Basic Investigation

The Genesis Stent: A New Low-Profile Stent for Use in Infants, Children, and Adults With Congenital Heart Disease

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Placement of intravascular stents that can reach adult size in infants and smaller children has been limited by the large profile and poor flexibility of currently available stents. In vitro and in vivo testing of the Genesis stent was performed to evaluate crimpability, predeployment flexibility, and radial strength. Comparisons were made to the Palmaz iliac and IntraStent (IS) LD stents. Nine physicians placed 30 Genesis stents in swine pulmonary and systemic arteries to evaluate stent deliverability/crimpability. Two swine were recovered and underwent a second catheterization 8 weeks later, where the stents (n = 8) were reexpanded to maximal size. Angiographic and intravascular ultrasound (IVUS) assessments were performed. In vitro testing revealed the Genesis stent to have superior crimpability, flexibility, and comparable radial strength to the Palmaz iliac stent, and superior crimpability and radial strength and comparable flexibility to the IS LD series. During in vivo testing, the physicians graded the Genesis stent superior to the Palmaz stent regarding crimpability and deliverability, and superior to the IS LD stent in regard to crimpability, and comparable to or superior in deliverability. In the chronic animals, the Genesis stent was expanded up to maximal diameter 8 weeks following implantation. Angiographic and IVUS revealed no fractures no in-stent restenosis. The Genesis stent can be easily delivered through smaller sheaths, which will facilitate their use in infants and smaller children with vascular stenosis. *Cathet Cardiovasc Intervent 2003;59:406–414.* © 2003 Wiley-Liss, Inc.

Key words: stent; infants; congenital; stenosis; children

INTRODUCTION

Use of intravascular stents for treatment of vascular obstructions in congenital heart disease was first introduced by Mullins et al. [1] in 1988. Since then, stents have been used to treat pulmonary artery and systemic venous obstructions [2–4] and more recently systemic arterial obstructions [5–7]. Due to rigidity of the stent and the sheath size required for delivery, use of presently available stents that can be dilated to adult size is technically very difficult in infants and smaller children.

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Renal stents, which can be delivered through smaller sheaths and have increased predeployment trackability, are technically easier to use in infants and smaller children. Unfortunately, these stents cannot be dilated to adult size and frequently require surgical removal and/or patch augmentation of the blood vessel when the child grows. In this report, we present in vitro and in vivo experience with the Genesis stent (Cordis, Warren, NJ), a new low-profile flexible stent that can be expanded from infant to adult size.

MATERIALS AND METHODS

The Genesis stent was initially developed for the treatment of biliary stenosis. The stent underwent further modifications to meet four criteria: improved predeployment flexibility; ability to be dilated from 5 to 20 mm in diameter; deliverability through a small (6–7 Fr) sheath; and comparable radial strength to the Palmaz iliac series stents at all diameters. Testing evaluated predeployment crimpability, flexibility, deliverability, radial strength, and stent shortening characteristics. Both premounted and unmounted stents were tested.

In Vitro Testing

Stent design. The Genesis stent is made of stainless steel and has a closed-cell configuration. In contrast to the Palmaz stent (Johnson and Johnson, Sommerville, NJ), also having a closed-cell design, sigma hinges have been interpositioned between each cell (Fig. 1). The Genesis stent will be available in 19, 25, 29, 39, and 49 mm preexpansion lengths. Table I compares the general characteristics between the Genesis, Palmaz, and IS LD stent series.

Crimpability. The Genesis, Palmaz, and IntraStent double-strut LD (IS LD; EV3, Plymouth, MN) stent series were hand-crimped on 5–8 mm OptaPro (Cordis) balloon angioplasty catheters. The stent/balloon catheter was advanced through 6, 7, and 8 Fr sheaths. The smallest sheath that allowed easy delivery of the stent was recorded. The sheaths tested were Brite Tip (Cordis) and Flexor (Cook, Bloomington, IN) sheaths. The minimal crimp diameter was measured for Palmaz and Genesis stents, respectively.

Flexibility. Predeployment flexibility of the Genesis stent was measured by determining the amount of force (in pounds) required to flex the stent. Similar testing was performed for the Palmaz iliac and IS LD stents. Testing was performed using a three-point bend technique on the stent alone. The test is an adaptation of American Society for Testing and Materials (ASTM) D790. This test is designed to evaluate the flexibility for any material and was adapted for testing the stents. In the ASTM test, the distance between supports is maintained at approximately 1″. In the adaptation for testing stents, the support is the length of the stent, allowing the ability to test stents under 1 ″ (∼ 25 mm) in length.

