In Vitro Evaluation of Side-Branch Creation in Metal Stents by Balloon Dilatation

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ABSTRACT

Purpose: To determine the effects of strut mesh dilatation in seven commonly used stents used in interventional radiology.

Methods: Dilatation through the strut mesh opening on each stent was made by using balloons to artificially create a side branch in translucent plastic tubing. The stents used in the study included both balloon expandable stents (Palmaz stents, Omnilink, and Express) and self-expandable stents (Symphony, SMART, Memotherm, and Wallstents). Stent diameters tested in this study were 8 mm and 14 mm, except for the Omnilink and Express, which were 8 mm and 12 mm (commercially available up to 10 mm, but were overdilated to 12 mm). Side-branch dilation was made with 4-mm and 6- mm balloons for the 8-mm stents and 6-mm, 8-mm and 12-mm balloons for the 12/14-mm stents.

Results: Of the self-expandable stents, the Wallstent demonstrated the greatest dilation and maintenance of enlarged mesh opening after dilatation. Side-branch dilatation of the Memotherm, Symphony, and Smart stents had little effect on the mesh opening. Of the balloon expandable stents, Palmaz stent did not respond to dilatation, resulting in balloon rupture and entrapment. The Omnilink and Express stents exhibited good malleability and progressive spherical enlargement in response to dilatation.

Conclusion: The Wallstent was the most suitable self-expandable stent for creation of a side branch. The Memotherm, Symphony, and Smart stents are not amenable to side-branch formation due to their elastic nature. The Palmaz stent should not be used in situations where a creation of side branch is anticipated because of its rigid nature and fixed strut joint, which can lead to balloon entrapment. Both the Omnilink and Express stents can be used when creation of a side branch is planned.
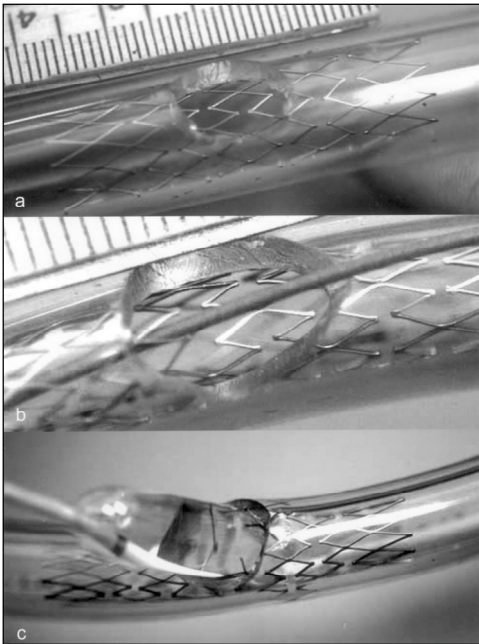
Figure 1A-C. Stent deployment within the plastic tube covering the side hole (A). Insertion of a guidewire through the stent strut mesh opening that covers the ostium of the side branch (B). Balloon catheter advanced in between the stent struts in the region of the ostium of side branch and inflated to 10 ATM by an inflation device (C).

INTRODUCTION

The use of metallic stents in the treatment of peripheral arterial and venous stenosis is well established. Indications include the treatment of arterial and venous stenosis not adequately treated by percutaneous transluminal angioplasty (PTA), [1] chronic arterial occlusion,[2] flow-limiting PTA-induced arterial dissections,[3] as well as post-PTA arterial or venous recoil.

There is a potential risk of side-branch stenosis and compromised flow when metallic stents are placed over the ostium of secondary branches. To solve this problem with coronary stents, balloon dilatation of the side-branch ostium through the stent strut mesh opening has been reported. There has been extensive research, both in animal experiments[4] and in vivo,[5,6] on stent strut deformity of various coronary stents. These studies have documented the effects of sidewall balloon dilatation to maintain the patency of side-branch vessels after primary stent deployment. Deformity and mild narrowing of some stent designs were reported.[4-6] However, in our literature search, we did not find any documentation on the effects of sidewall dilatation with larger peripheral vascular stents. In this article, we report the results of an in vitro experiment of serial balloon dilatations through the stent strut mesh opening of variable stent designs commonly used in the treatment of peripheral vascular disease.

