facilitate a clearer understanding of fractures and their clinical relevance.

Evaluation of Stent Fractures

An important consideration when evaluating and discussing stent fracture is that it is inevitably a time-related phenomenon. In situ stent fracture is attributable to fatigue, and fatigue is a cumulative and stochastic process. Thus, the duration of follow-up is a key consideration, and estimates of stent fracture should be expressed in such terms, either as time

to stent fracture or freedom from stent fracture or as a rate. This concept is important both for studies that analyze stent performance and for routine clinical evaluation. Even when stent integrity has been documented early after implant, the possibility of later fracture should be recognized and periodic radiographic evaluation may be worthwhile, particularly if there is evidence of hemodynamic changes.

Another important aspect of assessing stent failure during follow-up is the ability of current imaging modalities to detect fractures in stents with different geometric (design and dimensions) or material (radio-opacity, artifacts) composition. For example, fracture of a single strut in a large stent with a simple design and made of highly radio-opaque material is likely to be easier to detect with simple radiographic examination than a fracture in a small stent with complex design and low radio-opacity. Dynamic imaging such as fluoroscopy, or high-resolution imaging such as computed tomography, will be better for detecting subtle fractures than chest radiographs alone, but there are obvious drawbacks. Ultimately, detection requires attention to the possibility and patterns of fracture, and an awareness of the issue is the key.

Clinical Stent Fracture: Circumstances of Stent Fracture in CHD

Stent Fracture and Stent Type

Historically, almost all stents used in patients with CHD were developed and approved for other indications, including biliary, coronary artery, and peripheral artery pathology. However, this is beginning to change because more devices are being developed for specific CHD-related applications. Balloon-expandable stents are favored for most CHD interventions, and they are the focus of this review. However, self-expanding stents are used for certain procedures and will likely be a common platform for future generations of transcatheter valves.

The frequency and patterns of stent fracture in CHD applications sometimes seem to differ according to the type of stent, most likely because of differences in material, geometry, and manufacturing. In some cases, differences between stents may be more or less pronounced depending on the implant site. The types of stents with the most extensively reported history in CHD applications are various generations of Palmaz stainless steel stents, including the Palmaz 8 and 5 series, the Palmaz XL series, and the Palmaz Genesis lines (Cordis Endovascular, Miami, FL). Another stent that has been used often in patients with CHD is the NuMed Cheatham Platinum (CP) stent (NuMed Inc, Hopkinton, NY), which has undergone modifications and is used in bare and covered versions, and as the stent frame for the Melody TPV (Medtronic Inc, Minneapolis, MN). These and other stents used elsewhere in the world for treatment of CHD were summarized in a recent review by Peters et al.

There are a few clear examples of how stent fracture patterns differ between stent types. An obvious comparison is between Palmaz Genesis and older generation Palmaz iliac and renal stents, which are all similarly fabricated from laser cut stainless steel tubes. The newer Palmaz Genesis stents, which have equivalent or superior radial strength to previous generations...
of Palmaz stents on bench testing seem to present different fracture susceptibility in vivo. The design of the Genesis stent incorporates S-shaped sigma hinges that link adjacent rings of cells, imparting flexibility during delivery and limiting shortening during expansion. However, these hinges seem to constitute a relatively weak link, and fracture of Genesis stents often occurs circumferentially through planes of sigma hinges (Figures 4 and 6; Movie IV in the online-only Data Supplement), either partially or completely. These points of weakness also seem prone to overloading axial compression or extension during stent re-expansion, which can also result in fractures. On the other hand, they may facilitate easier intentional through-cell fracture when a branch is jailed by the stent. In contrast, when Palmaz iliac and renal stent fractures are observed clinically, they tend to be complete longitudinal. These differences can complicate efforts to apply the above terminology broadly because features of a fracture may be less obvious with one stent type than another.

Fracture of balloon-expandable stents in patients with CHD may be caused either by implantation or redilation of a stent (iatrogenic fracture caused by overloading), or by fatigue within the implant environment (in situ fracture). Iatrogenic fractures can be inadvertent or intentional, and have various causes and implications.

Inadvertent Iatrogenic Stent Fracture

Unintentional iatrogenic stent fractures can occur under several different circumstances. A partial overloading fracture may result accidentally from flaring of the stent, either as deliberate flaring to conform to a large or curved implant environment or as a side-effect of attempted expansion/re-expansion of a stent within a resistant lesion. In such cases, the fracture in the flared portion of the stent should not have a significant structural impact because it is unlikely to be essential to treating the target lesion.