To perform the test, the internal space of the stent is filled by finger crimping the stent onto 0.060″ polyethylene tubing. This prevents the stent from buckling and hinging on a given point. The stent, crimped onto the 0.060″ tubing, is placed in the V-block. The load, which is measured in pounds of force, is focused on the midpoint of the stent. The force is applied using a cylindrical mandrel with a 0.5″ diameter. The load is continuously monitored and values are determined at given displacements. Comparisons between each stent type were made at similar lengths (i.e., a 16 mm IS LD was compared to an 18 mm Palmaz and Genesis 19 mm stent). The results were used to compare the flexibility between each stent series of similar length. Finally, to normalize the loads to the stent length, a moment is calculated. The moment is determined using the formula $M = P(L/4)$, where P is the load and L is the length of the stent.

Radial strength. The Genesis, Palmaz, and IS LD stents underwent a series of radial strength testing at 10, 12, and 15 mm expanded diameters. Radial testing was performed within a latex tube. The latex tubing, which has an internal diameter that represents the target nominal expansion diameter (i.e., 10, 12, 15 mm), was cut slightly longer than the stent. Expansion of each stent was performed to balloon-rated burst pressure, with the stents becoming imbedded within the latex tubing.

The balloon was removed, and special mandrels, which have an outer diameter that corresponded to the latex tubing internal diameter, were carefully positioned onto the ends of the tubing to within 0.5 mm of the stent ends. The mandrel/tube/stent assembly was inserted into the radial strength testing fixture. The fixture consists of a clear cylindrical lexan chamber with two tightly fitted end caps. The chamber was slowly pressurized such that the latex tubing begins to compress uniformly the stent radially along its length. Within the stent, the pressure remains at atmospheric level, and gradually a pressure differential develops between the outside and inside of the stent. The test was concluded at the collapse or failure of the stent. The peak pressure recorded just prior to stent failure was considered the maximal radial strength.

Stent shortening. Three Genesis, Palmaz, and IS LD stents were serially dilated on 10, 12, 14, 15, and 18 mm balloon catheters. The length of each stent was measured at 12, 15, and 18 mm diameter, respectively, to assess amount of stent shortening with expansion. The mean percent foreshortening was calculated for each stent series and comparisons were made.
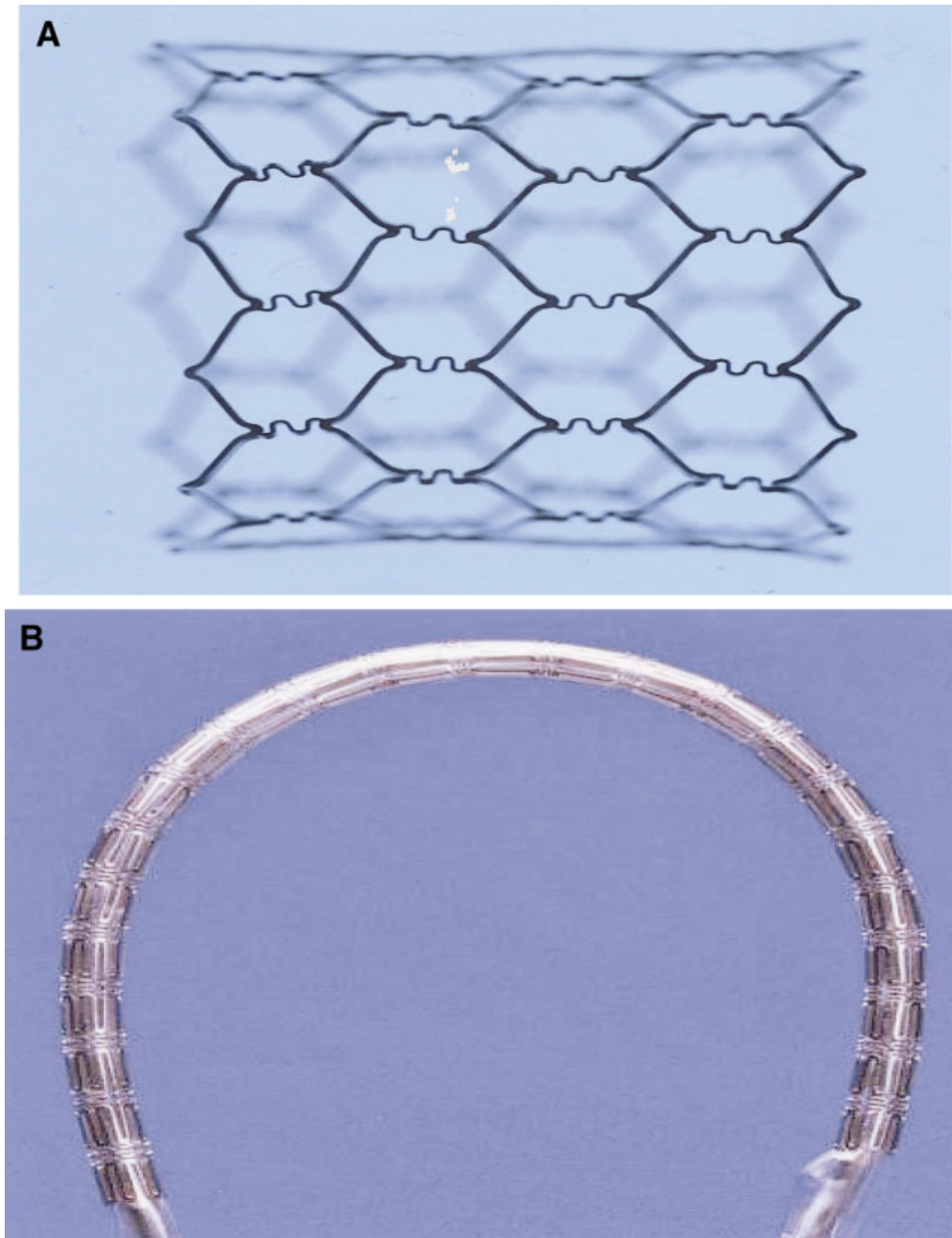
Fig. 1. A: An expanded Genesis stent is shown. The sigma hinges are interposed between each cell. B shows the flexibility of the Genesis stent hand-crimped on a Cordis PowerFlex balloon catheter. [Color figure can be viewed in the online issue, which is available at www.interscience. wiley.com].