MATERIALS AND METHODS

An experimental vascular model was created from 14-mm and 12-mm inner-diameter translucent plastic tubes for larger stents (depending on the stent diameter), and 8-mm inner-diameter tubes for medium-sized stents. A side hole was then created within the tubes to mimic a side branch. Within the models, the stents were deployed in such a way as to cover the side hole (Figure 1A). A Bentson 0.035" guide wire (Cook, Bloomington, Ind.) was inserted through the stent strut covering the ostium of side branch (Figure 1B). Using an over-the-wire technique, a balloon catheter was then advanced inside the stent strut covering the ostium of the side branch and was inflated to 10 ATM by a pressure-control inflation device (Figure 1C). Shape observations and photographs were performed before, during, and after balloon inflations. Measurements were also taken of the stent strut mesh opening in longitudinal and transverse dimensions with a calibrated caliper; note in stents with intercalated struts, the greatest dimension was recorded. The experiment was performed twice with identical technique.

Eight stent designs were involved in our experiment. The large-diameter stents consisted of three balloon-expandable stents: 308 Palmaz stent (Johnson & Johnson, Warren, NJ) dilated to 14 mm, 10-mm Omnilink (Guidant, Menlo Park, Calif.) dilated to 12 mm, and a 10-mm

Express (Boston Scientific, Natick, Mass.) dilated to 12 mm. These stents were deployed inside the plastic tubes using balloons of the desired final diameter. The rationale for overdilatation of the Omnilink and Express stents was to provide a more uniform stent population for the large-diameter stents. Four self-expandable stents, a 14-mm Wallstent (Boston Scientific, Natick, Mass.), a 14-mm SMART stent (Cordis, Warren, NJ), a 14-mm Symphony stent (Boston Scientific, Natick, Mass.), and a 12-mm Memotherm stent (Bard, Murray Hill, NJ) were also used. Six-mm, 8-mm, and 12-mm diameter dilatation balloon catheters (Ultrathin, Boston Scientific, Natick, Mass.) were used to sequentially dilate through the large-diameter stent strut mesh opening.

This study used three medium-diameter balloon expandable stents (294 Palmaz stent dilated to 8 mm, Omnilink dilated to 8 mm, and Express dilated to 8 mm) and 4 self-expandable stents (8-mm Wallstent, 8-mm SMART stent, 8-mm Symphony stent, and 8-mm Memotherm stent). The strut mesh opening of these stents was sequentially dilated with 4-mm and 6-mm diameter balloons catheters.

RESULTS

The results for the study were averaged and are shown in Figure 2 and 3.

For the large Palmaz stent (Figure 4a) the size of stent strut mesh opening was minimally increased after dilations with a 6-mm balloon without significant increase in overall area, but the shape of the strut mesh opening changed from hexagonal to circular (Figure 4b). After dilation of the large Palmaz stent with either the 8-mm or the 12-mm balloon catheter, balloon rupture and balloon entrapment within the stent strut mesh opening was observed (Figure 5). With the medium Palmaz stent, there was progressive shape distortion from hexagonal to circular with the 4-mm and 6-mm balloons; however, there was balloon entrapment within the stent strut mesh

opening but without balloon rupture.

For both the medium and large Wallstents (Figure 4C), the size of stent strut mesh opening was progressively increased following the size of dilated balloons (Figure 4D). With the largest balloon in both Wallstent groups, there was minimal distortion of the stent, causing 1-mm bowing of the dilated struts into the lumen of the stent (Figure 4D).

