Pediatric Curriculum

Stents: What's Available to the Pediatric Interventional Cardiologist?

Frank Ing,* мо

INTRODUCTION

DOCKE.

In 1988, Mullins et al. [1] first reported the use of stents in pulmonary arteries and veins. Since then, the use of stents to treat narrowed vessels and surgical grafts in congenital heart disease has expanded tremendously [2-23]. Many coronary and peripheral stents have been developed for adults, but none specifically for children. In fact, all stents used by pediatric cardiologists in children with congenital heart disease are adaptations from stents used in adults. As such, not all stents available for use in adults are appropriate for pediatric use. The purpose of this article is threefold: to discuss the desirable features of stents as applied to the pediatric population; the various stents available for pediatric use as related to the vascular site of the intended implantation; and the specific features of the available stents. In addition, we performed balloon dilations on various stents under fluoroscopy to evaluate its geometric changes during expansion. While all attempts were made to include as many stents as possible, we recognize that some stents may have been overlooked and not included in this study.

General desirable features of stents include biocompatibility. That is, the stent must be relatively resistant to thrombosis and must promote minimal neointimal growth. The stent must have a low profile with a smooth surface. The stent must be designed with a minimal surface area and must contain minimal impurities. It must also be immune to fatigue and corrosion. It must have good visibility under fluoroscopy for implantation and subsequent evaluation. It must also have reliable expansion with a high expansion ratio. For the pediatric population, in addition to the above requirements, it must also have a small delivery system in order to minimize vascular trauma, usually at the femoral venous or arterial entrance site. The stent should be flexible enough to negotiate the turns within the cardiovascular system such as the right ventricular outflow tract. Most importantly, it must have the feature of further expandability over time as the child grows to adult size. The stent selected must have a potential maximal stent diameter that approximates the normal-adult-size vessel in which that stent will be implanted.

SELF-EXPANDING VS. BALLOON-EXPANDABLE STENTS

All currently available stents can be divided into two broad categories as self-expanding stents and balloonexpandable stents. In general, self-expanding stents are constrained within a delivery sheath that is delivered to the site of stenosis. The sheath is withdrawn to expose the stent that self-expands to dilate the stenotic segment. Unfortunately, these stents are designed to expand to a specific diameter, no bigger or smaller. Therefore, if these stents are selected, it must be implanted into a vessel that does not have any growth potential. Hence, in most cases, these stents are not useful in growing children unless it is implanted into a vessel that has no further growth potential such as in a fully grown adolescent or a surgical shunt, baffle, or conduit. Most commonly used self-expanding stents include the Wallstent (Schneider, Minneapolis, MN) [24-37] and the SMART stent (Cordis Endovascular, Miami, FL; Fig. 1) [38-41]. The advantages of the self-expanding stent in general are that they do not require a balloon for expansion and can be delivered through a lower-profile delivery system. They are very flexible and can traverse tortuous vessels.

Cardiology Division, Children's Hospital of San Diego, San Diego, California

*Correspondence to: Dr. Frank Ing, Cardiology Division, Children's Hospital of San Diego, San Diego, CA 92123. E-mail: fing@chsd.org

Received 13 June 2002; Revision accepted 9 June 2002

DOI 10.1002/ccd.10342

Published online in Wiley InterScience (www.interscience.wiley.com).



Fig. 1. A: Expanded Wallstents of various sizes. B: Expanded SMART stents of various sizes. Some stents have platinum markers at the stent edges for enhanced radiopacity (black arrows).

They do not contain any stainless steel components and therefore are MRI-safe. However, the main disadvantage is that they cannot be further dilated to accommodate growth of the child. While the SMART stents have only an 8%–10% foreshortening (Fig. 2A), the Wallstents have significant foreshortening after expansion (Fig. 2B). Both have much lower radial strengths than balloon-expandable stents.

BALLOON-EXPANDABLE STENTS

ϿϹϏΕ

The advantages of balloon-expandable stents include reliable expansion, the ability to be further expanded over time, and relatively good radial strength. In addition, there is a relatively long history of its use in congenital heart disease and much experience with this group of stents among pediatric interventional cardiologists. However, the disadvantages are that they are relatively more stiff and require larger delivery systems compared to the self-expanding stents.

In general, balloon-expandable stents can be categorized into four different sizes: small, medium, large, and extra large. Small stents are used almost exclusively in coronary arteries and vein grafts in adult patients following coronary artery bypasses. In general, these stents cannot be expanded larger than 3–6 mm in diameter. Since pediatric cardiologists rarely get involved with stenotic coronary arteries, we will not be discussing



Fig. 2. A: A Wallstent self-expanding under fluoroscopy. Note the significant foreshortening. B: A SMART stent self-expanding under fluoroscopy. This design minimizes foreshortening.

this group of stents. Medium stents can be expanded to a maximum diameter of 10–12 mm. This group of stents is appropriate for implantation in segmental and subsegmental branch pulmonary arteries, femoral and innominate veins, pulmonary veins, and Blalock-Taussig shunts. Large stents can be expanded to a maximum diameter of 18 mm. They are appropriate for main and proximal branch pulmonary arteries, lobar branch pulmonary arteries, the superior and inferior vena cava, proximal iliac vein, aorta, Fontan baffles, and surgical homografts and conduits. The extra-large stent can be expanded to a maximum diameter of 24–25 mm and are appropriate for

ϿϹΚΙ

the aorta and large right ventricular baffles or homografts and Fontan baffles.

MEDIUM STENTS

Medium stents that are available for use include the Palmaz 4 series (Johnson and Johnson Interventional Systems, Warren, NJ) [39–43], the Corinthian series (Johnson and Johnson Interventional Systems) [44,45], the Bridge stent (Medtronic-AVE, Santa Rosa, CA) [46,47], and the NIR stent (Boston Scientific-Meditech, Natick, MA) [48–52]. The Palmaz stent is constructed



Fig. 3. The Palmaz stent is made of stainless steel and laser-cut slots (small white arrow), which becomes diamond-shaped cells (large white arrow) when expanded.