In Vivo Testing Performed Only on Genesis Stent

Acute phase. This phase of the study tested stent crimpability, deliverability, and the ability to retrieve a preexpanded Genesis stent back into the sheath. Nine physicians, with a combined experience of over 60 years in stent placement in patients with congenital heart dis-

ease, participated in this part of the study. A total of 22 Genesis stents were placed in swine pulmonary arteries, ascending and descending aorta, and the inferior vena cava. Both premounted and unmounted 19/29/39 mm Genesis stents were advanced on Cordis OptaLP and OptaPro angioplasty catheters ranging from 5 to 14 mm

TABLE I. General Characteristics Between the Palmaz, Genesis, and IS LD Stents

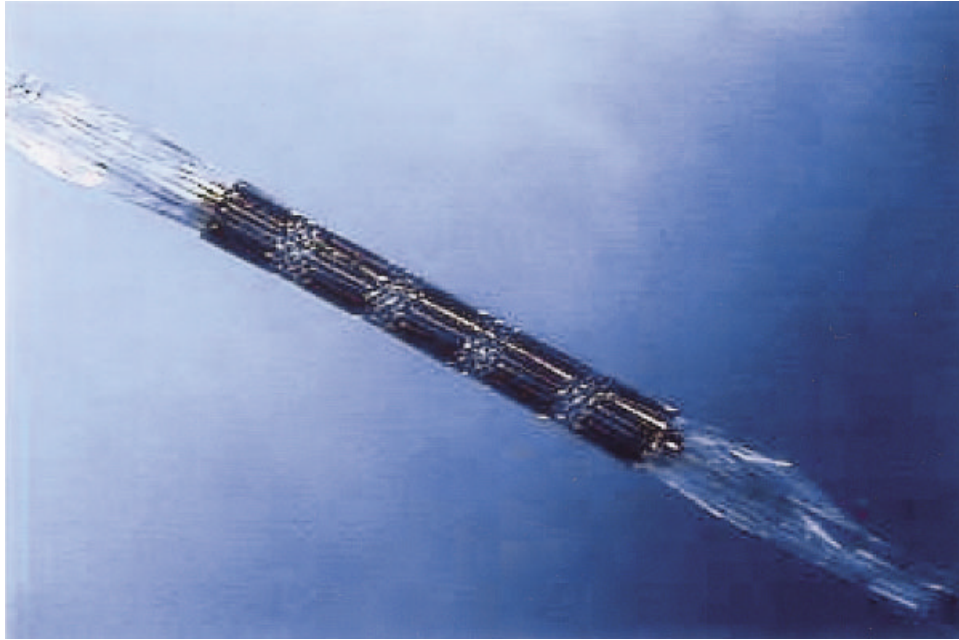|	Genesis 19/29/39	Palmaz P188/308	IS LD 16/26
Nominal expansion sizes	5–20 mm	7–18 mm	7–20 mm
Final wall thickness	0.0095″	0.0055″	0.0076″
Minimal crimp diameter	0.066″	0.093″	
Del Sh on 5–7 mm catheter	6 Fr	8 Fr	8 Fr
Del Sh on 8–12 mm catheter	7 Fr	9 Fr	9 Fr
Del Sh on 14–16 mm catheter	8 Fr	10 Fr	10 Fr

Del Sh, Delivery sheath

Fig. 2. Photograph of a hand-crimped Genesis stent on a Cordis OptaPro balloon catheter. After crimping the stent onto the balloon catheter, the balloon catheter was carefully inflated to 0.5–0.7 atm pressure. This caused the ends of the balloon catheter to expand slightly, thereby nesting the stent onto the balloon catheter. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com].

in diameter through 6–8 Fr Brite tip sheaths. The method of nesting unmounted Genesis stents on the balloon catheters went as follows. The physician hand-crimped the Genesis stent onto the balloon catheter. Prior to advancement of the stent/balloon catheter into the sheath, the balloon was partially inflated to 0.7 atm. This caused partial expansion of the balloon ends, thereby fixing the stent onto the balloon catheter (Fig. 2). The physicians then graded these characteristics of the Genesis stent as superior, comparable, or inferior in comparison to their previous experience with Palmaz and IS LD stents.

