Bench Testing of Mechanical Properties of Low-Diameter Balloon Expandable Covered Stents Currently Available for Use in Pediatric Patients

Benjamin Blais[1], Karen Carr[1], Sanjay Sinha[1,2], Daniel Levi[1]

[1]UCLA Mattel Children's Hospital, Los Angeles, USA. [2]CHOC Children's Hospital, Orange, USA 65

BACKGROUND

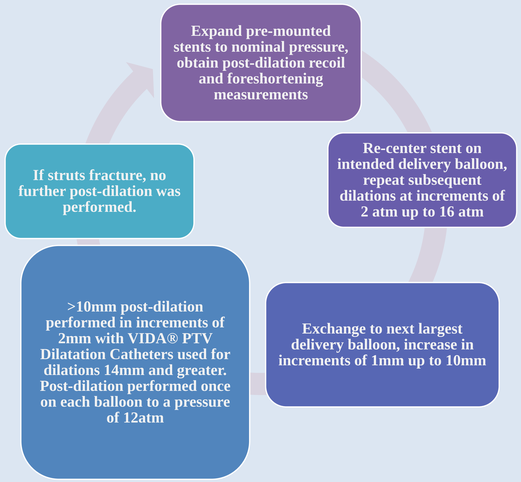
Covered stents have been a useful addition to the armamentarium of interventional cardiologists. In congenital heart disease (CHD), covered stents including the Atrium iCast, Gore VBX, and Lifestream stents (LS) can treat ruptures, dissections, and aneurysms in small vessels. For clinical decision making in growing patients, it is important to understand the mechanical characteristics of these stents including their length, diameter, foreshortening, recoil, ease of intentional fracture and limits of fabric sheath and stent strut integrity at various levels of post-nominal dilation. This study provides bench testing and comparisons of the above commonly used low-diameter and commercially available covered stents.

OBJECTIVES / AIMS

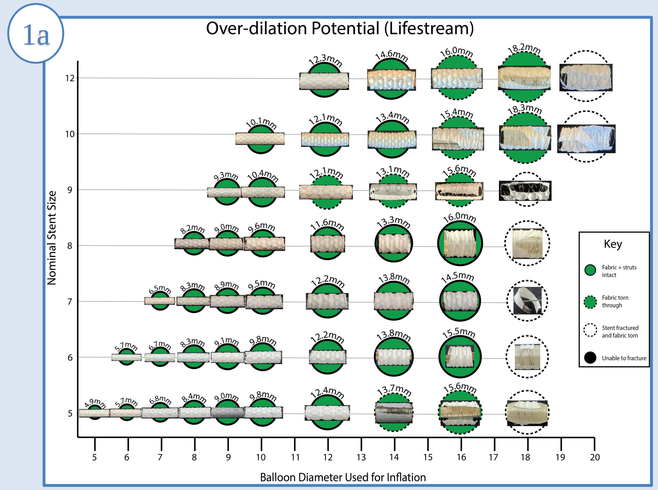
To provide in-vitro bench testing of a variety of covered stents at various levels of balloon expansion, including over-dilation with high pressure non-compliant balloons.