Fig. 4. An expanded Corinthian stent. Note the smooth edges (small white arrow) and the Omega hinge (large white arrow), which provides more flexibility.

out of a 316 L stainless steel tube with laser-cut slots that form seven cells per row (Fig. 3). While the intended maximal diameter is only 6 mm, it can be overdilated up to about 10 mm in diameter. Available lengths range from 10 to 39 mm. They can be implanted through 6-7 sheaths. During our own laboratory testing, these stents demonstrated a foreshortening of 19%-23% when dilated to 9 mm diameter and 33%-40% at 10 mm diameter. General radial strength is good. The Corinthian stent is made of the same stainless steel as the Palmaz stent, but has an Omega hinge between the rows of cells (Fig. 4). It has a seven-cell configuration and can be dilated to a maximum of 12 mm diameter. Available lengths range from 12 to 39 mm. Foreshortening is similar to the Palmaz 4 series. At 10 and 12 mm diameter, there is a 38%-41% and 55%-60% foreshortening, respectively. These stents can be implanted through 6-7 Fr sheaths. Radial strength is comparable to the Palmaz 4 series. The NIR stent is also made out of stainless steel and has a U-shaped hinge between rows of cells (Fig. 5). It comes in seven- and nine-cell configurations and is available in 14-19 mm lengths only. Maximal diameter is about 8 mm. The nine-cell stent has only a 15%–16% foreshortening when dilated to 8 mm diameter. It requires a 6-7 Fr sheath for delivery and radial strength is good. The Bridge stent is made of stainless steel with laser-welded sinusoidal elements (Fig. 6). It can be dilated to about 14 mm diameter and comes in 28-100 mm lengths. They are available premounted on a balloon or unmounted.

DOCKE



Fig. 5. An unexpanded NIR stent with U-shaped hinges (small white arrow). Hinges elongate during stent expansion to minimize foreshortening (large white arrow).

They require a 7-8 Fr sheath for delivery. This stent has the least amount of foreshortening compared to the other medium-sized stents. At 10 mm diameter, there is 3%– 15% foreshortening at 12 mm about 15%–18%; at 14 mm, there is about 22% foreshortening. Overall radial



Fig. 6. The Bridge stent is composed of rows of sinusoidal elements (A) with smooth edges (B) and are laser-fused (C).

TABLE I. Comparison	of Medium-Siz	zed Stents
---------------------	---------------	------------

	Palmaz 4 series	Corinthian	NIR stent	Bridge AVE
Design	316 L SS tube; laser-cut slots	Omega hinge; 7-cell configuration	SS; U-hinge; 7- and 9-cell configuration	SS laser-welded sinusoidal elements
Sizes	Maximum diameter, 10 mm; 10–39 mm length	Maximum, 12 mm; 12–39 mm length	Maximum, 8 mm; 14–19 mm length	Maximum, 14 mm; 28–100 mm length
Sheath	6–7 Fr	6–7 Fr	6–7 Fr	7-8 Fr (premounted, 10 mm)
Foreshortening	9 mm, 19%– 23%; 10 mm, 33%–40%	9 mm, 24%–26%; 10 mm, 38%– 41%; 12 mm, 55%–60%	9-cell configuration; 8 mm, 15%–16%	10 mm, 3%–15%; 12 mm, 15%; 14 mm, 22%
Radial strength	Good	Good	Good	Good; (fair at 14 mm diameter)
Advantages	Much experience in pediatric cardiology	Flexible; maximum to 12 mm diameter; rounded edges	Less foreshortening; rounded edges	Flexible-trackability; rounded edges; maximum to 14 mm diameter; less foreshortening
Disadvantages	Stiff; sharp edges	c	Little experience in pediatric cardiology; smallest maximum diameter	Little experience in pediatric cardiology

strength is good, but weaker at 14 mm diameter. Table I summarizes the design, available sizes, sheath size needed for implantation, foreshortening, and general radial strength of each medium-sized stent.

Advantages and Disadvantages

Advantages of the Palmaz stent are that there is much experience of this stent in pediatric cardiology. It was the first available stent used by pediatric cardiologists. However, they are rather stiff stents and have sharp edges (Fig. 7), which increases the risk of balloon rupture during dilation. The Corinthian stent is much more flexible than the Palmaz stent and has rounded edges (Fig. 4). It can be dilated up to a maximum diameter of 12 mm. In general, the Palmaz 4 series has been replaced by the Corinthian stents. The NIR stent also has rounded edges and there is relatively less foreshortening compared to the first two stents. But it has a smallest maximal diameter and there is little experience with this stent among pediatric cardiologists. The Bridge stent is also very flexible and trackable through sheaths. It too has rounded edges. This stent has the largest maximal diameter among medium-sized stents at 14 mm and has the least amount of foreshortening; however, the radial strength tends to be less due to the larger cell size at the larger diameters. Again, there is little experience with this stent among pediatric cardiologists. Table I summarized the advantages and disadvantages of the medium stents. Figures 8 and 9 compare the appearance of the various medium-sized stents before and after full expansion.

LARGE STENTS

The available large stents include the Palmaz 8 series (Johnson and Johnson Interventional Systems) [1–3], the Doublestrut LD stent (Sulzer-IntraTherapeutics, St. Paul, MN) [53,54], and the Cheatham-Platinum (CP) six-zig stent (Numed, Hopkinton, NY) [55].

The Palmaz 8 series are designed similarly to the 4 series except it has 10 cells in each row. Maximal dilat-

DOCKET



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