Chronic phase. Two swine were used for the chronic phase of the study, which evaluated stent expandability at late redilation, shortening characteristics at larger diameters, and in vivo stent/vessel wall interactions in regard to neointimal buildup or endothelialization characteristics. The stents were delivered into pulmonary arteries,

systemic arteries, and the superior vena cava. The swine were recovered from the procedure and 8 weeks later were brought back to the animal laboratory where the stents were redilated to 18 and 20 mm diameter. Angiography and intravascular ultrasound (IVUS) imaging were performed prior to and following redilation. Following explantation, the stents were analyzed grossly and fluoroscopically for final dimension, length, and fractures.

RESULTS
In Vitro Testing

Crimpability. Though the Genesis stent is 42% thicker than its Palmaz counterpart, the minimal crimp diameter of the Genesis stent is 30% less than that of the Palmaz stent (Table I). This allows the Genesis stent to be delivered through sheaths 1–2 Fr sizes smaller than

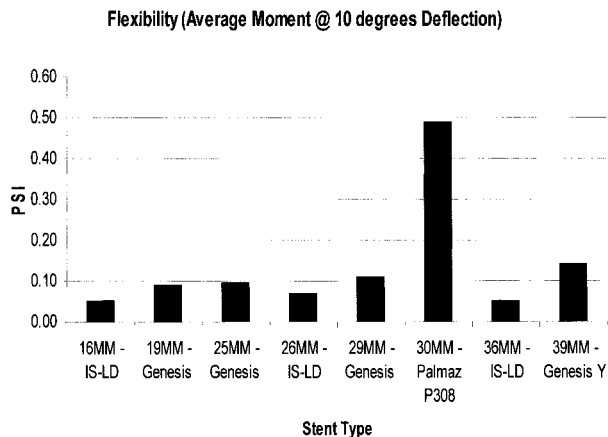Flexibility (Average Moment @ 10 degrees Deflection)

Fig. 3. Results of preexpansion flexibility testing of the Genesis, Palmaz, and IS LD stents are presented. The graph delineates the comparisons between each stent. The stent type is depicted on the x-axis, and the amount of force (in pounds) required to flex the stent is depicted on the y-axis.
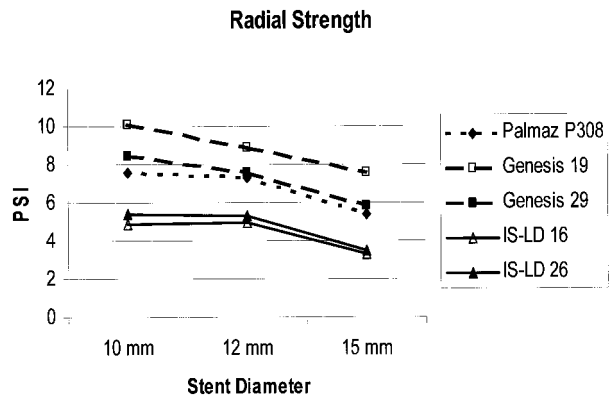
Radial Strength

Fig. 4. Radial strength comparison between the Genesis 19/29, Palmaz 308, and IS LD 16/26 series stents is shown in this graph. The x-axis denotes the final diameter tested. The y-axis represents the amount of force per square inch required to compromise stent lumen. The Genesis series has comparable radial strength to the Palmaz series and approximately twice the radial strength to the IS LD series at all diameters.

those required for delivery of the Palmaz iliac or IS LD stent series when crimped on comparable balloon catheters. Due to the open-cell configuration of the IS LD stent, a minimal crimp diameter was not able to be obtained. In order to calculate a minimal crimp diameter, the stent has to be able to be uniformly crimped throughout its entire length. With the open-cell configuration of the IS LD stent, uniform compression of the stent was unable to be achieved. Table I compares the minimal sheath sizes required for delivery of the Genesis, Palmaz, and IS LD stents on Cordis OptaPro balloon angioplasty catheters. For a given balloon catheter, unmounted Genesis stents were able to be advanced easily through sheath sizes, which were 1–2 Fr sizes smaller than either the Palmaz or the IS LD stents.

