

Coronary Artery Bifurcation Disease

Treating native coronary artery bifurcation stenoses with the Devax Axxess dedicated bifurcation stent.

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Coronary bifurcation lesions are generally considered some of the most complex lesions to be treated with percutaneous coronary intervention and are frequently associated with greater acute and late complications.¹ Despite improvements in technique and technology, many questions remain regarding the optimal treatment for bifurcation disease. Unfortunately, smaller studies and the absence of large-scale randomized trials have left the treatment of bifurcation disease with more questions than answers.

Bifurcation lesions are often defined as involving a branch vessel ≥ 2.25 mm arising from a main vessel.² Patterns of bifurcation disease are also defined and classified according to the location (main branch only, side branch only, or both main vessel and side branch).³

CURRENT TECHNOLOGY

Current technology and techniques are flawed and continue to produce challenges. Techniques for modifying plaque in bifurcation treatment have not demonstrated a benefit in randomized trials.⁴ Restenosis rates with bare-metal stenting have been reported as high as 40% (mainly involving the ostium of the side branch).⁵ With the advent of drug-eluting stents, there are concerns of both safety and efficacy.⁶ Furthermore, there is little consensus on the type of bifurcation technique to use (eg, crush, culotte, T-stent, Y-technique).⁷⁻⁹ These techniques require *in situ* distortion of stent geometry and result in poor stent apposition, multiple stents, multiple layers of stent, poor side-branch coverage, and strut overhang into vessels. Today, many operators prefer stenting the main branch with a drug-eluting stent, with provisional stenting of the side branch if a suboptimal balloon angioplasty result is present.

Many novel technologies are being evaluated to aid in the treatment of this complex lesion subset.¹⁰ Modification of stent design will likely play an important role in the treatment of bifurcation disease. Most newer

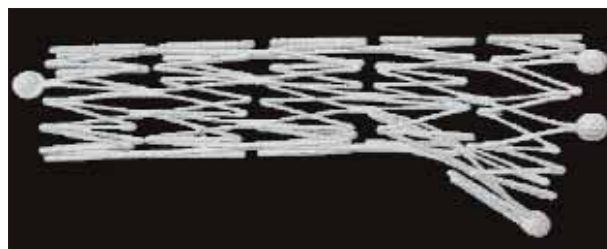


Figure 1. The Devax Axxess Stent (Devax, Inc., Irvine, CA) has three radiopaque markers distally and one proximal marker.

devices are grouped into classes, the first of which includes provisional bifurcation devices that stent the main vessel first. Access to the side branch is maintained if further intervention is needed. Another class of dedicated devices includes those that treat both the main vessel and the side branch. In addition are dedicated side-branch stents that are designed to treat the side branch first. The Axxess stent is unique in that its conical shape supports the bifurcation at the level of the carina.

We present a patient with bifurcation disease treated with the Axxess drug-eluting stent. This stent is a self-expanding, conical, nitinol stent that conforms to the bifurcation, allowing access to both branches (Figure 1). The stent is coated with parylene and a layer of bioabsorbable polymer containing and controlling the release of the antiproliferative sirolimus analogue, biolimus A9 (Biosensors International, Newport Beach, CA). The advantage of this dedicated bifurcation stent is its ability to expand in both the main vessel and side branch, thus providing complete coverage at the level of the carina (Figure 2) but potentially sparing the flow-divider from coverage. The angle between the branch vessels should be $<60^\circ$. The AXXESS PLUS trial evaluated 139 patients in a controlled, multicenter trial.¹¹ The 6-month MACE (death, Q- and non-Q-wave myocardial infarction, target lesion revascularization) rate was $<10\%$, and a 7% restenosis rate in stented side branches was observed.