An inadvertent partial or complete fracture may also occur during re-expansion in longitudinal stent elements designed to minimize stent shortening (such as the sigma hinges in Genesis stents), particularly if the stent is near or at its maximal diameter (Figures 4 and 7). This type of fracture can be attributable to overcompression or tension on the longitudinal connecting elements. For example, axial compression causing collapse of longitudinal struts may occur when there is resistance to expansion of a central segment of the stent and eccentric expansion with a balloon that is large relative to the resistant segment, which can create a prominent centrally directed axial vector to the expansion force (Movie V in the online-only Data Supplement). Alternatively, when a stent is re-expanded after its initial implant, axial stretching may result in overloading extension fracture of longitudinal struts, particularly if the rings of the stent are expanded to their maximum size or close to it, and if the balloon used to redilate the stent engages a portion of the stent before others. Such fractures can be subtle or extreme, may be associated with embolization or displacement of stent elements (Figures 4 and 7), and can compromise the function of the stent. Complex radial and axial fractures in this setting may result in unraveling fragmentation of the stent (Figure 7).

Intentional Iatrogenic Stent Fracture

There are circumstances in which it may be desirable to fracture a stent intentionally. One type of intentional iatrogenic partial fracture is a through-cell fracture, which may be performed either at the time of stent implant or at a subsequent catheterization. For example, if a stent is implanted across the orifice of a branch or tributary of the primary therapeutic target, it may be possible to access the jailed branch through a cell of the stent and inflate a balloon across the cell in an effort to preserve unobstructed flow to or from the jailed territory (Movie VI in the online-only Data Supplement). In such situations, adequate opening of the stent cell may result in overloading fracture of ≥1 struts, which generally should not compromise the integrity of the stent vis-à-vis the original target lesion. However, there may be unpredictable distortion of the stent adjacent to the fracture, which should be anticipated and considered in the context of the specific situation (Movie VI in the online-only Data Supplement). Although we have performed this maneuver on a number of occasions, the only published report of which we are aware concerning this technique was a recent abstract.

Another, potentially more important type of intentional iatrogenic fracture is a complete longitudinal overloading fracture of a previously implanted stent that has been expanded to its maximum achievable diameter but is too small for the clinically desirable result (Movie VII in the online-only Data Supplement). For example, if a biliary stent is implanted in a proximal pulmonary artery (PA) branch of a small child at a diameter of 6 mm, but has a maximum diameter of 10 mm, full expansion at a later date may leave the patient with residual obstruction across the maximally dilated stent. In some circumstances, it may be desirable and possible to fracture such a stent intentionally to allow further enlargement of the vessel beyond the maximum diameter of the intact stent. This form of deliberate overloading stent fracture can be achieved in some circumstances with ultra-high-pressure, ultra-non-compliant balloons, such as the Conquest or Atlas lines (Bard Peripheral Vascular, Inc, Tempe, AZ).

There are few published reports of intentional fracture of previously implanted stents in patients with CHD, but this technique has been described in the branch PAs, RVOT, systemic veins, and aorta. In our experience, deliberate overloading fracture of an entire stent or the struts of an individual cell has been a useful technique in select circumstances, but there is limited information about the likelihood and factors affecting successful fracture, or about the potential consequences.

In Situ Stent Fracture

Depending on the site of implant, in situ stent fractures attributable to fatigue are more common and clinically relevant than iatrogenic fractures. In some circumstances, the primary stresses that likely led to the fracture are obvious, but in
Clinicl Overview of Stent Fracture in CHD
In situ stent fractures have been recognized since the earliest reports of stent therapy for CHD, and have been reported in various implant locations, including the RVOT, branch PAs, aortic coarctation (COA), pulmonary veins, and sites within the heart.