Flexibility. Results of predeployment stent flexibility in comparison to the Palmaz and IS LD stents is depicted in Figure 3. The measurement is in pounds required to flex the stent. The IS LD and Genesis stents have similar preexpansion flexibility profiles, with the IS LD being slightly superior to the Genesis series. Both were considerably more flexible than the Palmaz series, measuring at least four times more flexible than the Palmaz stent.

Radial strength. The Genesis 19/29, Palmaz 308, and IS LD 16/26 stent series underwent radial strength testing following dilation to 10, 12, and 15 mm in diameter. The Genesis stent demonstrated radial strength equal to or better than the Palmaz and nearly twice that of the IS LD stent at all diameters (Fig. 4).

In vitro stent shortening. Minimal stent shortening ($< 5\%$) was observed between all stents at 10 mm. At 15 mm, the P308 stents shortened 25%, the Genesis stent shortened 16%, and the IS LD shortened 6%. At 18 mm

final diameter, the Palmaz P308 shortened nearly 45%. The Genesis series shortened 34% from initial length of 39 mm and 20% from initial length of 19 mm. The IS LD shortened 23 and 34% from initial lengths of 26 and 16 mm, respectively.

Acute-Phase In Vivo Testing

Flexibility/deliverability. All stents were successfully delivered to their desired location. In one case, a premounted Genesis stent on a 5 × 2 cm OptaPro balloon angioplasty catheter was successfully advanced through the strut of a previously placed stent and expanded in a branch vessel without a long sheath. In assessing the Genesis predeployment flexibility, all nine operators graded the Genesis stent superior in comparison to the Palmaz iliac stent series. Of the six physicians who had experience with the IS LD stent, five felt the Genesis stent had superior flexibility and one graded the Genesis comparable to the IS LD stent.

Crimpability. Regarding stent crimpability, our in vivo experience correlated with our in vitro testing. All physicians felt the Genesis stent had superior crimpability characteristics to both the Palmaz iliac and IS LD series stents. This improved crimpability also allowed both premounted and unmounted stents, loaded on 5–12 mm Cordis OptaPro balloon catheters, to be pulled back into a 7 Fr sheath prior to deployment without causing stent dislodgment off the balloon catheter. The maneuver of retracting the stent/balloon catheter back into the sheath was performed with the sheath in the main pulmonary artery (MPA) and stent/balloon catheter being retracted back either from the distal right pulmonary artery (RPA) or from the left pulmonary artery (LPA).
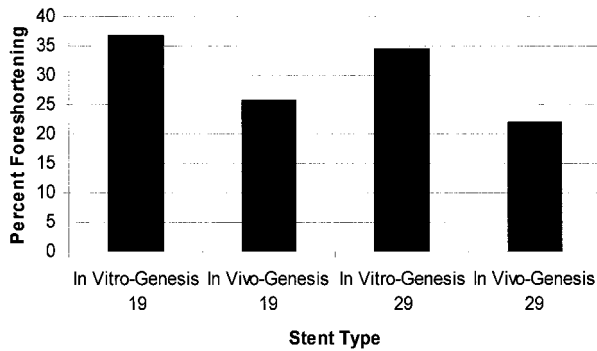
Fig. 5. In vitro vs. in vivo (8-week) dilation of the Genesis 19/29 stent at 18 mm diameter. There is an 11–12% decrease in the amount of foreshortening in the stents progressively dilated in vivo vs. in vitro dilation.

Chronic-Phase In Vivo Testing

A total of eight stents were placed in the pulmonary arteries (n = 3), superior vena cava (n = 1), and descending aorta (n = 4) in two swine. The stents were initially deployed on 10 (n = 2), 12 (n = 5), and 14 (n = 1) mm balloon catheters. Depending on native vessel size, five stents were redilated to 18 mm, and three redilated to 20 mm diameter. The amount of stent shortening between acute (in vitro) and late (in vivo) redilation of the Genesis 19/29 mm stents is depicted in Figure 5. There was a decrease of 11–12% in the amount of shortening observed following late dilation in chronic animals compared to the degree of shortening observed at acute dilation. This appears to be due to straightening of the sigma hinges associated with serial dilation within the vessel wall (Fig. 6). Angiography and IVUS imaging noted no significant neointimal buildup, intrastent thrombus or plaque, or stent fractures. There was no evidence of vascular dissection, tear, or vessel injury observed at the ends of the stents following redilation. At explantation, all stents appeared uniformly dilated.

