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Advanced Bifurcation Systems' mother-daughter platform

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This paper also includes accompanying supplementary data published at the following website: www.eurointervention.org

Description of the device and methodology

The Advanced Bifurcation Systems (ABS Los Angeles, CA, USA) line of modular bifurcation systems is a novel stent platform designed to uniformly mould all coronary bifurcations regardless of angles and sizes in a simple, intuitive procedure. Orientation and alignment of main branch (mother) and side branch (daughter) segments is automatic with complete tissue coverage, evenly conforming to the anatomy without overlapping stent struts, while providing continuous side branch access. The ABS line of devices consist of a modular, dual-catheter, independently movable positioning system (currently 7 Fr) for complete multi-branch as well as provisional side branch stenting.

The full bifurcation stenting system (MD-BI) consists of two balloon catheters, mother-daughter balloon catheter and daughter balloon catheter and two stents, mother-daughter stent and daughter stent. The mother-daughter balloon catheter (MDC) has a mother-daughter stent (MDS) with an aperture through which the daughter balloon catheter (DC) extrudes and leads the system. The MDS is fully circumferentially (360 degrees) crimped on the MDC, only distal to this aperture. The MDS is only partially crimped proximal to the aperture in such a fashion that the shaft of the DC can slide back and forth. In other words, the MDS is only partially longitudinally and circumferentially crimped on its delivery balloon in different segments. The daughter balloon catheter has a stent mounted only on the distal half. Additionally, the mother balloon catheter has a "sleeve" proximally through which the daughter catheter is loaded. This sleeve ensures the coaxial movement of the mother and daughter catheters. The daughter catheter leads the system by a few centimetres. A clip placed at the proximal hub of the two catheters allows for simultaneous or independent movement of the catheters. After predilatation, the system is loaded on the two wires (main and side branch wires) and advanced until it reaches the carina at which point it can not be advanced any further. The DC balloon, which now is in the daughter vessel, is pulled back, while the MDC balloon is held in place. Pull-back is completed when the proximal half of the DC is in the proximal segment of the MDS and the two proximal balloon markers are aligned next to each other. The DS, which is on the distal half of the DC balloon, is now abutting the mother stent, and a bifurcating stent is assembled on the site. The DC balloon is then inflated first, which simultaneously deploys the proximal segment of the MDS, as well as the DS, thus ensuring perfect alignment of the two stents and proper orientation of the proximal segment of the MDS. This automatic alignment is accomplished using the only fixed (non-variable) structure in any bifurcation, namely the carina. This simultaneous deployment and alignment also ensures full tissue coverage. The MDC balloon is inflated next followed by kissing inflation. The sequences of system deployment is shown in Figures 1A, 1B.

The diameter sizing of the system is based on the equation governing the sizes of branching arteries according to the concept of pseudo-fractals known as the Finet's law. This states that the diameter of a mother vessel is 0.678 times of the sum of the two daughter branches: $M = 0.678 (D_1+D_2)$.

The provisional side branch stenting (MD-P) device has a shorter balloon on the DC and does not have a stent mounted on it. The deployment method is otherwise similar.

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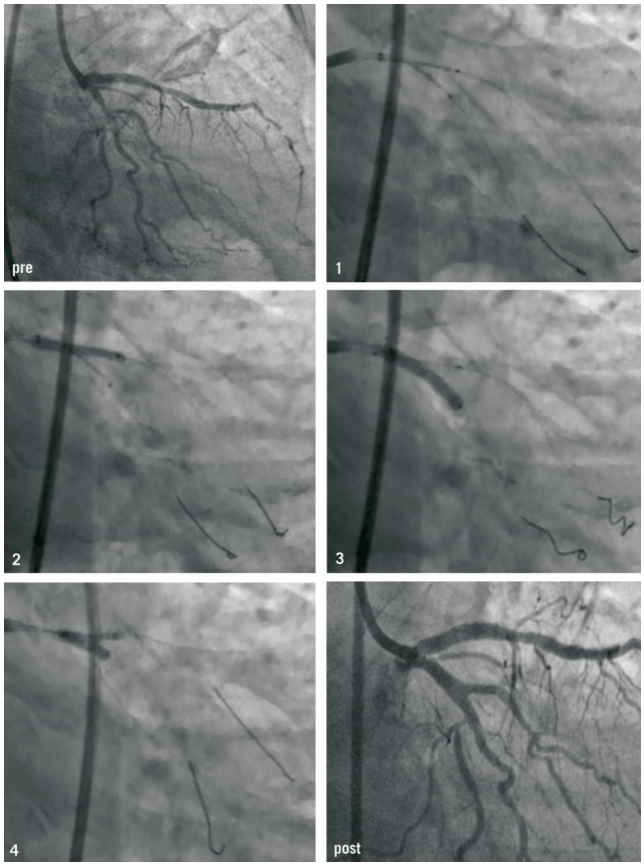

Figure 1A. Deployment sequence (left circumflex / obtuse marginal bifurcation). 1) System assembly at the carina; 2) Daughter balloon inflation; 3) Mother balloon inflation; 4) Kissing inflation.