For the medium-sized SMART stent (Figure 4E), no change in the size or shape of the strut mesh opening was observed after applying any of the balloons. For the large SMART stent, mild irregular shape distortion was observed after applying the 12-mm balloon (Figure 4f), whereas no change was observed after applying smaller balloons.

In both sizes of Memotherm stents (Figure 4G), 8 mm- and 12-mm diameters, separation of one stent strut joint was observed after applying the largest balloons of each groups (Figure 4H).

For the 8-mm and 14-mm diameter Symphony stents (Figure 4I), minimal distortion of stent strut mesh opening was observed after applying the largest balloon and no change after applying the small and mid-size balloons. Also, with the 8-mm and 12-mm side-strut balloon dilatation, there was joint separation in the 14-mm Symphony stent (Figure 4J).

In the 8-mm and 12-mm diameter Omnilink stent (Figure 4K), there was a significant progressive enlargement of the stent strut mesh opening, with a change of shape from triangular to circular. The 12-mm stent was created from a 10-mm Omnilink by overdilatation with a 12-mm balloon inside a 12-mm tube at 10 ATM. With overdilatation, there was a change of the stent strut design, from a more intercalated design to more rectangular design, allowing easier entry into the strut mesh opening with the guidewire and catheter (Figure 6). In the 6-mm and 8-mm balloons, the strut mesh opening responded
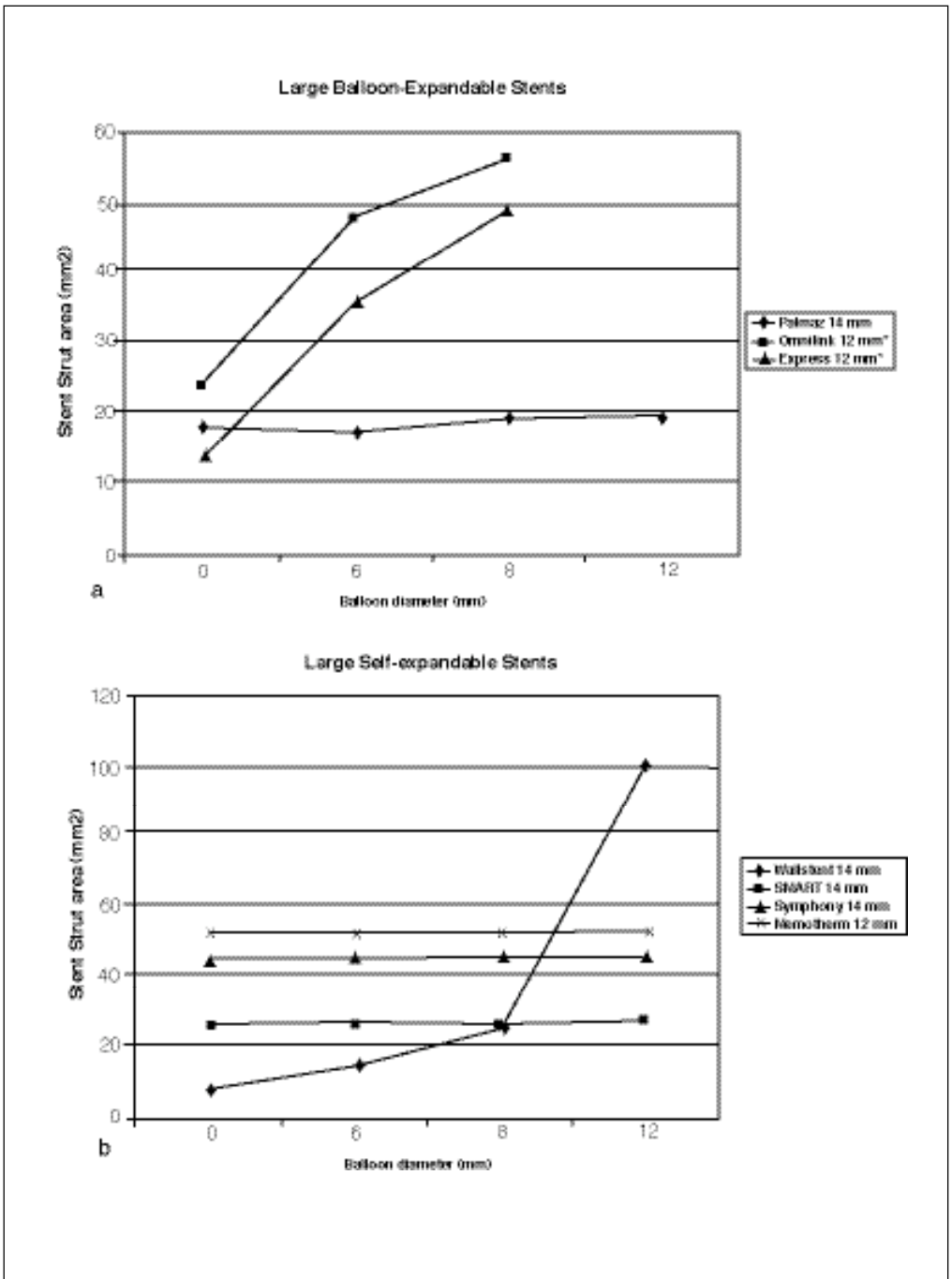
Figure 2. Comparison of the changes in the dilated mesh opening area after varying sizes of balloon dilation in the large-stent group.