Specific Clinical Considerations
RVOT Stents and Transcatheter Pulmonary Valves
The RVOT seems to be one of the highest risk implant environments for stent fracture, both of bare metal stents and stented percutaneous valves. As several groups reported, stents and stent-mounted valves used to treat obstructed RVOT conduits fracture relatively often, and many of the fractures reported in published series were characterized by conduit obstruction immediately behind the anterior chest wall, such that the stent was effectively compressed between the chest wall and the heart. Stresses on a stented RVOT have not been defined, but from a gross visual perspective, conduit stents seem to be subject to long segment or focal compression, flexion, and occasionally torsion, sometimes in combination. In the most extreme cases, as the heart beats, there is obvious compression and flexion of the conduit and stent between the cardiac mass and the anterior chest wall (Figure 3; Movies III and VII in the online-only Data Supplement). In some circumstances, the stented conduit is apposed to and subjected to cyclic compression by the aortic root, which is often dilated in these patients (Movie I in the online-only Data Supplement). Homograft conduit calcification (Figure 3) may also play a role by contributing to luminal irregularity and nonuniform compliance, potentially causing focal stent deformations and bending stresses. Most of the stents that have been observed to fracture in the RVOT are in homograft conduits, and embolization of fragments from fractured bare metal stents is not rare (Figures 3 and 7). The tendency of fragments to embolize may be related to local factors such as variable apposition to the vessel wall or lack of endothelial overgrowth of the stent, given that a homograft conduit does not typically contain a normal endothelial layer.

Bare or covered RVOT stents are similar in many respects to stent-mounted TPVs. After the early clinical experience with TPV replacement using the Melody valve, it became clear that fracture of the platinum-iridium stent frame was a relatively common finding, and was sometimes associated with recurrent and sometimes severe conduit obstruction (Figure 5; Movies I and VIII in the online-only Data Supplement). Factors associated with fracture of TPV stents are similar to those for bare RVOT stents, and many are related to the mechanical implant environment. After the extent and importance of this problem was recognized in early experience with TPV therapy, many operators adopted a practice of implanting ≥1 bare metal stents before placing the valve. Based on outcomes in the US IDE trial, this practice has a significant protective effect, even for implants in high-risk conduits. A system for classifying TPV stent fractures described by Nordmeyer et al is discussed in an earlier section of this article.

Branch PA Stents
One of the most common uses of stents in CHD is the treatment of branch PA stenosis. There is limited information on the frequency and significance of in situ or intentional stent fracture in the branch PAs, but several studies have focused on this issue. In a case–control study of patients with branch PA stents who had a follow-up catheterization ≥3 years after implant, 21% of stents were found to be fractured, with most fractures in the mediastinal PAs rather than lobar or sublobar branches. Others have reported a lower frequency, but many patients in that series had much shorter follow-up. This discrepancy highlights the importance of time in evaluating stent fracture, although differences in angioplasty and stenting practices may also play a role in the susceptibility of stents to fracture.

Although there is insufficient data from which to determine the importance of the various conditions that may contribute to the propensity of PA stents to fracture, the available information implicates several environmental factors. Branch PA stents exposed to large external cyclic compressive forces seem to be particularly susceptible to fracture. For example, stents in the mediastinal right branch PA, behind or adjacent to the ascending aorta and often anterior to the proximal descending aorta, have the highest risk of fracture (Figure 2; Movie II in the online-only Data Supplement). The presence of a reconstructed ascending aorta, a larger aortic root, or a right aortic arch, all of which may narrow the anatomic aortopulmonary window, are also associated with fracture of stents in the PA branch that passes under the aortic arch (Figure 2). The proximal left PA may be prone to flexion-related stent fracture in patients with tetralogy of Fallot, in whom there is an abnormally acute main PA-to-left PA angle with pronounced dynamic kinking at the origin of the left PA. Another population in which unique anatomic features may be important is patients who have undergone an arterial switch operation with the Lecompte maneuver, which may leave the central PAs closely related to the ascending aorta anteriorly and laterally.

Other features of the stented PA (eg, residual strain in the stented vessel, potential compliance inhomogeneity, etc) may be important as well, but there are no published data on these factors.

Coarctation of the Aorta
Stent therapy has become central to the management of COA, particularly in older children and adults. Multiple studies, both case reports and larger series, have documented fracture of stents used to treat COA, as summarized in Table 2. However, the frequency of COA stent fracture is not well characterized. In some series, stent fractures seem to be relatively common, depending on the type of stent used, but in others, the frequency is quite low. This disparity may be related to the fact that radiographic follow-up is not necessarily routine after COA stenting, and when performed it may be for a limited duration. Given that many of the reported cases of fractured COA stents were not associated with clear clinical consequences, and that stent fracture is a time-dependent phenomenon, there is probably substantial ascertainment bias.
in the identification of such fractures. Prospective studies with required radiographic follow-up, such as the ongoing COAST trial, may provide a more accurate estimate of the frequency of stent fracture after COA stenting.