History

Treatment of coronary bifurcations has posed significant challenges in interventional cardiology. Cylindrical stents designed to address arterial disease in linear segments are not suited for coverage of bifurcations which require addressing a third-dimension, not coaxial with the delivery catheters. Current techniques employing these stents are limited by a gap in tissue coverage or excessive metal coverage, as well as potential loss of side branch access during the implantation. Heterogeneity of bifurcation disease in terms of angles, sizes and plaque location has posed additional difficulty for development of dedicated bifurcation stenting technologies.

Dedicated bifurcation stent systems are either main branch stents for provisional side branch stenting, or side branch stents only. They are limited by one or more of the following: 1) proper positioning / alignment; 2) inadequate or excessive tissue coverage; 3) guaranteed guidewire access; 4) guidewire wrap; 5) requirement for additional stents; and, 6) additional step for final kiss. After deployment, they all require multiple additional devices and sequences for complete treatment of the lesion. A simple and effective bifurcation system that reproducibly permits stenting in any anatomic circumstance would be of clinical importance.

The ABS modular bifurcation system (Advanced Bifurcation Systems, Los Angeles, CA, USA) is designed to ensure automatic alignment of

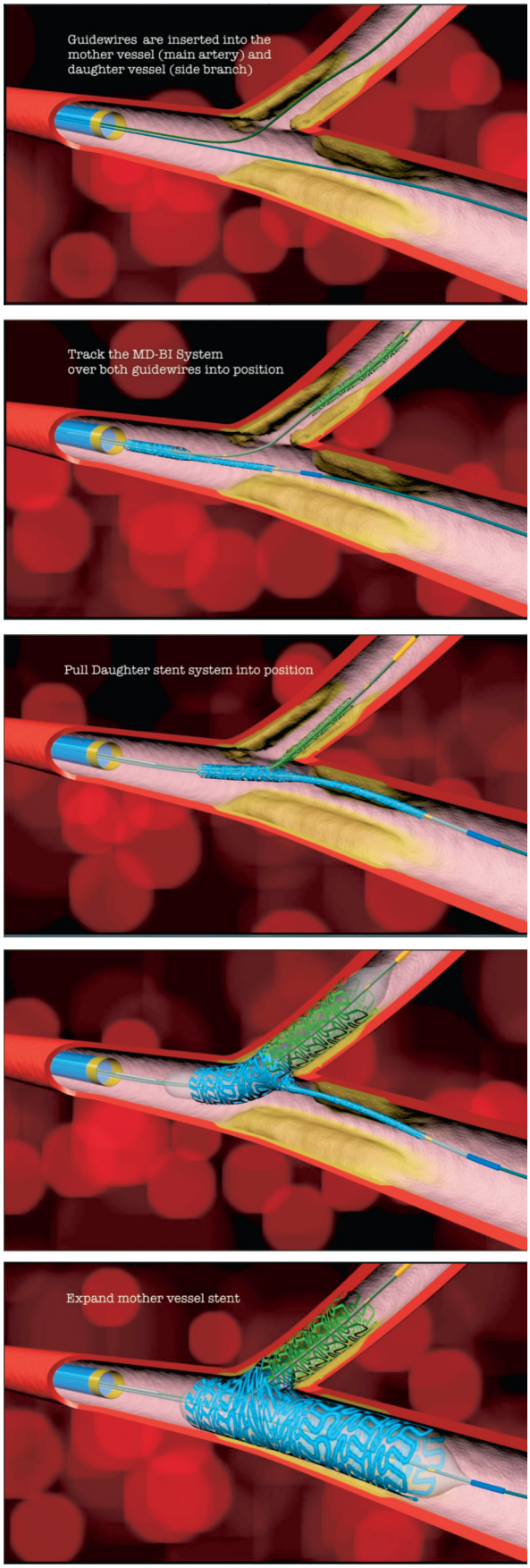

Figure 1B. Schematic of deployment sequence.

the mother (main branch) and daughter (side branch) stents with complete tissue coverage, as well as guaranteed side branch access, without the requirement of additional devices for conclusion of the procedure. We present the first human implantations and early follow-up of this unique complete bifurcation platform.