DISCUSSION

This study demonstrates the advantageous properties of the new Genesis stent and its potential use in infants and smaller children with congenital heart disease. Furthermore, we demonstrated the feasibility of redilating the Genesis stent, to maximal diameter, at a later time. Reexpansion of the Palmaz iliac stent series can be performed years later, eventually reaching diameters appropriate for adult-size patients [8]. Unfortunately, due to the large sheath size required for delivery and the rigid predeployment configuration of the Palmaz iliac series stent, placement of these stents in infants and smaller children can be technically difficult. The large stent size

has limited the interventionist's options and, in some cases, has led to placement of smaller renal/coronary series stents in these patients. Use of smaller stents limits expansion capabilities and will necessitate future surgical interventions [9,10]. The Genesis stent series, with its low profile and flexibility, will make it technically easier for the interventionist to deliver a stent capable of reaching adult size in infants, children, and adults with congenital heart disease.

Deliverability

The Genesis stents can easily be advanced through sheath sizes that are 1–2 Fr smaller than those required for iliac or other large-diameter stents currently available. Though recent innovative modifications to delivery techniques have been devised to allow the Palmaz iliac series stents to be preloaded and advanced in a 7 Fr sheath, this technique requires the distal part of the sheath to be predilated, thus allowing enough room for the balloon/stent to fit through the sheath. This increases the outer diameter of the sheath to be greater than 7 Fr. Furthermore, in 15% of the cases, this technique has been associated with perforations of the balloon catheter prior to deployment of the stent [11]. Delivery using this technique can also be cumbersome in infants and smaller children, as the balloon, stent, and sheath have to be advanced over the wire as a unit. We feel the increased crimpability of the Genesis stent, and therefore lower profile, is due in part to the hinges being interpositioned between each cell.

