

Percutaneous Coronary Intervention for Bifurcation Disease

Current techniques and future technologies.

BY GERALD YONG, MBBS (Hons), FRACP, AND TIMOTHY A. SANBORN, MD

Bifurcation disease accounts for up to 15% of all coronary disease treated by percutaneous coronary intervention (PCI).^{1,2} It represents one of the most difficult technical challenges in PCI and remains a common reason for referral to coronary artery bypass grafting. In a review of one surgical revascularization series, bifurcation disease is a reason for referral to surgery in 38% of cases.³

Several registries have shown that PCI for bifurcation disease fares worse than for nonbifurcation disease in both immediate procedural and long-term outcomes. In the NHLBI Dynamic Registry in the late 1990s, PCI for bifurcation disease is associated with a 50% increase in in-hospital myocardial infarction and a lower angiographic success rate of 86% compared to 94% with nonbifurcation disease.¹ In longer-term follow-up, PCI for bifurcation disease, compared to nonbifurcation disease, is associated with a higher 9-month incidence of major adverse cardiac events (MACE) driven by higher target lesion revascularization (TLR) rates and higher binary restenosis rates.^{1,2} The presence of a bifurcation lesion is also associated with an increased risk of stent thrombosis. Two case-controlled studies in the drug-eluting stent (DES) era have shown a four- to sixfold higher prevalence of bifurcation disease in patients with stent thrombosis compared to those without stent thrombosis.^{4,5}

CURRENT INTERVENTIONAL TECHNIQUES FOR BIFURCATION DISEASE

Initial attempts with coronary angioplasty for bifurcation lesions are complicated by a high rate of occlusion of the main vessel or, more commonly, of the side branch.^{6,7} Kissing-balloon dilatations have improved procedural outcomes but are associated with high restenosis rates of 37% to 50%.^{8,9} Coronary stents with their scaf-

folding property have reduced the acute complications of bifurcation angioplasty, especially acute closures. However, long-term outcomes with bare-metal stents (BMSs) are still poor. Restenosis rates have been reported to be as high as 38% in the main vessel and 50% in the side branch.^{10,11} TLR rates have ranged from 18% to 38%.^{2,10}

DESs appear to improve long-term outcomes in bifurcation stenting compared to BMSs, although no direct comparison has been performed. Compared to historical BMS data, DESs have lower rates of restenosis. The incidence of significant side-branch stenosis at follow-up angiography in most series is 10% to 20%, which is an improvement from BMSs.¹¹⁻¹⁶ In a recent retrospective analysis of the ARTS II study, which evaluates the outcome of patients with multivessel disease stented with sirolimus-eluting stents, there is no difference in the 1-year incidence of MACE rates or revascularization rates (9% vs 7.8%) between those with bifurcation disease and those without bifurcation disease.¹⁷

However, even with coronary stents, there remain technical issues of the best approach to treat the bifurcation to achieve optimal procedural outcomes and, more importantly, long-term success with low restenosis rates and low MACE rates. The issues to consider include use of a simple versus complex PCI strategy, type of complex PCI strategy, and final kissing-balloon dilatation.

SIMPLE VERSUS COMPLEX STRATEGY

One debate in PCI for bifurcation disease is whether to adopt a simple strategy of stenting only the main vessel with provisional stenting of the side branch or a more complex strategy of stenting both vessels. The single-vessel strategy typically involves provisional T-stenting with initial dilatation of the main vessel or side branch fol-