with progressive spherical enlargement (Figure 4L).

There was progressive spherical enlargement with the 8-mm Express stent.

The 10-mm Express stent dilated to 12 mm with a 12-mm balloon at 10 ATM within a 12-mm tube. As with the Omnilink, overdilatation produced flattening of the tandem
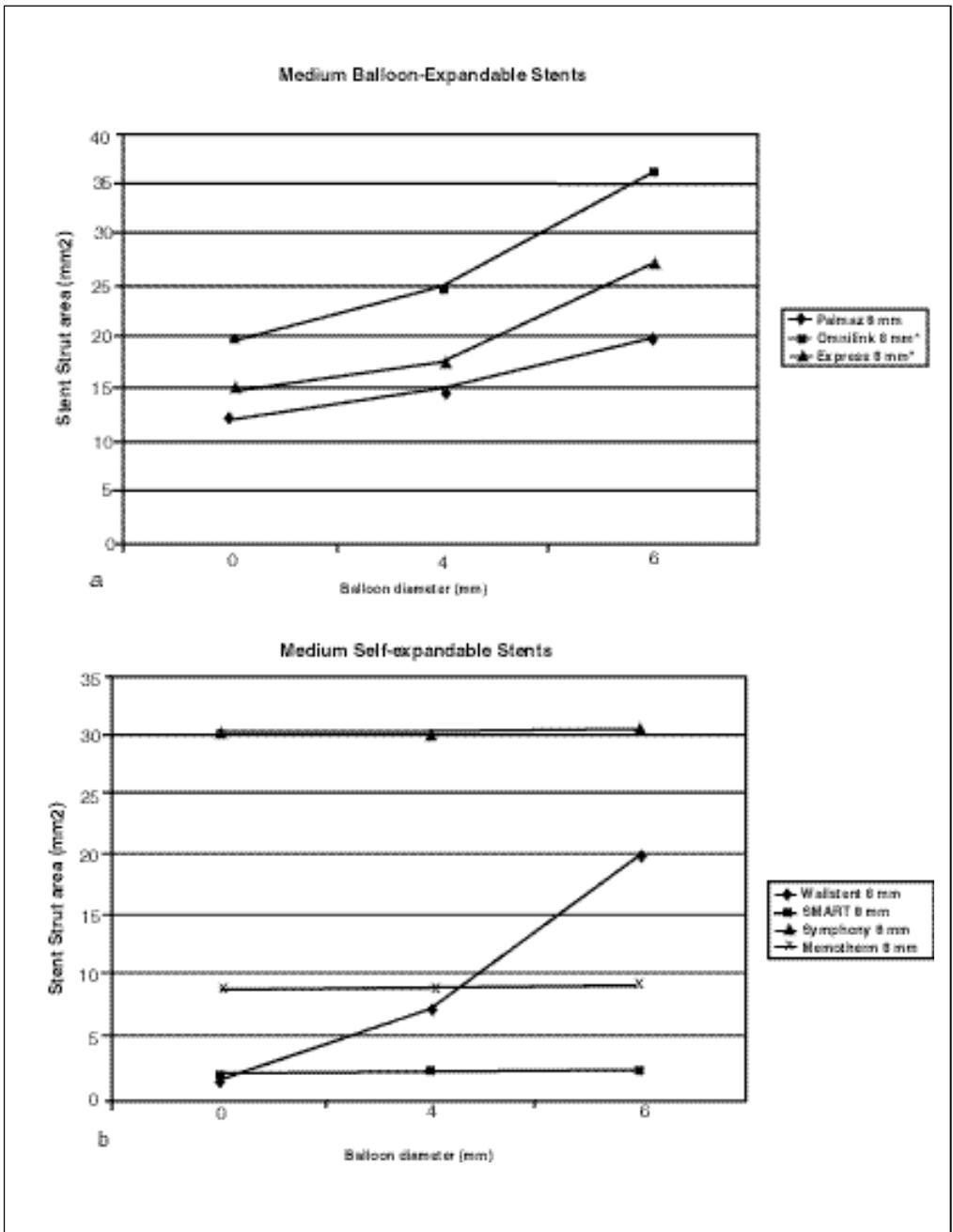
Figure 3. Comparison of the changes in the dilated mesh opening area after varying sizes of balloon dilatation in the medium-stent group.

