Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022) 100035

Contents lists available at ScienceDirect

Journal of the Society for Cardiovascular Angiography & Interventions

journal homepage: www.jscai.org

Original Research

# Stretched to the Limit: Comparing Polytetrafluoroethylene-Covered Endovascular Stents Through Serial Dilations

Ernesto Mejia, MD, Emily C. Kish, RN, Martin L. Bocks, MD, John S. Lozier, MD *

*Division of Pediatric Cardiology, University Hospitals, Rainbow Babies and Children's Hospital, Case Western Reserve University, Cleveland, Ohio*

A B S T R A C T

*Background:* Covered stents are used during congenital cardiac interventions to treat stenotic or injured vessels or to exclude unwanted vascular connections. The ability to postdilate a stented vessel to keep pace with somatic growth is critical in children. In this study, we aimed to compare *in vitro* performance of 2 brands of covered stents during serial dilations to demonstrate the threshold for stent fracture and polytetrafluoroethylene tear and define recoil and foreshortening characteristics.

*Methods:* iCast and VBX stents of various sizes were measured before and after expansion and through serial dilations. Dilations were performed at 2-mm increments until stent fracture, polytetrafluoroethylene tear, and "napkin-ring" formation, to a maximum of 22-mm diameter.

*Results:* The 5- and 6-mm VBX stents fractured during dilation with 10-mm balloon; the 7-mm VBX stents fractured on the 14-mm balloon; and the largest VBX stents fractured on the 20- or 22-mm balloons. iCast stents experienced partial fracture during dilation with the 14- or 16-mm balloons and complete fracture past dilation with 16-mm balloons. VBX stents recoiled less at nominal diameters. Both stents had similar foreshortening at nominal diameters, although VBX stents had more significant foreshortening with postdilation.

*Conclusions:* All iCast stents experienced partial fracture with dilation between 14- and 16-mm diameter and had unpredictable fracturing patterns. VBX stents showed a more predictable fracture pattern and had less recoil with nominal inflation but more foreshortening with postdilation. These findings may add clinical benefit and empower physicians to make optimal decisions regarding future planning of interventions in children with congenital heart disease.

## Introduction

Bare-metal endovascular stents have been used to treat patients with congenital heart disease since the 1980s.[1] More recently, covered stents have become increasingly used to treat high-grade stenoses or to repair or exclude areas of injured vasculature following angioplasty or bare-metal stenting in the congenital population. A major limitation of implanting any type of stent in a baby or small child is that the stent must be redilated at regular intervals to keep pace with somatic growth and avoid iatrogenic vascular stenosis. Many stents that have a low enough profile to be implanted in small pediatric patients are not labeled to be postdilated to significantly larger sizes. For these stents, the 2 options for dealing with growth restriction are to refer for surgical transection with patch arterioplasty or to intentionally fracture the stent using a larger noncompliant balloon ("unzipping"). The downside to the first option is that it exposes the patient to the morbidity of surgery. The downside to the second approach is that the stent may not fracture longitudinally but instead foreshorten severely into a "napkin ring" configuration, which may preclude further dilation, and can lead to vessel injury or exposure of the original lesion. Furthermore, even if a stent is successfully unzipped longitudinally, it typically only fractures along a single side, which may not allow for unfettered circumferential growth of the stented vessel in the future. It is therefore of paramount importance to understand the postdilation characteristics of any stent that is used off-label in small children when the intention is to further dilate the stent.

Several studies have reported the postdilation characteristics of low-profile bare-metal stents that are used in the congenital heart population.[2-6] Other studies have looked at the potential for unzipping of bare-metal stents to allow for restenting.[7] Blais et al reported the serial postdilation characteristics of both low-profile covered stents currently commercially available in the U.S.—The Viabahn VBX stent (W.L. Gore & Associates) and the Atrium iCast stent (Atrium Medical). However, this study was limited by not including smaller diameter iCast stents or the large VBX "L" stents and postdilation only to 20-mm diameter.[5] Finally, the use of covered stents in children requires an understanding of the

*Abbreviations:* ePTFE, expanded polytetrafluoroethylene; PTFE, polytetrafluoroethylene.