TABLE 1. DEDICATED BIFURCATION DEVICES CURRENTLY USED IN HUMANS

Stent	Manufacturer	Guide Size	Description
Stents With Side Ports			
SLK-View	Advanced Stent Technology/ Boston Scientific Corporation	8 F	316L stainless-steel stent with a side aperture located centrally. No scaffold at the side aperture. Balloon delivery system is an over-the-wire catheter with a dual lumen proximal shaft separating distally into a balloon through the entire stent and a side-sheath exiting through the aperture. Radiopaque markers are at the proximal end, distal end, center, and end of the side sheath.
Multilink Frontier	Abbott Vascular	7 F	316L stainless-steel stent with a side portal. Short scaffold covers the side-branch ostium. Radiopaque markers delineate the proximal end, distal end, and location of the side portal. The delivery platform consists of a catheter with dual balloons (a main branch balloon and a short tapered side-branch balloon) connected by a single-inflation lumen and dual-guidewire lumen.
Invatec Twin Rail	Invatec	6 F	316L stainless-steel stent with a side portal. Short scaffold covers the side-branch ostium. The delivery platform consists of a catheter with dual balloons (a main-branch balloon and a full-length side-branch balloon) connected by a single-inflation lumen and dual guidewire lumen.
Nile Croco	Minvasys	6 F	Cobalt chromium stent with a side portal. Short scaffold covers the side-branch ostium. The delivery platform consists of a catheter with two joined but independent balloons, which requires separate inflation.
Petal	Boston Scientific Corporation	7 F	Platinum chromium stent with a side portal. Short scaffold covers the side-branch ostium. The Taxus Petal stent is coated with paclitaxel with nonbioabsorbable translute polymer.
Carina Device			
Axxess-Plus	Devax, Inc.	7 F	Nitinol self-expanding stent with conical shape (larger distal diameter than proximal diameter) coated with biolimus A9 using a bioabsorbable polymer.
Side-Branch Stents			
Tryton	Tryton Medical, Inc.	5 F	Cobalt-chromium stent with three zones: a distal tubular stent zone for stenting the side branch, a deformable transition zone to straddle the ostium, and a proximal main-vessel zone terminating in a circumferential band approximating the diameter of the main vessel through which a routine stent for the main vessel may pass. Mounted on two types of delivery balloons: a tubular 2.5-mm balloon or a tapered 2.5-mm to 3.5-mm balloon. The system tracks over a single guidewire and does not require rotational orientation.
SideGuard	Cappella	6 F	Nitinol self-expanding stent. The self-expanding proximal end is very flexible and designed to naturally conform to the geometry of the bifurcation and side-branch ostium.

lowed by stenting of the main vessel. If there is unsatisfactory result with the side branch after main-vessel stenting, it is rewired and dilated through the struts of the main-vessel stent (preferably with kissing dilatation) and, if still unsatisfactory, stented.¹⁸ Fractional flow reserve assessment of the “jailed side branch” has commonly failed to show functional significance (fractional flow reserve <.75), even in cases where there is a >75% steno-

sis at the ostium of the side branch.¹⁹

Several randomized and nonrandomized studies with BMSs have shown either noninferiority or superiority of a simple strategy compared to complex strategy.^{10,20-22} In the era of DESs, studies have also failed to demonstrate an advantage of more complex double-vessel stenting strategies over a simple provisional T-stenting strategy.^{11,15,23,24} The largest of these is the Nordic Bifurcation Study, which

randomized 413 *de novo* bifurcation lesions (with main vessel ≥ 3 mm and side branch ≥ 2 mm) to a simple strategy or dedicated bifurcation strategy (with mostly the crush or culotte techniques).¹⁵ By protocol, in the simple strategy arm, after stenting the main vessel, the side branch is to be wired and dilated only if there is less than TIMI 3 flow and then stented only if there remains TIMI 0 flow. Dilatation after main-vessel stenting is performed in 32% of these cases, and only a further 4% has required stenting. At 6 months, incidence of stenoses $>50\%$ in the side branch was 11% to 19% and in the main vessel was 2.6%, with no difference between the treatment groups. There is significantly lower contrast load and fluoroscopy time with the simple strategy. An approximately 500-patient trial, known as BBC-1, which has a similar design to the Nordic Bifurcation Study, is currently underway, and the results of these two trials are anticipated to provide firm guidance on an appropriate strategy in PCI for bifurcation disease.

COMPLEX DOUBLE-STENT STRATEGY

There are a variety of double-stent strategies, which are well summarized by Iakovou et al.²⁵ In brief, they include strategies with simultaneous stenting of both main vessel and side branch (simultaneous kissing stents and V-stents), strategies involving stenting the side branch followed by stenting the main vessel (crush technique, T-stents, and modified T-stents), strategies involving stenting the main vessel then stenting the side branch (provisional T-stents and reverse crush), culotte technique, and a variety of Y or "skirt" techniques involving placement of a proximal stent immediately proximal to the bifurcation carina followed by distal stents in the main vessel or side branch, with varying degrees of overlap with the proximal stent.