architectural design to a more rectangular conformation (Figure 4M). The 12-mm Express stent responded to the dilation of the strut mesh opening with progressive spherical enlargement (Figure 4N).

DISCUSSION

Metallic stents have been used to treat various vascular abnormalities in both the coronary and peripheral vasculatures. The problem of impaired flow to side branches
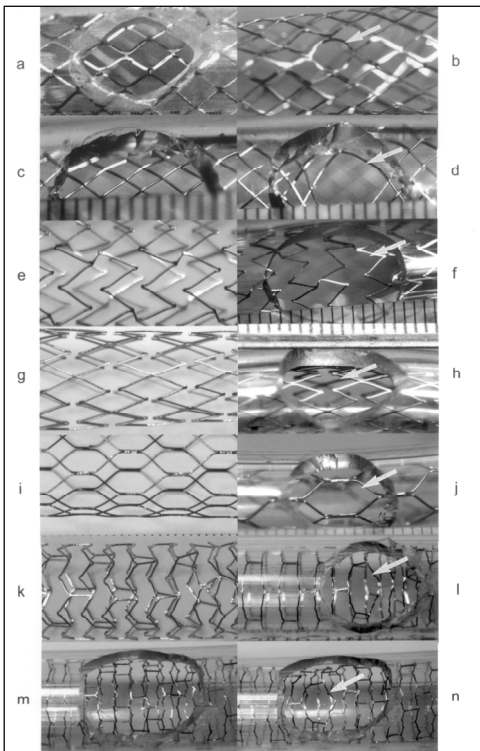
Figure 4 A-N. Photographs of the configuration of stent mesh opening. Palmaz, pre (A) and post (B) side-branch creation by balloon dilatation, demonstrating minimal deformation and without significant enlargement of the strut mesh diameter. Wallstent, pre (C) and post (D) side branch creation, showing a significant enlargement of mesh opening after ballooning. Smart, pre (E) and post (F), Memotherm, pre (G) and post (H), and Symphony, pre- (I) and post (J), with no response in shape or lumen to balloon dilatation of the side strut mesh opening. Omnilink pre (K) and post (L) and Express pre (M) and post (N) both demonstrated progressive spherical enlargement of the stent strut mesh opening with increasing balloon diameters. Note area of interest, indicated with arrow.