This platform addresses all bifurcation scenarios. The system is based on the concept of a mother vessel branching into two daughter vessels and the anatomic and physiologic concept of "pseudo-fractal" properties of arterial trees. This platform encompasses a complete line of products covering the entire range of bifurcation treatments including complete bifurcation stenting (MD-BI), provisional side branch stenting (MD-P), ostial side branch stenting (MD-O) and a dedicated left main system (MD-LM).

Technical specifications

ABS devices consist of a mother-daughter stent (MDS) on an over-the-wire balloon catheter (MDC) and a daughter stent (DS) on a monorail catheter (DC). The system is loaded on two wires and advanced until it reaches the carina. The leading DC is then pulled back into the MDS so that the proximal markers of the two delivery balloons are aligned. The bifurcation stent is now assembled at the carina. The DC balloon is inflated first. This inflation partially deploys and rotates the proximal segment of the MDS to align with the daughter vessel automatically. It simultaneously deploys the DS. The MDC balloon is then inflated to deploy the MDS. Kissing balloon inflation fully deploys the system. Note that the two balloon segments in the mother vessel are always co-axial and can not wrap around each other, as they may with current kissing techniques.

The MDS is 18 mm in length while the DS stent is 8 mm. The delivery balloon of the MDS is the same length as the stent. The delivery balloon of the DS is twice the length of the DS. The DS is mounted on the distal half of the DC.

The current sizes for the system are 3.0-3.5 mm for the MDS and 2.5-3.5 mm for the DS. The system is available in all combinations of the above sizes.

Indications for use

The ABS system is indicated for all coronary bifurcation lesions where the side branch is 2 mm or larger in diameter.

Tips and tricks for delivery

The ABS platform is simply applicable. The daughter catheter is rapid exchange and the mother catheter is over-the-wire to minimise the chances of wire-wrap. The system can be loaded on the daughter catheter first and advanced to the point where the DC is in the coronary artery and the MDC is just proximal to the tip of the guide catheter. The mother vessel can then be wired through the over-the-wire lumen of the mother catheter to avoid wire-wrap. The hybrid monorail / over-the-wire system reduces the chances of wire-wrap and permits easier handling of the device. The system advances smoothly since it is tracked over two wires. The leading ultra-low profile daughter catheter facilitates the advancement and delivery as well.

(Pre)-clinical experience

Bench testing

Extensive bench testing has been done in a variety of models and phantoms with different sizes and angles. Proper deployment and coverage has been validated visually under high magnification as well as fluoroscopically with simulated angiograms.

Animal study

The ABS System was implanted in two sets of acute as well as chronic porcine implant models. In the acute study, the animals underwent up to three implants each (Figure 2). Their hearts were studied for implant characteristics. Forty-five day follow-up angiogram was performed in the chronic implants. Euthanised pigs had bifurcation stents in the LCx/OM, LAD/ Diag, and PDA/PLB. Device sizes ranged 3.0-3.5 mm/2.5-3.0 mm. Visual inspection showed well-apposed stents with complete coverage of the carina. Survival pigs had bifurcation stents in the LCx/ OM with a device size of 3.0/3.0 mm. Forty-five day angiograms revealed moderate restenosis in the body of the daughter branches of two pigs. No restenosis was noted in the mother vessel or the carina in any of the pigs.

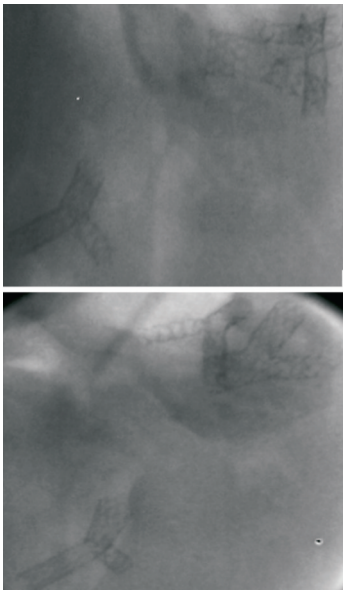

Figure 2. Porcine heart with three bifurcation stents.