There are no randomized controlled trials comparing various double-stent strategies. With nonrandomized data, there are suggestions of lower TLR rates with the crush technique compared to T-stenting,¹³ and simultaneous kissing stents have been associated with relatively low TLR rates of 4% to 5%.^{26,27}

FINAL KISSING BALLOON

Final kissing-balloon dilatation involves simultaneous balloon dilatation in the main vessel and side branch as the final step in the procedure of PCI for bifurcation

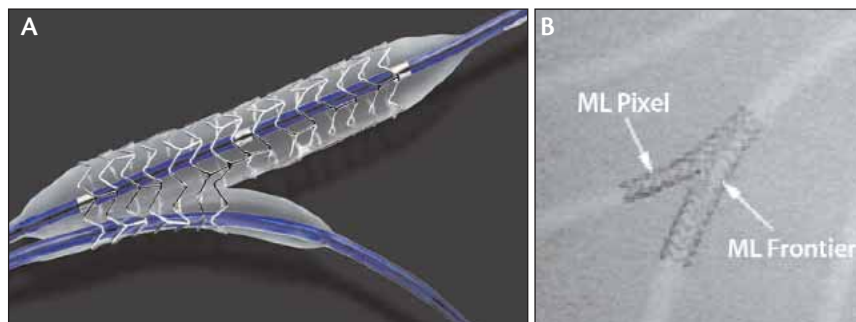


Figure 1. Multilink Frontier Bifurcation stent consisting of a stainless-steel stent with a side portal, having a short scaffold that covers the side-branch ostium. A proprietary 7-F delivery system divides into a main-branch balloon with a short-side branch balloon (A). Once deployed, further stenting into the side branch can be performed distal to the side-portal scaffold (B).

(Courtesy of Abbott Vascular.)

disease. It is increasingly seen as mandatory if the side branch undergoes either balloon angioplasty or stenting after deployment of a main-vessel stent. It is performed as part of the simultaneous stenting strategy in simultaneous kissing stents, V-stents or Y-stents. With a provisional T-stenting technique, after deployment of the main-vessel stent, balloon dilatation through the stent struts has been shown to cause significant stent deformity that may cause restenosis or stent thrombosis, which is at least partially rectified by the kissing balloon.^{28,29} With strategies involving stenting the side branch first (crush or modified T-stent), there is also underexpansion of the side-branch stent near the ostium, which requires kissing-balloon postdeployment of both stents.^{29,30} Absence of final kissing balloon, especially in the crush technique, is associated with increased restenosis and increased need for TLR.^{12,13}

CONSENSUS AND GUIDELINES

Due to the variability of individual bifurcation lesions, there are no guidelines regarding the appropriate strategy for PCI of bifurcation disease. The European Bifurcation Club incorporates a panel of European interventional cardiologists attempting to derive some consensus for the treatment of bifurcation disease. After their first two annual meetings, consensus on the techniques of bifurcation PCI has been reached on the following:^{31,32}

- With BMSs, a stepwise provisional T-stent strategy should be used and is considered the gold standard.
- With DESs, the optimal strategy is under evaluation. This is despite the results of the Nordic Bifurcation Study. The consensus is to await the results of BBC-1.
- After complex stenting, kissing-balloon inflation should be performed.

FUTURE TECHNOLOGY: DEDICATED BIFURCATION DEVICES

Despite advances in PCI technology, problems remain and are associated with PCI of the bifurcation lesion, especially when a complex strategy is adopted. These include:

- Failure to rewire across struts of the main-vessel stents into the side branch to perform kissing dilatation or further stenting as needed. In several series on crush techniques using DESs, the final kissing balloon is only successfully performed in 75% to 90% of cases.^{11,13,14,33}
- High metal burden with either double stent layers (crush, modified T-stent, culotte) or false carina (V-stent or simultaneous kissing stents), which may be a nidus for stent thrombosis.
- Malapposition of the stent (T-stent technique or crush technique without kissing balloon), which may be a nidus for restenosis or thrombosis.
- A relatively high rate of restenosis, especially in the side branch, even with DESs.

Dedicated stents and systems for bifurcation lesions are being designed to address these issues and to reduce the risks of restenosis and thrombosis associated with bifurcation PCI.³⁴ There are currently three forms of designs: stents with side ports, carina devices, and side-branch stents.

At present, there are only two dedicated bifurcation devices with antiproliferative drug coating that have been used in man: the Axxess-Plus stent (Devax Inc., Irvine, CA) coated with biolimus A9 and the Taxus Petal stent (Boston Scientific Corporation, Natick, MA) coated with paclitaxel.