Delivery of the Genesis stent through kink-resistant flexor/guiding sheaths (Cook Flexor/Cordis Brite tip sheaths) decreases the technical complexity of stent delivery in infants and smaller children. This technique should not be associated with increased risk of balloon perforation, as the balloon/stent is not forcibly introduced into an undersized sheath. Furthermore, the improved trackability of the stent will decrease the likelihood of losing sheath position or encountering stent dislodgment when crossing a stenotic segment. We feel that the stent's improved crimpability, combined with the nesting technique used, allowed for the operator to retract the stent/ balloon catheter back into the sheath without stent dislodgment. Another technique to seat the stent onto the balloon catheter is called cold nesting. The stent is hand-crimped onto the balloon catheter in the usual fashion. A small steel tube, whose internal diameter matches that of the internal diameter of the delivery sheath, is advanced over the stent/balloon catheter. The balloon is maximally inflated inside the steel tube. The balloon is then deflated to 0–0.2 atm pressure, with the steel tube removed. The stent is then advanced in the usual fashion through the sheath, now being nested on the balloon catheter. In the premounted version of the stents, the interventionist will
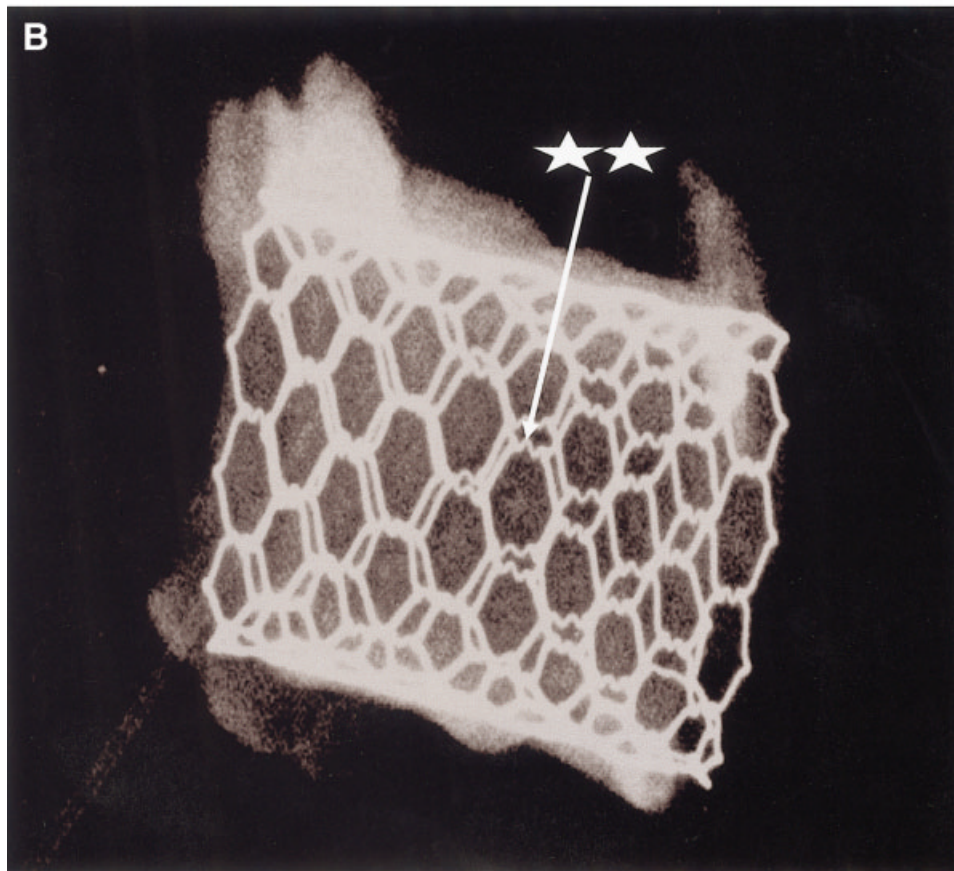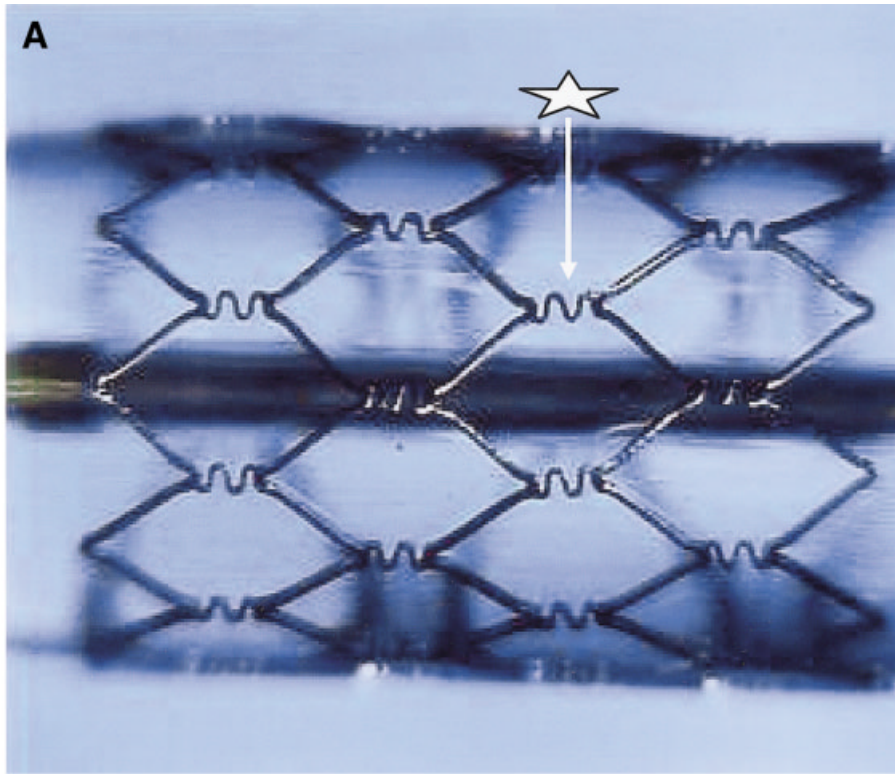
Fig. 6. Relative lengthening of the sigma hinges observed with in vivo dilation. A is an expanded Genesis stent. The sigma hinges, depicted by a star, remain relatively foreshortened. In contrast, B is an X-ray image of a Genesis stent dilated in a swine pulmonary artery. Further lengthening of the sigma hinges can be seen, represented by two stars. Relative lengthening of the sigma hinges accounts for the decreased foreshortening observed with in vivo dilation depicted in Figure 5. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com].
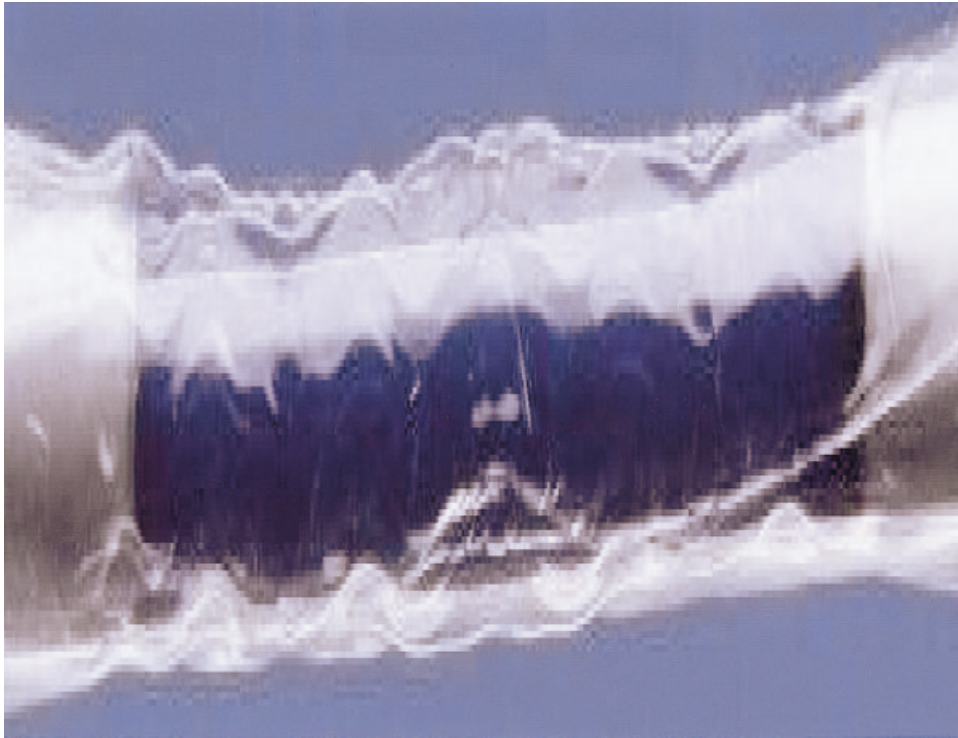
Fig. 7.   A photograph of a premounted Genesis stent loaded on a Cordis balloon catheter. The premounted stent shows balloon material protruding between the struts of the stent. The premounted stent will have increased stent/balloon interface, thereby decreasing the likelihood of encountering stent dislodgment during deployment. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com].