*Keywords:* Covered stents; congenital heart disease; pediatric interventional cardiology; stent fracture.

* Corresponding author.
*E-mail address:* john.lozier@uhhospitals.org (J.S. Lozier).

https://doi.org/10.1016/j.jscai.2022.100035
Received 9 November 2021; Received in revised form 18 February 2022; Accepted 22 February 2022

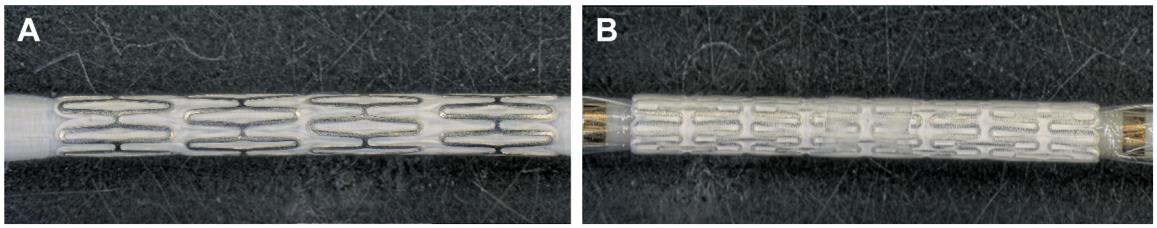



**Fig. 1.** Unexpanded stents. (**A**) Viabahn VBX stents are made of independent rows of diamond-shaped zigs connected by a single short strut. Each row of zigs adds approximately 5 mm to the length of the stent. Gore's expanded polytetrafluoroethylene (ePTFE) covering is fused to the inside of the stent only. (**B**) Atrium iCast stents are balloon-expandable covered stents consisting of a 316L stainless-steel hybrid cell frame design, with a consistent number of zigs per ring for each nominal size. The frame is encapsulated by PTFE both on the internal and external surface of the frame. PTFE, polytetrafluoroethylene.

behavior of the polytetrafluoroethylene (PTFE) covering during post-dilation, as a PTFE tear may lead to the loss of therapeutic efficacy.

Gore's VBX stents are made of independent rows of diamond-shaped zigs connected by a single short strut (Fig 1A). Each row of zigs adds approximately 5 mm to the length of the stent. The circumference of the 5-mm and 6-mm nominal VBX stents is comprised of 6 diamond zigs, the 7-mm and 8-mm VBX stents have 8 diamond zigs circumferentially, and the large 8-mm (8L) VBX stents have 12 diamond zigs circumferentially. Gore's expanded PTFE (ePTFE) covering is fused to the inside of the stent only. In comparison, iCast stents are balloon-expandable covered stents consisting of a 316L stainless-steel hybrid cell design. Each row has a consistent number of zigs per row for all stent sizes, with cross-links between each row of struts. Each iCast stent is manufactured the same, with the exception of length; thus, the nominal diameter is dependent only on the size of the premounted balloon. Furthermore, the iCast frame is encapsulated by PTFE both on the internal and external surface of the stent (Fig 1B).

Our study compares the *in vitro* performance characteristics of iCast and VBX covered stents when subjected to serial balloon postdilation, with focus on stent fracture, napkin ring deformation, and tearing of the PTFE covering.