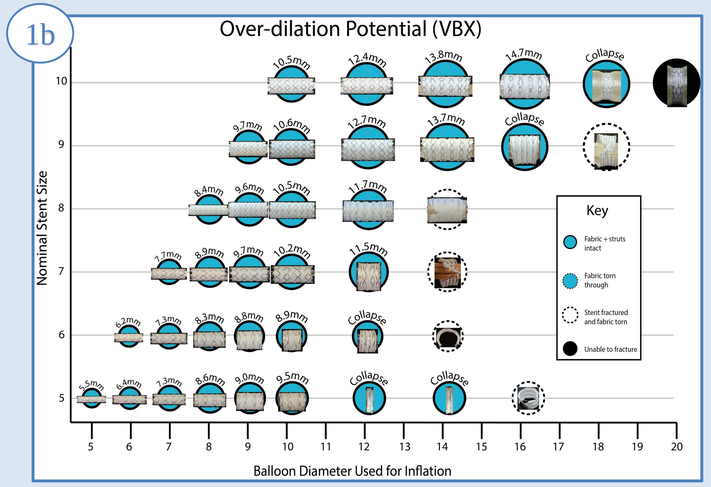
METHODS

Testing protocols were derived from FDA standards outlined in an open-access format through ASTM Compass [4]. Serial dilations of one of each available 5-12mm diamter Gore Viabahn VBX™ (Gore Medical, Flagstaff, AZ), Atrium iCast™ (Atrium Medical, Merrimack, NH) and LIFESTREAM™ (LS) stents (BD Bard, Tempe, AZ) were performed in 1-2mm increments, up to 20mm. Post-dilation measurements were taken to calculate foreshortening, recoil, and stent/cover integrity were photographically documented (see supplemental images). Additional data characterizing fabric-coating tears and stent fracture were also collected.



RESULTS





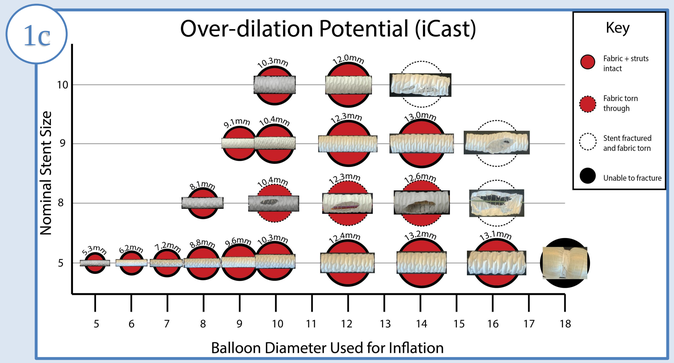


Figure 1 (a,b,c): Over-dilation potential of Lifestream (1a), VBX (1b), and iCast (1c) stents. Each row depicts photographs of the same single stent (nominal diameter 5 to 12mm) after incremental over-dilations from the nominal delivery balloon up to the 20mm high-pressure balloon. The circles associated with the stent are a proportional representation of the over-dilation stent diameter achieved after inflation with that balloon (diameter labeled above the circle). See key for more information.

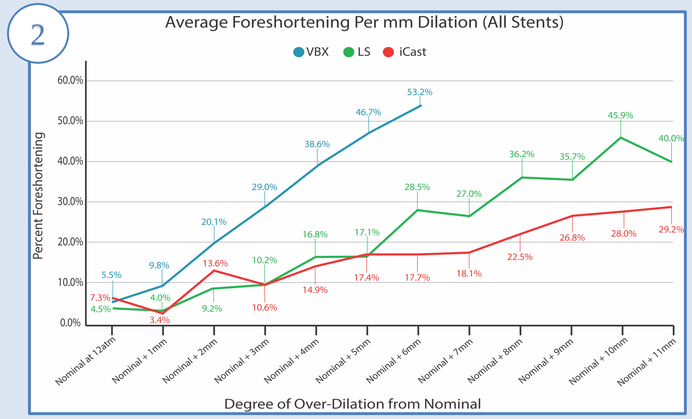


Figure 2: Foreshortening of each stent type per millimeter of over-dilation above nominal, beginning with the nominal balloon inflation at 12 atm as a starting reference point. The percent foreshortening shown is the mean across all stent sizes.