covered by the primary stent has been demonstrated in coronary circulation. Investigators have employed balloon dilation through the stent strut covering the ostium of side branch as a method of treating such compromised side-branch vessels.[4-7] Problems after balloon dilation through stent strut opening covering the side-branch ostium of coronary stent have been reported in the literature. These problems include balloon entrapment between

the stent strut,[8] as well as stent deformity with and without some degree of stenosis within the stent.[4-6] Baldus et al have designed a new balloon-expandable side-branch stent with larger cells in the center of the stent for the facilitation of angioplasty and stenting of side-branch stenosis in coronary lesions.[9] Balloon dilation and stenting through the stent strut mesh opening covering side-branch ostium has only been reported and approved for compromised side branches of coronary lesions. In our general practice, we also encounter the same situation in the peripheral vasculature. Potential problems with side-branch covering include covering of the hypogastric artery during iliac stenting, covering of the major venous confluences during SVC stenting, covering of the hepatic veins during IVC stenting, accidental covering of the contralateral iliac during iliac stenting, and in the biliary system with hilar stricture of the biliary system with stent covering of the contralateral hepatic duct. Although in most cases covering these side branches has no significant immediate sequela, the side branches may develop compromised flow and thrombosis. The stents for peripheral and central vasculatures have different properties than coronary stents, including the diameter of stent, size of stent strut mesh openings, configuration of the mesh, and mechanical response of the stent to balloon dilatation. We investigated the effects of dilatation through the strut mesh opening in 6 stent designs that we currently use for peripheral and central vascular lesions.

The Wallstent is composed of Elgiloy, a metal alloy woven into a criss-cross pattern to form a tubular braid configuration. This braided design provides high compliance and radial strength. In both the small- and large-diameter Wallstents, there was significant expansion of the mesh opening of the stent and minimal shape distortion after serial balloon dilatation. Balloon angioplasty through the stent strut mesh opening resulted in displacement of the struts. This overlap of the struts near the area of dilata-
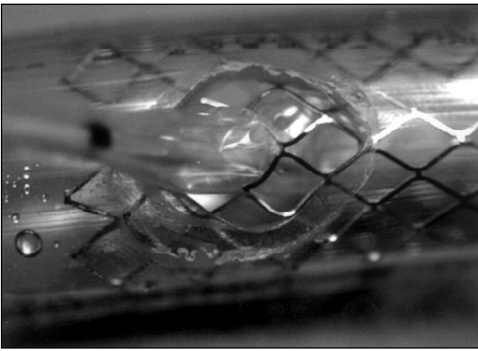
Figure 5. Balloon rupture and entrapment within the stent strut mesh opening of the Palmaz stent after dilatation.
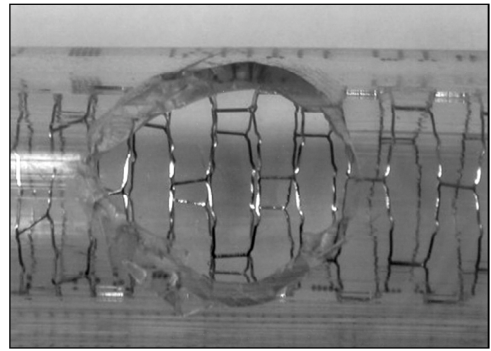

Figure 6. Flattening of the intercalated design to more rectangular design after 2-mm overdilatation of the Omnilink.

tion maintained the dilated lumen and conformed to the spherical shape/size of the balloon.