## Methods

A bench testing protocol and environment were developed and strictly followed to limit procedural and observational variability or measurement bias. A single operator performed all of the serial inflations, and a different investigator performed all measurements. Seven iCast stents and 8 VBX stents of various sizes were used (Table 1). The unexpanded stents were imaged and measured using a Keyence VHX-F series digital microscope and its proprietary software (Keyence Corporation of America). The stents were expanded with their premounted balloons to nominal pressure. The stent diameter and length were measured with the balloon inflated and deflated. Recoil was calculated as the percent change in stent diameter after balloon deflation. Subsequent dilations were performed using noncompliant Conquest or Atlas balloons (Bard Peripheral Vascular, Inc) at 2-mm diameter intervals up to a maximum of 22 mm, with additional measurements made after each expansion. Each balloon dilation was performed to the balloon's rated burst pressure. Balloon diameter and inflation pressure were recorded at times of stent fracture, PTFE tear, and "napkin ring" formation. Balloon dilations were stopped once the stent was completely fractured and the covering completely torn, or at a maximum of 22-mm diameter.

**Table 1.** Nominal stent sizes in mm (diameter × length).

| Viabahn VBX stents | Atrium iCast stents |
|---|---|
| 5 × 15 | 5 × 16 |
| 5 × 19 | 5 × 22 |
| 6 × 29 | 6 × 22 |
| 7 × 15 | 6 × 38 |
| 7 × 19 | 7 × 22 |
| 7 × 29 | 7 × 38 |
| 8L × 29 | 8 × 38 |
| 8L × 39 | - |

Statistical analysis for comparing stent recoil and foreshortening was performed using a 2-tailed, 2-sample, equal-variance *t* test, with significance defined as $P \leq .05$.

## Results

A total of 15 stents were dilated in the protocol, with all achieving complete stent fracture and complete PTFE tear (Fig. 2). Results of each stent's dilation are shown in the Central Illustration.

### *Stent fracture*

The VBX stents fractured in a manner predicted by their nominal diameter. The 5- and 6-mm-diameter VBX stents fractured completely, or unzipped, during dilation with the 10-mm balloon (100% and 67% oversized, respectively). The 7-mm VBX stents fractured completely in 2 cases and partially in 1 case during dilation with the 14-mm balloon (100% oversized). The 8L VBX stents fractured completely with either the 20-mm (8 × 29L stent) or 22-mm (8 × 39L stent) balloons (~180% oversized). In some instances, napkin ring formation preceded fracture in VBX stents, even during the same balloon inflation. The independent rows of diamond-shaped struts moved freely toward each other during napkin ring formation prior to eventual strut fracture (Video 1). In all cases, fracture of the VBX stents occurred at the single strut connecting the diamonds. In comparison, all of the iCast stents fractured either partially or completely during dilation with the 14- or 16-mm balloons (range: 75%-220% oversizing). Fracture occurred at unpredictable locations on the stent frame; in some cases, the combination of fractures resulted in the remaining intact struts forming a large-diameter oval-shaped ring that resisted complete fracture until 20- or 22-mm-diameter dilation (Fig. 3).

### *PTFE tear*

The ePTFE of the VBX stents tore only during or after stent fracture. All of the iCast stents experienced partial or complete PTFE tear prior to stent fracture, most often with the 10- and 12-mm dilations (Central Illustration).

### *Recoil*

When expanded by their premounted balloons, VBX stents recoiled an average of 3.4% ± 0.7%, while iCast stents recoiled an average of 8.5% ± 2.3% (*P*-value < .01). Both stents had similar recoil with post-dilation: the iCast stents recoiled by an average of 5.8% ± 2.2%, whereas the VBX stents recoiled by an average of 5.5% ± 1.3% (*P*-value .75).

### *Foreshortening*

The VBX and iCast stents experienced similar foreshortening with nominal balloon dilation at equivalent diameters, with an average of 4.2% ± 2.1% on the VBX stents and 5.9% ± 3.2% in the iCast stents (*P*-