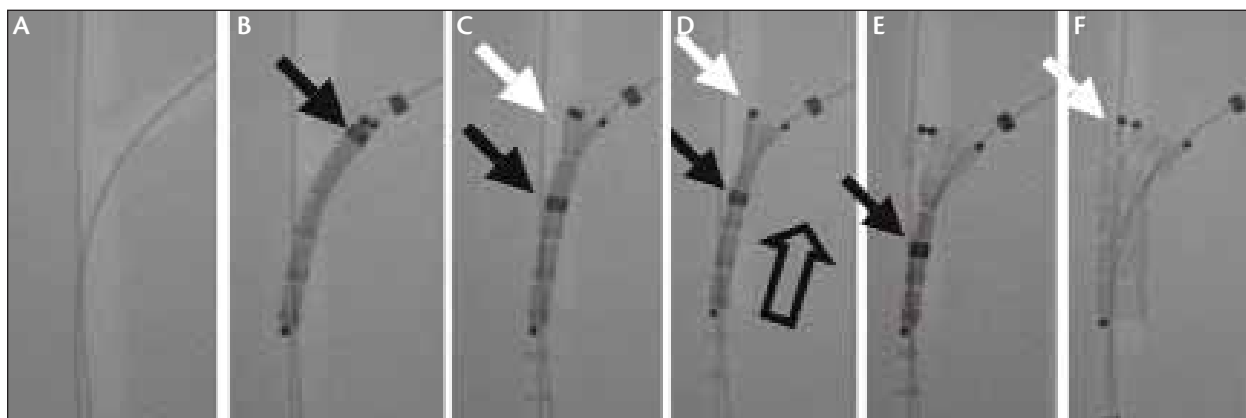


Figure 2. A Devax Axxess stent deployed in silicon phantom bifurcating vessel. Wires are passed to both branches (A), and the lesion is predilated. The Axxess device is advanced to the most angulated branch (B) (black arrow indicating the sheath marker overlying the three distal markers on the stent struts). In C, the sheath has been partially withdrawn, allowing the stent to partially expand distally (white arrow). In D, the entire device has been withdrawn partially into the main vessel so that the struts have expanded into the less-angulated branch; the device is then advanced (open arrow) so that it lies in the bifurcation surrounding the carina (E). The sheath is withdrawn completely (E,F) allowing the device to expand fully. The trapped wire in the straight branch is withdrawn and is readvanced through the stent. Then, kissing postdilatation is carried out.

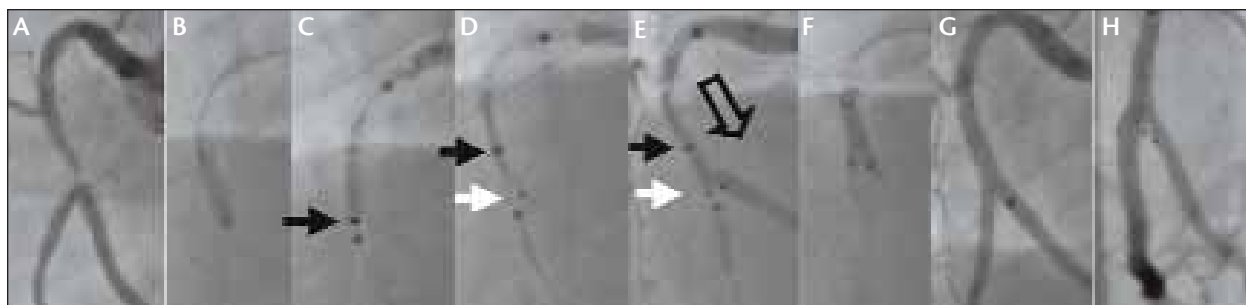


Figure 3. Baseline angiography in our patient using an 8-F guide (A) shows a bifurcation stenosis (Medina classification 1,0,0) stenosis in segment 2 of the right coronary artery, involving an early arising posterior descending coronary artery. After passage of Balance wires (Abbott Vascular, Santa Clara, CA) to both branches, the lesion was predilated (B) with a 3-mm X 12-mm Sprinter balloon (Medtronic, Inc., Minneapolis, MN). The 3.5-mm X 14-mm Axxess device was advanced to the branch that was the most angulated (C). The sheath (black arrows) was partially withdrawn, allowing the distal stent struts to expand into both branches (white arrow) (C,D). The device was advanced (open arrow) so that the distal markers surrounded the carina (E). Simultaneous kissing-balloon postdilatation (3-mm X 12-mm and 2.5-mm X 12-mm Maverick balloons) inflated to 10 atm (F). Final angiography in the left anterior (G) and right anterior (H) oblique projections shows an excellent result. There were no adverse events during the hospital admission.