Human study

Patients with de novo bifurcation lesions were enrolled in this pilot, non-randomised, multicentre trial evaluating the safety, technical feasibility, and acute efficacy of the ABS platform. The primary endpoint is 30-day composite MACE (death, MI, and target vessel revascularisation). Secondary endpoints are procedural success and safety at six months. Angiographic follow-up is planned at six months to assess restenosis at the target lesions.

Preliminarily results are available for 10 patients. The ABS full bifurcation stenting system (MD-BI) was deployed in the following bifurcations (seven so far): LAD- Diag (n=2), LCx-OM (n=3), and PDA-PLB (n=2) (Figure 3). The provisional system (MD-P) has been deployed in three patients so far. All lesions were Medina 1, 1, 1.

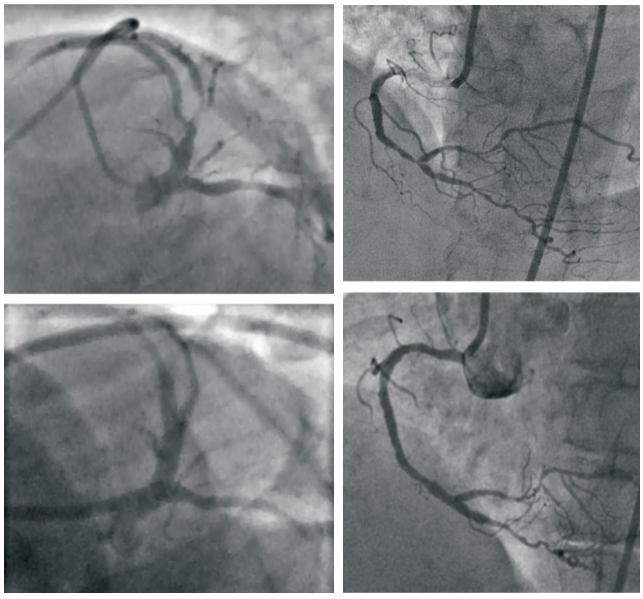

Figure 3. Pre- and post- angiographic results. Proximal LAD - Diagonal

Average patient age was 55. The 30-day composite MACE was 0%. Delivery rate and procedural success and was 100%, and there was no residual stenosis by IVUS (Figure 4), which revealed good stent apposition with complete coverage of the vessel carina. Six month composite MACE as well as TVR has remained 0%. All patients are free of angina. Angiographic follow-up to date has been completed in four patients and has revealed edge restenosis in two side branch vessels only (Table 1).

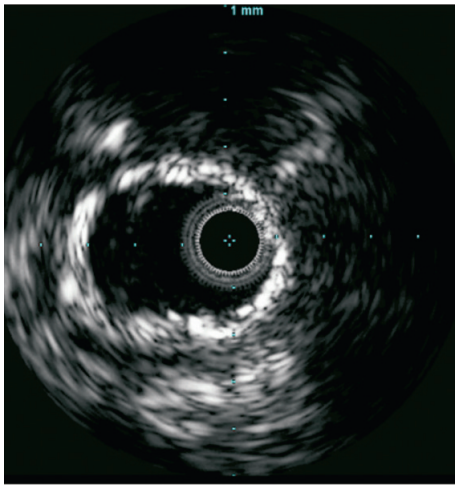

Figure 4. IVUS of the mother vessel.

Table 1. Primary and secondary endpoints.

30-day MACE	
Death	0%
MI	0%
TVR	0%
6-month MACE	
Death	0%
MI	0%
TVR	0%
Restenosis	
M1	0/10
Carina	0/10
D1	1/10
D2	1/10

Conclusion

This is the first report of a truly modular system which leads to assembly of a bifurcating stent at the carina. This platform has addressed the shortcomings of all side-hole stents concerning proper positioning and orientation. The platform also lends itself to provisional side branch stenting in a fashion that, should the side branch require a subsequent stent, the positioning would be done in such a way that there would be no gap in tissue coverage. Additionally, the hybrid monorail / over-the-wire system mitigates wire-wrap. The two catheter components of this system can be moved independently or simultaneously. Consequently, the system can be advanced according to the operator's preference for the anatomy and location of the bifurcating lesion, hence ensuring delivery. This intuitive dedicated system not only simplifies bifurcation stenting as compared to the traditional culotte, crush and provisional-T techniques, but also leads to proper tissue coverage in a shorter procedure time, requiring fewer additional devices.

In summary, the ABS System is a novel stent platform designed to reproducibly permit stenting in bifurcation lesions regardless of branch angulation. This first-in-human implant study provides preliminary evidence of feasibility and short-term efficacy. Additional long-term and larger scale studies are needed to further validate this unique device.