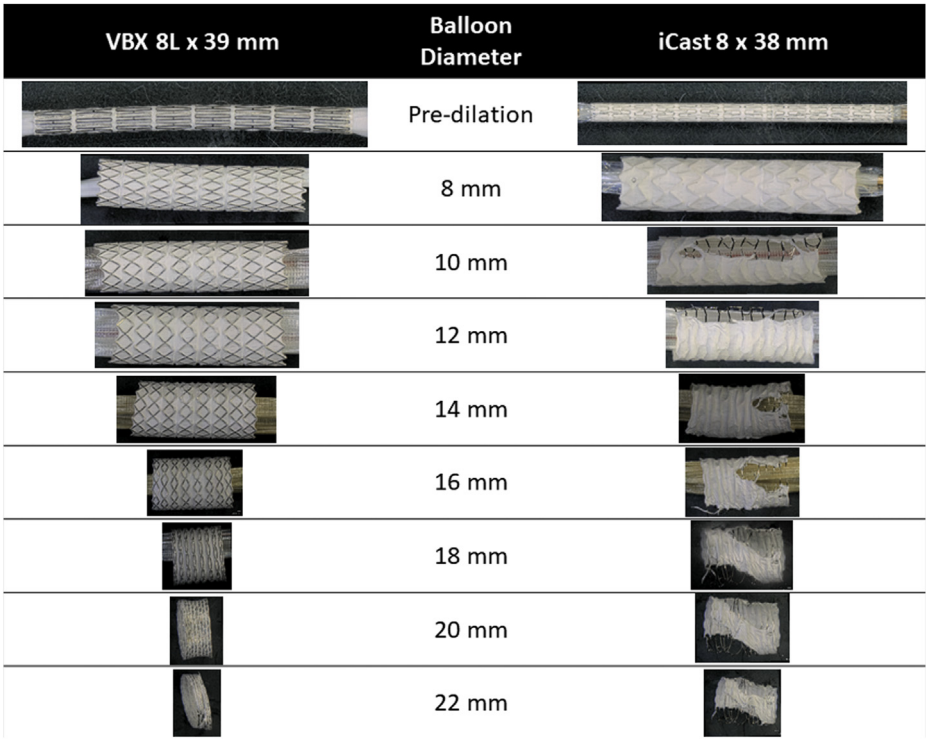
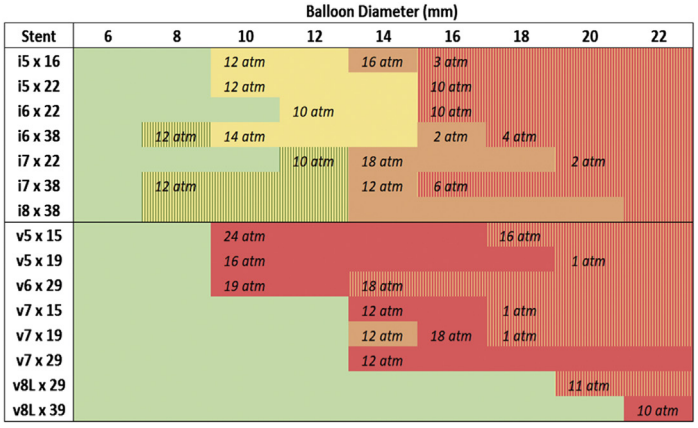



**Fig. 2.** Serial dilations of VBX and iCast stents. Comparison of serial dilations of the largest tested stents (VBX 8L × 39 mm vs iCast 8 × 38 mm). The VBX "L" stent remained structurally intact until fracture at 22-mm dilation; however, significant foreshortening occurred. The iCast stent experienced PTFE tear at 10-mm dilation, with strut fracturing starting at 14-mm dilation. PTFE, polytetrafluoroethylene.




**Central Illustration.** Color-coded results of serial dilation of iCast (i) and VBX stents (v). All of the iCast stents fractured either partially or completely during dilation with the 14- or 16-mm balloons. PTFE tore on all iCast stents prior to stent fracture. In comparison, the 5-mm and 6-mm-diameter VBX stents fractured completely during dilation with the 10-mm balloon; the 7-mm VBX stents fractured completely in 2 cases, and partially in 1 case, during dilation with the 14-mm balloon; and the VBX 8L stents fractured completely with either the 20-mm (8L × 29) or 22-mm (8L × 39) balloons. VBX ePTFE covering did not tear before stent fracture. ePTFE, expanded polytetrafluoroethylene; PTFE, polytetrafluoroethylene.