Most reported cases of COA stent fracture have been Genesis or CP stents.\(^{39,86,87,89–95}\) Genesis stent fractures are typically transverse (Figure 6; Movie IV in the online-only Data Supplement), through the sigma hinges. Fracture patterns of CP stents used to treat COA vary. However, with the earlier generation CP stents that did not have gold-brazed welds, fractures tended to be through the zig-to-zig welds transversely.\(^{86,87,92,93}\)

The mechanism of stent fracture in COA is unknown, but may vary from case to case or be due to a combination of factors. Most cases of COA, whether native or recurrent after surgery, occur at the isthmus, the junction between the aortic arch and the descending aorta. This location in the aorta is a natural point of flexion/bending because it marks the transition from the mobile arch to the fixed descending aorta.\(^{96}\) Thus, during the cardiac cycle, COA stents that create a rigid framework spanning the natural fulcrum of the isthmus may be exposed to cyclic bending stresses (Movie IV in the online-only Data Supplement). Stents in other segments of the arch, or in unusual circumstances such as COA of a circumflex arch (which is characterized by a retroesophageal course and often an acute arch angle), may be subject to dynamic motion and stress as well (Movie IV in the online-only Data Supplement). COA stents may also be exposed to high residual hoop stress at the COA site, combined with regional stent weakening attributable to shear stress at the point of compliance mismatch (ie, at the waist) during deployment (Figure 6).

**Intracardiac Stents**

Although most stents implanted for treatment of CHD are intravascular, a small number are deployed within the heart or in muscular portions of the pulmonary or systemic outflow tract.\(^{32,45–49}\) Stents used to enlarge interventricular communications or treat subaortic stenosis are prone to fracture,\(^{42}\) but fracture does not seem to be a significant problem affecting stents used to palliate native pulmonary outflow tract obstruction\(^{99}\) or to open the atrial septum.\(^{45}\) As TPV devices designed for the large RVOT become a clinical reality,\(^{53,60}\) it is possible that stents anchored in myocardium will become more common, and fracture dynamics may be particularly important in that area.

### Clinical Implications of Stent Fracture in CHD

By definition, the structural integrity of a stent is compromised once the fatigue point is reached. Clinically, however, we must consider whether the compromised integrity leads to impaired efficacy, that is, whether the fractured stent is able to serve its purpose of stenting the vessel open and is unobstructed. Fracture of implanted cardiovascular devices can result in failure of the device, sometimes with catastrophic\(^{97}\) or otherwise clinically significant\(^{5,5,5}\) consequences. However, device fracture does not necessarily result in failure or dysfunction, as illustrated by minor stent fractures in TPV devices\(^{11}\) and most fractures of septal occlusion devices.\(^{1–3}\) Thus, in considering the performance of implanted cardiovascular devices, it is important to differentiate between device fracture and device failure.

The manifestations of stent fracture may vary considerably. The effect of stent fracture and compression on lumen size and hemodynamic obstruction is a function both of the relief of vessel stenosis from angioplasty and stenting in the first place, and the cross-sectional area of the lumen. When exposed to high or complex multiaxial compressive forces, a fractured stent may collapse almost completely or fracture...
along multiple planes (Figure 2). In a series, severe collapse was observed in 21% of fractured PA stents and, in 32% of cases, there was severe obstruction of the stented segment (Figure 2), but most of the stent fractures identified were associated with modest collapse and mild obstruction.99 Similarly, for RVOT and TPV stents, more extensive fractures typically result in more severe obstruction, whereas minor fractures can be hemodynamically inconsequential.41 Among reported cases of COA stent fracture, some are clinically silent, whereas others are associated with recurrent obstruction, migration or embolization of stent fragments, and aneurysm formation (Table 2).