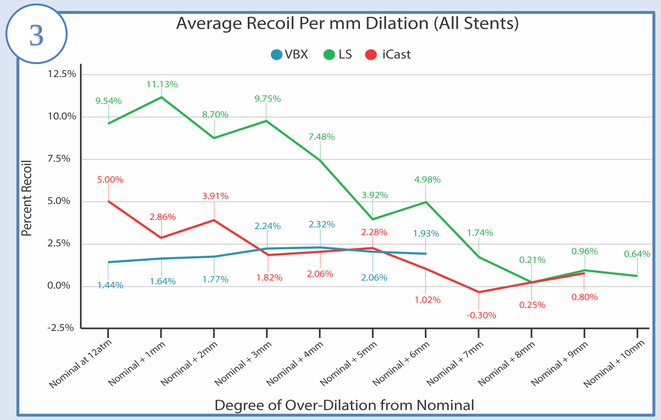


Figure 3: Recoil of each stent type per millimeter of over-dilation above nominal, also averaged across all stent sizes.

DISCUSSION

Interventionalists treating neonates and young children have low diameter covered stent options approved for use in adult patients with peripheral vessel stenoses. Data on the over-dilation potential of these stents and their coverings do not exist but are critical knowledge for their use in growing pediatric patients.

LS stents utilize an open cell design with variable "zigs" per row depending on nominal size. The 5-8mm stents have an identical number of zigs per row. LS stents >8mm are manufactured from 30% larger tubes (with greater thickness). We found that the 5-8mm stents performed similarly on over-dilation reaching 14.5 to 16mm before fracturing on the 18mm balloon, whereas the 10 to 12mm stents reached >18mm diameter before fracturing on the 20mm balloon. All LS stents tested could be intentionally fractured. The ePTFE of LS stents typically tore after 9mm of dilation above nominal for the 5-8mm stents, and after 5mm above nominal for the 9 to 12mm stents. Foreshortening was moderate for LS stents, with the smaller diameter-for-length stents stents foreshortening more overall on maximal dilation (range 30-45%). Average recoil was considerable at 5-10% on over-dilation up to 6mm above nominal.

ICast stents utilize an analogous open-cell stent design but have a consistent number of "zigs" per ring for each nominal size. Thus, the performance on over-dilation of the iCast stents of lower nominal sizes (5 and 8mm) was comparatively superior to the more limited dilation potential of the larger sizes (9 and 10mm). Regardless of the nominal diameter, the 5, 8, 9 and 10mm stents all reached about 12-13mm of overdilation before fracture or collapse. This design is specifically intended to have low foreshortening and uniform expansion. iCast stents overall had the least foreshortening by a maximal range of 19-29%. The 5mm iCast stent performed similarly to the LS 5mm stent, expanding to 13.1mm without covering tear or fracture with under 30% foreshortening but then collapsed into a ring and could not be fractured.

ICast stents are treated with complete encapsulation of the struts in the PTFE coating. The larger iCast stents lost covering integrity with the least over-dilation at 2-7mm above nominal. ICast stents had an average recoil of 3-6%, lower than that of the LS stents, but slightly above that of the VBX stents (1-2%). iCast stents therefore have the apparent advantage of minimal foreshortening and low recoil, with relatively uniform over-dilation potential regardless of the initial nominal size, likely due to the consistent number of circumferential "zigs" used in the design.

VBX stents have a closed-cell design with independent rows of stainless-steel struts to maximize flexibility. The number of closed cells or "zigs" in each ring increases with size. Correspondingly, their over-dilation diameter achieved before fracture or collapse was relatively reliable (3-5mm above nominal) regardless of starting nominal diameter. Though predictable, this is a comparatively low over-dilation potential. They showed an average foreshortening of 9% per 1mm of over-dilation with all sizes of stents (except the 8mm) eventually narrowing into a ring on over-dilation. Following collapse, further dilation was limited; the 5mm and 6mm stents, for example, fully collapsed on the 12mm balloon, limiting their diameters to around 9mm.

Notably, the 10mm diameter VBX stent could not be fractured after collapse. All other VBX stents were able to be intentionally fractured. VBX stents had the least recoil overall (<3%). The VBX covering always tore most often at dilations 8-9mm above their nominal diameter, but with a wide range (6-11mm above nominal). The VBX stent design of closed-cells and independent strut rings enhances flexibility, appears to promote low recoil, and allows for reliable over-dilation for 3-4mm above nominal, but appears to be associated with a tendency to foreshorten significantly, limiting their dilation potential and fracturability. This may be a limitation of use in situations that would require over-dilation greater than 5mm above nominal.