STENTS WITH SIDE PORTS

These are probably the most common designs of current dedicated bifurcation stents (Table 1). They consist of a tubular stent with a side port of varying diameter to facilitate access to the side branch and ease the performance of provisional T stenting. They may or may not include a short scaffold at the side port to provide coverage of the side-branch ostium. The delivery systems consist of a central balloon catheter to deliver the stent for the main vessel and either a side sheath or a balloon for the side branch. There are two wire lumens (through the main balloon and the side-branch sheath/balloon), which allow wiring of both the main vessel and side branch

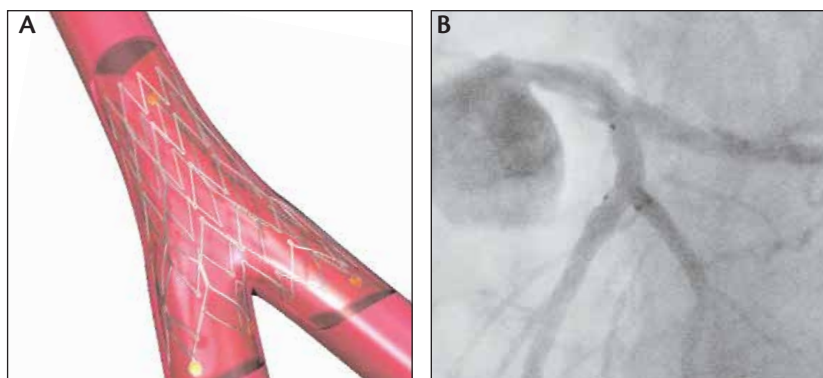


Figure 2. Axxess-Plus stent consisting of a self-expanding stent and distal flare allows the stent to expand into the bifurcation and cover the problematic anatomy at the carina (A). It has three distal markers that clearly show distal stent margin and stent expansion in both branch vessels (B).

(Courtesy of Devax, Inc.)

before deployment of the stent. Some devices have radiopaque markers delineating the site of the side port. Required guiding catheter sizes range from 6 F to 8 F.

Deployment procedures generally involve initial wiring of both the main vessel and the side branch and performance of any necessary predilatations. The bifurcation stent is delivered with the main vessel wire through the main balloon wire lumen and side-branch wire through the side-branch sheath/balloon lumen. The device is delivered in place when a resistance caused by the bifurcation carina is felt, or when the side port marker is over the side branch. Further interventions, including balloon dilatation, kissing balloon, or stenting of the side branch, can be performed through the side port. On the main vessel, further stenting proximal or distal to the bifurcation stent may be performed to cover the length of the main vessel disease.

First-in-man feasibility and safety studies are currently being performed on all stents listed in Table 1. The largest published series on the stents with side ports is the FRONTIER Registry, involving the Multi-Link Frontier Coronary Bifurcation Stent system (Abbott Vascular, Santa Clara, CA) (Figure 1).³⁵ In 105 patients in 11 centers worldwide, procedural success with no main vessel or side-branch stenosis >50% was 93%. The side branch was stented in 43%. At 6-month follow-up, in-stent binary restenosis in the main vessel was 25.3% and in the side branch was 29.1%. The TLR rate at 6 months was 13.3%.

The SLK-View stent (Boston Scientific Corporation) has been reported in feasibility studies with 84 lesions.^{36,37} Procedural success was 94%. At 6 months, restenosis was 28.3% in the main vessel and 37.7% in the side branch, with TLR occurring in 21.3%. The Invatec system (Invatec S.r.l., Roncadelle, Italy) has been reported in preliminary series to have a procedural success rate of 94%, 6-month

(Courtesy of Tryton Medical, Inc., Newton, MA.)

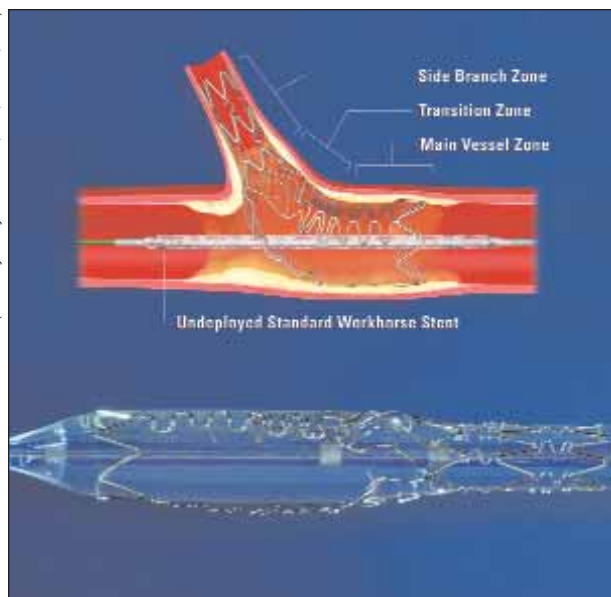


Figure 3. Tryton Side Branch Stent designed to treat the side branch first. A distal tubular stent zone is delivered to the side branch, a transition zone straddles and provides scaffolding to the side-branch ostium, and a proximal zone expanded to the circumference of the main vessel. After deployment, a conventional stent can be deployed through the expanded proximal circumferential band in the main vessel.