Other documented complications of stent fracture include aneurysm, pseudoaneurysm, vessel perforation, and embolization resulting in remote adverse effects. In reports of stent fracture in CHD, complications related to the fracture have been uncommon, and typically consist of failure of function and recurrent obstruction. In such cases, effective management is often achieved by coaxial implant of ≥2 additional stents, or additional stents and a valve when there is recurrent obstruction related to fracture of a stent-mounted TPV device.41

Conclusions

Stents have been used for >2 decades in patients with CHD, and they are now an integral tool in the management of many different conditions. Although stent fracture is clearly a real phenomenon, in most locations it seems to be rare, a notable exception being the RVOT. As with other implantable devices, fracture of a stent is not tantamount to failure, a critical distinction when considering the importance to stent fracture. At present, there are few, if any, conditions in which fracture is sufficiently widespread or serious to be a limiting factor in the appropriateness of stent-based therapy for CHD.

As stent technology evolves and with increasing interest in bioabsorbable stents and stents as drug delivery mechanisms even in CHD,98,99 there will be changes inevitably in the frequency, patterns, and even implications of stent fracture in congenital applications. Although stents are well established in the armamentarium of pediatric and congenital interventional cardiologists, their history in this field is still young relative to the life expectancy of most of these patients. Thus, we must take a long-term view when considering the potential implications of stents in their various applications. With the ongoing development of transcatheter valves, and with the prospect of more widespread incorporation of stent-based medical devices in CHD, the complexity and stakes involved may continue to grow.

To facilitate a more consistent and thorough understanding of the clinical features and importance of stent fracture in CHD, it will be important to consider this outcome in clinical trials involving stents or stent-mounted valves, registries, and other clinical studies. To this end, we have proposed a framework that we hope will be useful for standardizing evaluation and analysis of this issue. In addition to a more consistent and rigorous approach to the assessment of clinical stent fractures, the ultimate aim of developing more resilient stents for applications with a high risk of stent fracture will require a deeper understanding of the in situ forces to which a stent is exposed.

This is a complex task, but more sophisticated clinical imaging technologies and computational modeling, coupled with an improved understanding of the behavior of stents in vitro, are beginning to advance us in that direction.

Disclosures

Dr McElhinney serves as a proctor and consultant for Medtronic, Inc.

References


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Supplemental Material

Video Legends

Video 1. Three views of a fractured Melody TPV in an RVOT conduit, with pulmonary or aortic root angiography. The caudal view demonstrates that the fractured TPV is compressed and distorted from a rightward posterior direction, where it is directly apposed to the dilated aortic root (after a Ross procedure).

Video 2. An aortogram in the reconstructed aorta demonstrated dynamic movement and compression of a fractured Palmaz stent in the proximal right PA where it passes between the ascending and descending aortic segments.

Video 3. This four-dimensional computed tomography image of the heart in a patient with repaired tetralogy of Fallot demonstrates the dynamic geometry of the RVOT and main PA across the cardiac cycle.

Video 4. A) This fluoroscopic image demonstrates a transverse fracture of a Genesis stent used to treat COA. The mobility of the aorta during the cardiac cycle and potential for subtle cyclic bending stresses can be appreciated. B) This angiogram demonstrates a stent placed many years earlier in the transverse segment of an obstructed circumflex right aortic arch. There is prominent dynamic compression and a transverse fracture. C) This anteroposterior angiogram in the same patient demonstrates the retrotracheal course of the arch and the fracture right at the point where the stent passes behind the airway. This projection reveals almost no movement of the stent, in contrast to the lateral image, due to the fact that the flexion of the stent is in the anteroposterior direction.

Video 5. A Genesis stent in the SVC was redilated with a relatively large balloon, which expanded peripherally beyond the ends of the stent, resulting in axial compression and collapse/fracture of the longitudinal sigma hinges.

Video 6. A) In this previously placed arch stent that was jailing the left carotid artery, a cell was crossed into the carotid and a balloon inflated to enlarge the opening of the jailed vessel. The sudden pop towards the end of the clip is the point at which the strut fractured. Image courtesy of Dr. Michael Argilla. B) An ultra-non-compliant balloon was used to dilate through the cell of a previously placed right PA Genesis stent that was jailing the left PA. The
connecting segments of the stent can be seen to give as the central segment of the stent collapses and is displaced inferiorly.

Video 7. This left PA stent was redilated with an ultra-non-compliant balloon and deliberately fractured, allowing the artery to be enlarged beyond the maximal diameter of the stent.

Video 8. Anteroposterior and lateral angiograms demonstrating complete longitudinal/complex fracture of a Melody valve, with excursion of the posterior segment into the lumen of the conduit during systole.