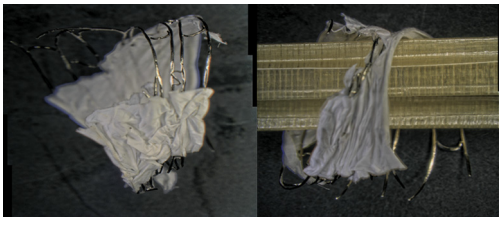


**Fig. 3.** iCast stent fracture pattern. Unpredictable fracture pattern of iCast stents (left) with occasional development of oval-shaped configuration prior to complete fracture (right).

value .28). However, VBX stents experienced significantly more foreshortening during serial dilations, including eventual "napkin ring" formation. When comparing final stent length at stent fracture to original stent length, VBX stents foreshortened an average of 38% ± 7.6% (Fig. 4A). The iCast stents foreshortened in a more consistent and gradual manner without achieving "napkin ring" formation, with an overall average foreshortening of 24.3% ± 6.2% (*P*-value < .01) (Fig. 4B).

## Discussion

In this study, we report the *in vitro* characteristics of 2 commercially available covered stents expanded with serial balloon dilation. VBX

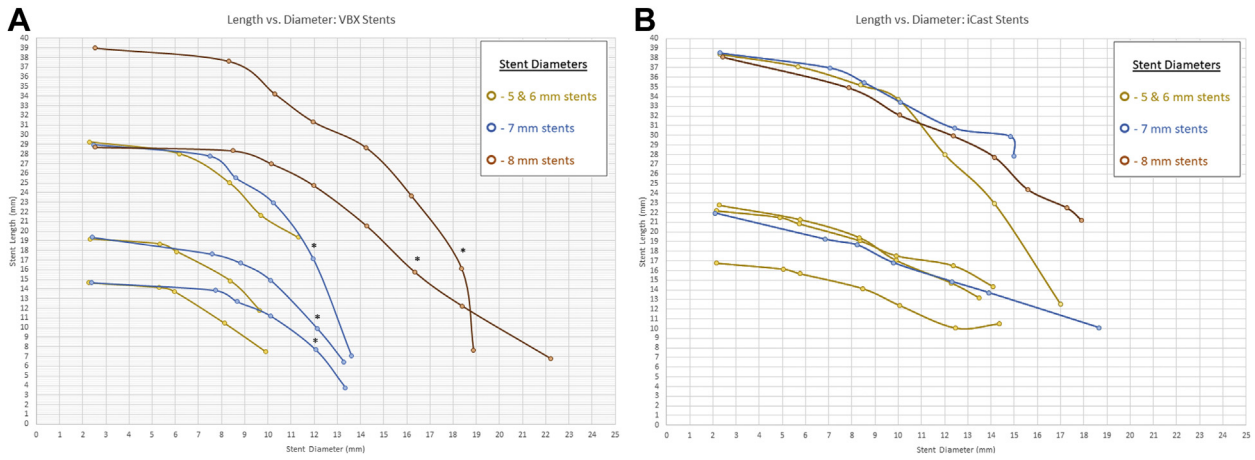



**Fig. 4.** Foreshortening during serial dilation. (**A**) Foreshortening of VBX stents. Length versus diameter through serial postdilation demonstrates significant foreshortening when VBX stents are dilated beyond 10-mm diameter in most cases. Asterisks denote "napkin ring" formation. (**B**) Foreshortening of iCast stents. Length versus diameter through serial postdilation demonstrates gradual foreshortening of iCast stents through all diameters, with no "napkin ring" formation. All stents were at least partially fractured at 14-mm diameter.

stents fractured longitudinally at diameters predicted by their nominal size. Although significant foreshortening was observed, including "napkin ring" formation, all of the VBX stents could be successfully unzipped. The regular conformation of the VBX stents, with the obvious weak spot of the single strut connecting the diamond-shaped cells, resulted in stent fracture in a predictable pattern. Furthermore, all ePTFE coverings of VBX stents tore during or after stent fracture, suggesting that in clinical use operators could reasonably rely on the ePTFE covering to remain competent up to the point of stent fracture.