A notable limitation of this study is that the stents tested included only those donated by the companies. Therefore, there was testing of only one stent of each size and a lack of other small diameter (6 or 7mm) iCast stents for direct comparison. An additional limitation includes the use of digital calipers in place of a non-contacting measurement device.

CONCLUSIONS

There are several FDA-approved balloon-expandable covered stents currently available for clinical use which maintain favorable mechanical characteristics when dilated beyond the nominal diameter. This report suggests that among the devices tested there were notable variations in recoil, foreshortening, fabric tears, and strut fracture that may be clinically relevant. LS stents may be most useful for lesions that require dilation well beyond nominal diameters where relatively low foreshortening is desired. The smaller (5 and 8mm) iCast stents may be considered for small vessel lesions as they performed much better than the larger diameter iCast stents which could only be dilated to nominal or just above nominal diameters. iCast stents had the least foreshortening and less risk for early fabric tears. VBX stents had comparatively very low recoil and may be useful for lesions that require a flexible device with <5mm over-dilation in which foreshortening is less of a concern. The in vitro behavior of the stents tested compared to those tested in vivo will be an area for future study.

REFERENCES

1. Peters B, Ewert P and Berger F. The role of stents in the treatment of congenital heart disease: Current status and future perspectives. Ann Pediatr Cardiol. 2009;2:3-23.
2. ASTM F2081-06(2017), Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents, ASTM International, West Conshohocken, PA, 2017, www.astm.org.
3. Ewert P, Schubert S, Peters B, Abdul-Khaliq H, Nagdyman N and Lange PE. The CP stent--short, long, covered--for the treatment of aortic coarctation, stenosis of pulmonary arteries and caval veins, and Fontan anastomosis in children and adults: an evaluation of 60 stents in 53 patients. Heart. 2005;91:948-53.
4. Tzifa A, Ewert P, Brzezinska-Rajszys G, Peters B, Zubrzycka M, Rosenthal E, Berger F and Qureshi SA. Covered Cheatham-platinum stents for aortic coarctation: early and intermediate-term results. J Am Coll Cardiol. 2006;47:1457-63.
5. Taggart NW, Minahan M, Caballka AK, Cetta F, Usmani K, Ringel RE and Investigators CI. Immediate Outcomes of Covered Stent Placement for Treatment or Prevention of Aortic Wall Injury Associated With Coarctation of the Aorta (COAST II). JACC Cardiovasc Interv. 2016;9:484-93.
6. Fujimoto K, Fujii T, Hata Y, et al. Stent unzipping using an ultra-high-pressure balloon: in vitro and animal experiments. Heart Vessels. 2018;33(3):239-245. doi:10.1007/s00380-017-1060-x
7. Bratincsak A, Moore JW, Gulker B, Choules B, Koren L, El-Said HG. Breaking the limit: mechanical characterization of overexpanded balloon expandable stents used in congenital heart disease. Congenit Heart Dis. 2015;10(1):51-63. doi:10.1111/chd.12175
8. Sathanandam SK, Haddad LM, Subramanian S, Wright D, Philip R, Waller BR. Unzipping of small diameter stents: an in vitro study. Catheter Cardiovasc Interv. 2015;85(2):249-258. doi:10.1002/ccd.25596
9. 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. doi:10.1161/CIRCINTERVENTIONS.115.003281
10. Sathanandam SK, Kumar TK, Hoskoppal D, et al. Feasibility and Safety of Unzipping Small Diameter Stents in the Blood Vessels of Piglets. JACC Cardiovasc Interv. 2016;9(11):1138-1149. doi:10.1016/j.jcin.2016.02.035