be able to launch the stent from a sheath placed proximal to the stenosis [12]. Although this maneuver was successfully performed with both mounted and unmounted stents, the mounted stents offer an added measure of safety, which is demonstrated in Figure 7. A premounted Genesis stent is observed loaded on a Cordis OptaPro balloon catheter. Protrusion of balloon material through the struts of the stent increases the amount of friction between the stent and the catheter. This decreases the risk of stent dislodgment when retracting the stent back into the sheath or repositioning the stent/balloon prior to deployment. Using premounted stents, or the techniques of nesting the stent onto the balloon catheter described, the operator would no longer be required to cross the area of stenosis with a sheath prior to stent deployment. The authors, however, feel that placement of the sheath across the stenotic region, when possible, remains the safest method for deploying intravascular stents.

Radial Strength

The Genesis stent has superior radial strength at all diameters in comparison to the Palmaz and IS LD stents. Concerns have been noted with stent recoil of the IS LD

stent when expanded above 12 mm in diameter [13]. In the authors' experience, stent recoil with the IS LD stent has been observed following treatment of baffle obstructions in a postoperative Mustard patient (W.H.), an obstructed lateral tunnel in a Fontan patient (J.V.), coarctation of the aorta (Z.A., T.F., J.V., C.M.), and proximal left pulmonary artery stenosis (T.F., C.M.). In each case, balloon redilation of the stent, or placement of a second, closed-cell stent within the previously placed IS LD stent, was required. Concerns for stent recoil with the IS LD version is supported by the dramatic decrease in radial strength observed when expanded larger than 12 mm in diameter. Stent recoil has not been observed with Palmaz stents. We anticipate, due to similar radial strength characteristics to the Palmaz stent, the Genesis stent will not be susceptible to stent recoil. This may be due in part to the closed-cell design of the Genesis and Palmaz stents in contrast to the open-cell design of the IS LD series.

Stent Shortening

An 11–12% decrease in the amount of stent shortening was observed with in vivo dilation of the Genesis stent in

comparison to in vitro dilation. Though this phenomenon is due to sigma hinge straightening, which was observed with in vivo dilation, the reason for the relative maintenance of stent length may be twofold. First, the stent becomes imbedded within the vessel wall. The vessel wall may decrease the amount of axial foreshortening of the stent with serial dilation. The second relates to balloon inflation dynamics. With the stent expanded on the balloon catheter outside of the body, the balloon tends to inflate outside the ends of the stent, spreading inward toward the center. The balloon catheter can compress the ends of the stent during inflation, exacerbating stent shortening. This was observed even with serial dilation of the stent with progressively larger balloon catheters. Conversely, when expanded within the confines of a vessel, though initial balloon expansion still occurred on the outside, there appeared to be more uniform expansion of the balloon, thereby decreasing the amount of axial compression on the stent. We feel these are the most likely reasons for the decrease in the amount of stent shortening observed with in vivo dilation of the Genesis stent.

Study Limitations

This study is limited to observations from in vitro and in vivo experimental testing in the swine model. Furthermore, the model involved normal vessels, i.e., without stenosis. Though the applications should apply to humans, testing of delivery and other characteristics of the stent was not performed specifically in human subjects. The in vivo physician comparisons of the deliverability and crimpability characteristics of the Genesis, Palmaz, and IS LD stents were subjective, with only Genesis stents being used for this portion of the study. Therefore, physician bias may have been introduced in this part of the study.

The Genesis stent offers a promising new alternative to the stents currently available for use in treatment of vascular obstructions in congenital heart disease. With improved deliverability and expandability of the Genesis stent, an interventionist will be able to deliver stents reliably in infants and smaller children that can be expanded to adult size over time.

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