Atrium iCast stents all fractured with either 14- or 16-mm balloon dilations and their PTFE began to tear with balloons as small as 10 mm. These findings are consistent with and add to previous reports that showed PTFE membrane tear of the iCast stents starting at 10- and 12-mm diameter.[2,5] Taken together, these data suggest the possibility that the PTFE on iCast stents may tear prior to stent fracture *in vivo*. Operators should be aware of the potential loss of PTFE integrity when postdilating, but not fracturing iCast stents.

The iCast stents have a hybrid cell frame design and fractured in an unpredictable pattern. In some cases, fractured struts jutted out from the stent, as seen in Figure 3. This irregular fracturing has the potential for unwanted vessel injury or perforation, long-term scarring, and balloon puncture during postdilation. Fracture predictability is likely to be favored by operators when implanting stents in children and planning for subsequent serial dilation.[3,8]

On the other hand, it is important to recognize that the napkin ring formation seen in the VBX stents is not without potential drawbacks. Although we were able fracture all VBX stents after napkin ring formation, it might not be possible *in vivo*. Further, napkin ring formation may lead to injury of the endothelium and vessel media or loss of therapeutic efficacy of the original stenosis.

Our study supports previously published data by Blais et al, which showed that iCast stents fracture when serially dilated past 14 mm, and recoil average was 3%-6%. We also confirm the published data that smaller VBX stents tolerate dilations an average of 4.2 mm above nominal diameter prior to membrane or strut fracture, with foreshortening of 40%-50%.[5] All 7-mm-diameter VBX stents tested in our study maintained structural integrity with dilations to 12 mm. We are the first to report bench testing of the VBX 8L stents: the 8L × 29 stent was postdilated to 18 mm and the 8L × 39 stent was dilated to 20 mm prior to ePTFE or strut fracture (Central Illustration).

Our study is unique in that we compare the performance of 2 small- to medium-sized covered stents, with a focus on serial dilation to diameters larger than previously published. We also report higher recoil of the VBX stents of 5.5% through serial dilations than the reported <2.5% by Blais et al.[5] Finally, Blais et al measured the stents using digital calipers, whereas we performed noncontact measurements using Keyence's proprietary software, as is recommended for *in vitro* analysis of endovascular stents.[9]

Sathanandam et al previously demonstrated the successful fracture of small bare-metal stents by serial dilation in an *in vitro* model, but only up to 6-mm diameter.[10] Crystal et al. reported complete linear fracture in 53.1% of all *in vitro* tested stents and only 60% of tested iCast stents.[2] Here we were able to fracture 100% of iCast and VBX stents. Stent fracture occurred in the smallest VBX stents at 10-mm diameter, and in the largest VBX stents at 22-mm diameter, which has not been previously reported. These results support the use of the VBX 8L stents in large central vessels, including the aorta and pulmonary arteries in growing children. In bare-metal stent dilation, serial incremental dilation has been associated with less foreshortening, uniform dilation to avoid napkin ring formation, and predictable fracture patterns.[2] Our data support this approach with both the VBX and iCast covered stents.

The Pivotal Trial showed VBX stent graft deployment achieved 100% technical success with 97% acute procedural success in adult peripheral vessels.[4] Boe et al reported the successful implantation of iCast stents in congenital heart disease.[6] As these covered stents become more widely used off-label in children, our *in vitro* data may be more relevant and better extrapolated to clinical practice, especially when treating severe stenosis or expanding previously implanted stents to larger diameters beyond 20 mm. Stent makers continue to develop stents that can be dilated beyond nominal sizes while maintaining radial strength, resulting in the ability to serially dilate stents to larger diameters, followed by stent fracture and restenting.[10]

## Limitations

This study is an *in vitro* study, and as previous authors have noted, caution is needed in interpreting the data with regards to *in vivo* performance of the stents.[2] The radial forces a living human vessel exerts on the stent should be considered when planning stent implantation, as this can significantly alter the performance compared to *in vitro* testing. Furthermore, *in vivo* napkin ring formation may not be as significant as *in vitro* models may predict.