CASE REPORT

A 67-year-old woman without a history of cardiac disease who presented acutely with evidence of an inferior wall myocardial infarction had successful reperfusion with thrombolytic therapy. Coronary angiography 2 days later showed a critical bifurcation stenosis (Medina classification 1,0,0) in segment 2 of the right coronary artery (Figure 3) involving a major branch vessel of >2.25 mm. Informed consent was obtained for enrollment into the DIVERGE trial, and 2 days later, she returned for percutaneous coronary intervention. The DIVERGE trial is an international, multicenter, single-arm study enrolling 300 patients with the Axxess stent. The study is designed to evaluate the

angiographic and IVUS outcomes at 9-month follow-up, as well as the long-term clinical safety of the Axxess stent system when used to treat a broad spectrum of bifurcation lesions. The steps in the deployment of this patient's Axxess stent and angiograms are summarized in Figure 3.

The patient was discharged on the antiplatelet treatment of aspirin and clopidogrel 75 mg daily for 6 months, as required by the DIVERGE trial. She returned several weeks early for protocol-mandated 9-month angiographic follow-up complaining of angina. Angiography showed continued success at the stented site (Figure 4). She had successful stenting of a new lesion in the left circumflex coronary artery and subsequently remains asymptomatic.

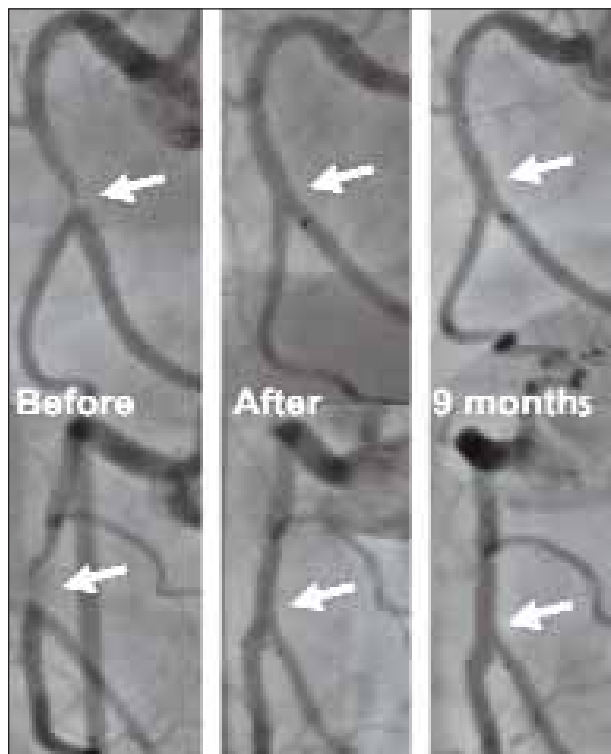


Figure 4. Right coronary angiography in the left anterior oblique projection (upper panels) and in the right anterior oblique projection (lower panels) before and after Axxess stent deployment and at 9-month follow-up showing a sustained excellent angiographic result.

DISCUSSION

We describe a patient with successful treatment of a right coronary artery bifurcation stenosis with an Axxess stent as part of the DIVERGE trial. The excellent immediate angiographic result achieved without additional stenting, was sustained at 9 months.

Provisional side-branch stenting is an option for treatment of bifurcation disease. With conventional stents, if delivery of an additional stent is needed to the side branch, it is technically challenging because the stent needs to be delivered through struts of the main-branch stent, leading to many of the issues previously discussed. With dedicated bifurcation stent technology, such as the Axxess stent, it is technically straightforward to deliver additional stents because they are placed at the distal end of the stent rather than through the side of the stent.

A conclusion of the randomized Nordic trial¹² was that using a conventional sirolimus-eluting stent, a simple strategy of stenting the main vessel and optional stenting of the side branch compared with elective stenting of both branches, was associated with reduced procedural and fluoroscopy times and significantly reduced the risk of proce-

dures-related biomarker elevation and can be recommended as a routine bifurcation stenting strategy. However, the Nordic trial is a trial of bifurcations with small side branches, with the mean side branch diameter of lesions randomized measuring <2.3 mm. The findings may not apply to bifurcations with large side branches. As shown in our case, the Axxess stent allows the strategy of safe provisional side-branch stenting of even large side branches.

Limitations of the Axxess stent may be that an 8-F guide catheter is needed. In addition, most patients need additional stents for complete treatment in cases in which the lesion spreads beyond the level of the carina into the distal parent vessel or the side branch.

CONCLUSION

Treatment of bifurcation disease remains a clinical challenge for the interventional cardiologist. There are many limitations to current techniques with conventional stents for the treatment of bifurcations. Newer technologies are promising and should help with the treatment of this difficult patient population. ■

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