The Palmaz stent is made of biocompatible 316L stainless steel, laser cut with closed-cell geometric design, forming a repeating diamond configuration. Due to the hexagonal cell construction of the Palmaz[10] stent strut opening, balloon rupture and entrapment occurred when expanding the 8-mm and 12-mm balloon through the stent strut of the 14-mm diameter Palmaz stent. In the 8-mm diameter Palmaz stent, there was progressive shape distortion from hexagonal to circular with the 4-mm and 6-mm balloons but without significant increase in overall diameter; there was also balloon entrapment within the stent strut with larger balloon diameter. These results corroborate the potential risk of balloon rupture and entrapment when dilating through the strut mesh opening of the Palmaz stent.[8]

The Express is a laser cut, stainless steel, balloon expandable stent incorporating Tandem Architecture™ system, which integrates wide Macro™ elements for radial strength and Micro™ elements for increased conformability. The Express can be overdilated by 1 mm to 2 mm with minimal sacrifice in radial strength. With overdilatation of the stent the struts open to a more rectangular configuration, making it more amenable to side-strut access for dilatation.

In both sizes, the Express demonstrated malleability, conforming to the shape of the balloon with progressive dilatation of the side-strut mesh opening.

The Omnilink, is a laser-cut, 316L stainless steel balloon expandable stent. The stent has a dense scaffolding pattern providing little unsupported surface area. The stent can be overdilated to provide greater diameter to the strut mesh opening and the 10-mm Omnilink dilated to 12 mm allowed easy access through the stent strut. The 8-mm Omnilink responded well to dilatation with progressive spherical enlargement. The stainless steel core of the stent was also malleable, with balloon expansion through the strut mesh opening, providing progressive increasing dilatation of the stent through the strut.The Symphony stent is a self-expanding hexagonal designed nickel-titanium alloy stent. The Symphony expands to the unconstrained diameter when exposed to body temperature. The large strut mesh opening of the Symphony stent demonstrated no deformity with side-branch dilatation in both the 8-mm and 14-mm stents.

The SMART stent is laser cut from a Nitinol alloy of nickel and titanium. The struts are hexagonal and connected through articulations, which provide shape memory and spring-like recoverability. In the 14-mm SMART stent, there was no alteration in size or shape distortion of the stent strut

mesh opening with the 6-mm and 8-mm balloon. After applying the largest (12-mm) balloon, one of the SMART stent joints disarticulated but with minimal over-all shape deformity. No changes were also observed in the 9-mm SMART stent.

The Memotherm stent has similar properties to the SMART stent. The Memotherm stent is self-expandable and composed of a biocompatible Nitinol mem-ory metal laser cut into a diamond shape. We observed no change in size or shape of the stent strut mesh opening of the 12-mm Memotherm stents until separation of 1 joint occurred after dilatation using the largest balloon. The basic design of the mesh of the SMART and Memotherm stent is very similar. The triangular configura-tions of the struts with articulations between the rows of the struts resulted in minimal change in the shape or size of the strut mesh opening after balloon dilatation, suggesting they may not respond to side-branch dilatation.

CONCLUSIONS

In our study of the self-expandable stents, the Wallstent demonstrated the most signif-icant increase in side-branch size and was the most appropriate self-expandable stent designs for balloon dilatation through the stent strut mesh opening covering the side-branch ostium. The Wallstent was the most conforming of the stents and demonstrated appropriate distortion to theoretically main-tain side-branch patency after angioplasty through the stent strut mesh opening. Due to the minimal size increment in the mesh opening of SMART and Memotherm stents, they appear not to respond to side-branch dilatation required for side-branch protec-tion. Of the balloon expandable stents, the Omnilink and the Express stents demon-strated malleability, making it possible to perform to adequate side-branch dilatation. Also, overdilatation of the Omnilink and Express appears to facilitate access to the side branch. With the Palmaz stent, balloon rupture and entrapment are real potential complications and side-branch dilation should be avoided. Further trials will be needed to corroborate the relevance of these results in vivo.

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