The iCast stents used in this study were past their expiration dates (between 2-9 years postexpiration); we find it unlikely that this altered performance of the stainless-steel struts; however, the PTFE performance may have been affected, although previous reports have also shown PTFE tear prior to stent fracture in iCast stents.[2,5] All VBX stents were tested before their expiration date.

## Conclusions

Compared to Atrium iCast stents, Gore Viabhan VBX stents fractured at predictable diameters based on their nominal size, with a more linear pattern of fracture. The ePTFE of VBX stents tore during or after stent fracture in all cases, while PTFE of iCast stents tore prior to stent fracture. The iCast stents experienced complete or partial fracture at 14- or 16-mm diameter, irrespective of original size, and fractured in unpredictable locations. This may be a disadvantageous feature of the iCast stents. VBX stents had less recoil at nominal diameters and more foreshortening during serial dilation. These *in vitro* performance characteristics should be considered when selecting covered stents in small children with congenital heart defects.

## Declaration of competing interests

The VBX stents were provided by the W. L. Gore & Associates, Inc. through a research agreement. The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Acknowledgments

The authors wish to thank Richard Tomazin at The Swagelok Center for Surface Analysis of Materials at Case Western Reserve University for his help on this project and the use of the Keyence digital microscope.

## Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Supplementary material

To access the supplementary material accompanying this article, visit the online version of the Journal of the Society for Cardiovascular Angiography & Interventions at https://doi.org/10.1016/j.jscai.2022.100035.

## References

1. Mullins CE, O'Laughlin MP, Vick 3rd GW, et al. Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins. *Circulation*. 1988;77(1):188–199.
2. Crystal MA, Morgan GJ, Danon S, et al. Serial versus direct dilation of small diameter stents results in a more predictable and complete intentional transcatheter stent fracture: a PICES bench testing study. *Pediatr Cardiol*. 2018;39(1):120–128.
3. Ing FF, Grifka RG, Nihill MR, Mullins CE. Repeat dilation of intravascular stents in congenital heart defects. *Circulation*. 1995;92(4):893–897.
4. Bismuth J, Gray B, Holden A, Metzger C, Panneton J. Pivotal study of a next-generation balloon-expandable stent-graft for treatment of iliac occlusive disease. *J Endovasc Ther*. 2017;24(5):629–637.
5. Blais B, Carr K, Sinha SP, Salem MM, Levi DS. Mechanical properties of low-diameter balloon expandable covered stents. *Catheter Cardiovasc Interv*. 2021;97(3):451–458.
6. Boe B, Zampi J, Schumacher K, Yu S, Armstrong A. The use and outcomes of small, medium and large premounted stents in pediatric and congenital heart disease. *Pediatr Cardiol*. 2016;37(8):1525–1533.
7. Morray BH, McElhinney DB, Marshall AC, Porras D. Intentional fracture of maximally dilated balloon-expandable pulmonary artery stents using ultra-high pressure balloon angioplasty: a preliminary analysis. *Circ Cardiovasc Interv*. 2016;9(4), e003281.
8. Morrow WR, Palmaz JC, Tio FO, Ehler WJ, VanDellen AF, Mullins CE. Re-expansion of balloon-expandable stents after growth. *J Am Coll Cardiol*. 1993;22(7):2007–2013.
9. *ASTM F2081-06(2017). Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents*. ASTM International; 2017.
10. Sathanandam SK, Haddad L, Subramanian S, Wright D, Philip R, Waller BR. Unzipping of small diameter stents: an in vitro study. *Catheter Cardiovasc Interv*. 2015;85:249–258.