overall binary restenosis rate of 33%, with TLR in 19%.³⁴

Drug-eluting platforms are being developed on bifurcation stents with side ports to reduce the incidence of binary restenosis and TLR. Currently, the only such device used in man is the Taxus Petal, with a first-in-man use on July 17, 2007 as the first case in the feasibility and safety study Taxus Petal I FHU.³⁸

CARINA DEVICE

The main carina device used in humans is currently the Axxess system (Figure 2). It consists of a conical-shaped stent with a larger distal diameter than proximal diameter. It is a nitinol, self-expanding stent. The current system, Axxess-Plus, is coated with biolimus A9, using a bioabsorbable polymer. Biolimus is an immunosuppressant with similar action to sirolimus or everolimus by inhibiting mammalian target of rapamycin (mTOR) activity.³⁹ The stent is deployed covering the proximal vessel and the bifurcation with the flared end of the stent at the carina. Further stents to the distal main vessel or to the side branch can be deployed distal to the Axxess-Plus stent (Figure 2).

The Axxess-Plus stent is the only drug-eluting dedicated bifurcation stent currently undergoing extensive

human study. The Axxess-Plus Clinical Study incorporated 132 patients from Europe, South America, and New Zealand, with bifurcation lesions stented with the Axxess-Plus stent.⁴⁰ All patients were stented with the Axxess-Plus stent, with 80.9% having additional stents placed distal to the Axxess-Plus (42% having stents into both the distal main vessel and side branch, 29.4% having stents into the distal main vessel only, and 9.6% with a stent into only the side branch). At 6 months, in-stent restenosis in the main vessel was 7.1% and in the side branch was 13.7%. In the cases where a drug-eluting side-branch stent was deployed, the incidence of side-branch stenosis was 7.9%. The TLR rate at 6 months was 7.5%. A larger, 600 patient, single-arm study, known as DIVERGE, will be performed to further evaluate the safety and efficacy of the Axxess-Plus compared with historical BMS controls.

“Improved outcomes with drug-eluting dedicated devices. . . suggest potential for further improvement by development of drug-eluting platforms. . .”

SIDE-BRANCH STENTS

These dedicated bifurcation devices are stents designed to treat the side branch first, with subsequent deployment of a normal tubular coronary stent in the main vessel. There are currently two such devices used in man: the SideGuard (Cappella Inc., Auburndale, MA) and the Tryton Side Branch Stent.

The Tryton Side Branch Stent (Figure 3) consists of three zones: a distal zone with usual characteristics of a tubular stent, a transition zone that can be deformed to provide radial strength and scaffolding within the ostium of the side branch, and a proximal main-vessel zone that mates with the main-vessel stent and terminates in a circumferential band approximating the diameter of the main vessel. Radiopaque markers on the delivery system delineate the proximal and distal end of the stent and the margins of the transition zone. The stent is deployed with the distal zone in the side branch, the proximal zone in the main vessel, and the transition zone straddling the side-branch ostium. A guidewire is then delivered through the expanded proximal main-vessel zone, and subsequently, a standard stent is deployed in the main vessel through the proximal zone. The TRYTON I study is the first in-man study of the Tryton Side Branch Stent. In 30 patients, the procedural

success rate was 97%, with no major adverse events between discharge and 30 days.⁴¹

CONCLUSION

Bifurcation lesions remain a challenging subset of coronary artery disease for PCI. Improvements in technology, including the use of DESs, have improved long-term outcomes, but there is still significantly increased risk of stent thrombosis and of restenosis involving the side branch. This is potentially due to technological limitations resulting from heavy metal burden, stent deformity, and poor stent apposition. Dedicated bifurcation devices have the potential to improve procedural and long-term outcomes. Currently, with non-drug-eluting dedicated systems, there remains a relatively high restenosis rate of 20% to 30% and TLR rates of 10% to 20%. Improved outcomes with drug-eluting dedicated devices, as seen with the Axxess-Plus Clinical Study, suggest potential for further improvement by development of drug-eluting platforms for the dedicated bifurcation devices. ■

Gerald Yong, MBBS (Hons), FRACP, is from the Cardiology Division at Evanston Hospital in Evanston, Illinois. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Yong may be reached at (847) 570-2000; gyong@enh.org.

Timothy A. Sanborn, MD, is from the Cardiology Division at Evanston Hospital in Evanston, Illinois. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Sanborn may be reached at (847) 570-2250; tsanborn@enh.org.

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