

Assessment With Optical Coherence Tomography of a New Strategy for Bifurcational Lesion Treatment: The Tryton Side-Branch Stent

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The Tryton-Side Branch Stent™ (Tryton Medical, Inc., Newton, MA, USA) is a dedicated stent designed to provide complete carinal coverage of bifurcational lesions. After implantation of a 18 mm cobalt chromium Tryton stent from the left circumflex into the obtuse marginal branch, recrossing with an everolimus eluting Promus stent and final kissing balloon dilatation, optical coherence tomography (OCT) (LightLab Imaging Inc., Westford, MA, USA) was performed with a non-occlusive technique with motorized pullback (3 mm/s) during continuous pump injection of iso-osmolar contrast, in both LCx and OM1. OCT imaging showed good strut apposition at the level of the carina, with full coverage and no stent protrusion at the ostium of the side branch. Few malapposed struts were present in the proximal main vessel in the segment of stent superimposition, with a maximal separation from to the vessel wall of 160 μm. The implantation of the Tryton-Side Branch Stent™ allowed full coverage of the side branch ostium with uniform apposition of the stent struts at the level of the carina assessed by OCT. © 2008 Wiley-Liss, Inc.

Key words: coronary bifurcation lesion; optical coherence tomography; stenting

INTRODUCTION

Stenting of bifurcation lesions with standard “work-horse” drug eluting stents is associated with increased rates of acute complications, stent thrombosis, and restenosis [1,2]. Difficulty with treating bifurcation lesions has led many groups to develop stents specifically designed to treat this lesion subset. The Tryton-Side Branch Stent™ (Tryton Medical, Inc. Newton, MA) is a cobalt chromium slotted tube, balloon expandable stent designed to integrate with a “work-horse” stent to provide complete carinal coverage during stenting of bifurcation lesions (Fig. 1) [3]. We report the first clinical assessment of this approach with optical coherence tomography (OCT).

A 55-year-old female with insulin-dependent diabetes, hypertension, hypercholesterolemia, and history of chronic stable angina was referred for percutaneous coronary intervention (PCI) of a high-grade bifurcation lesion involving the left circumflex (LCx) and the origin of the first obtuse marginal (OM1) (Medina 1.0.1) (Fig. 2) [4]. PCI was performed via a right radial approach through a 7.5 F guiding catheter (“Sheathless” Asahi, Tokyo, Japan). After predilatation, a Tryton Side-Branch Stent (2.5 mm × 18 mm mounted on a stepped balloon stent delivery system) was tracked to the lesion site with the side branch section in the OM1 and the main vessel section extending

proximally into the LCx. The stent was deployed after which the wire originally in the sidebranch (OM1) was repositioned into the distal LCx. A Promus Everolimus-Eluting Coronary Stent (3.5 mm × 18 mm, Boston Scientific Corporation, Natick, USA) was tracked through the proximal portion of the Tryton into the distal LCx. The Promus Stent was then deployed after which the sidebranch was rewired and simultaneous kissing balloon inflation performed (LCx: 3.0 mm × 12 mm balloon and OM1: 2.5 × 9 mm balloon both

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Tryton Side-Branch Stent

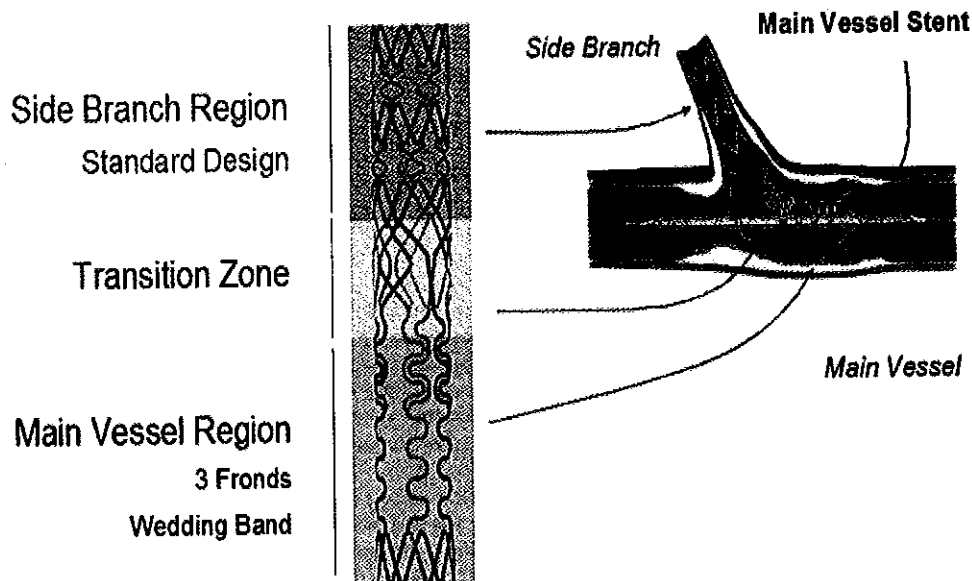


Fig. 1. Schematic of the Tryton Side-Branch Stent, a cobalt chromium slotted tube balloon expandable design (left panel) with three sections: side branch (placed in the side branch), transition (placed across the side branch origin), and main vessel (placed in the main vessel proximal to the side branch ori-

gin). A standard "workhorse" stent has been tracked through the Tryton Stent so that the stent covers the side branch origin and the proximal main vessel segment (right panel). [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Angiographic Evaluation



Fig. 2. Serial coronary angiograms obtained in the right anterior oblique projection demonstrating a left circumflex-obtuse marginal bifurcation. Left-hand panel (pre) was obtained at the start of the procedure. The right-hand panel (post) was obtained after treatment of the lesion using a Tryton-Side Branch Stent in conjunction with a Promus Everolimus-Eluting stent.

inflated to 12 atmospheres), achieving final TIMI 3 flow, without residual stenosis (Fig. 2).

OCT was performed in both the LCx and OM1 branches using the M2X Imaging system & ImageWire (LightLab Imaging Inc., Westford, MA) employing a nonocclusive technique with motorized pullback (3 mm/s) during continuous pump injection of iso-osmo-

lar contrast [5]. OCT images from both LCx and OM1 demonstrated good apposition particularly at the carina as well as throughout the stented segment (Fig. 3). Images obtained during both OM1 and LCx runs demonstrate overlapping stents with separation of 160 μm (Fig. 2 Panels E and e). This separation corresponds to $\sim 170 \mu\text{m}$ combining strut thickness of the Tryton Side-Branch Stent and Promus Everolimus-Eluting Stent [3,6]. Overall strut coverage was uniform with close apposition of struts to the arterial wall. Images with greatest strut-vessel wall separation (150 μm and 130 μm) are shown in Fig. 2 Panels B, b, and D, respectively.

The inability to provide uniform strut coverage to the carinal portion bifurcation lesions with standard stents is thought to be reason for the relatively poor outcomes with two stent techniques, e.g., crush, culotte, "T" stent, etc [7]. This OCT evaluation of the Tryton Side-Branch Stent deployed with a "workhorse" drug-eluting stent demonstrates the uniform coverage and strut apposition similar to what has been observed in straight segments following single stent placement. Early experience employing the Tryton strategy for the treatment of bifurcation lesions have yielded very encouraging results with 3% target lesion revascularization (late loss = 0.17 mm) without any

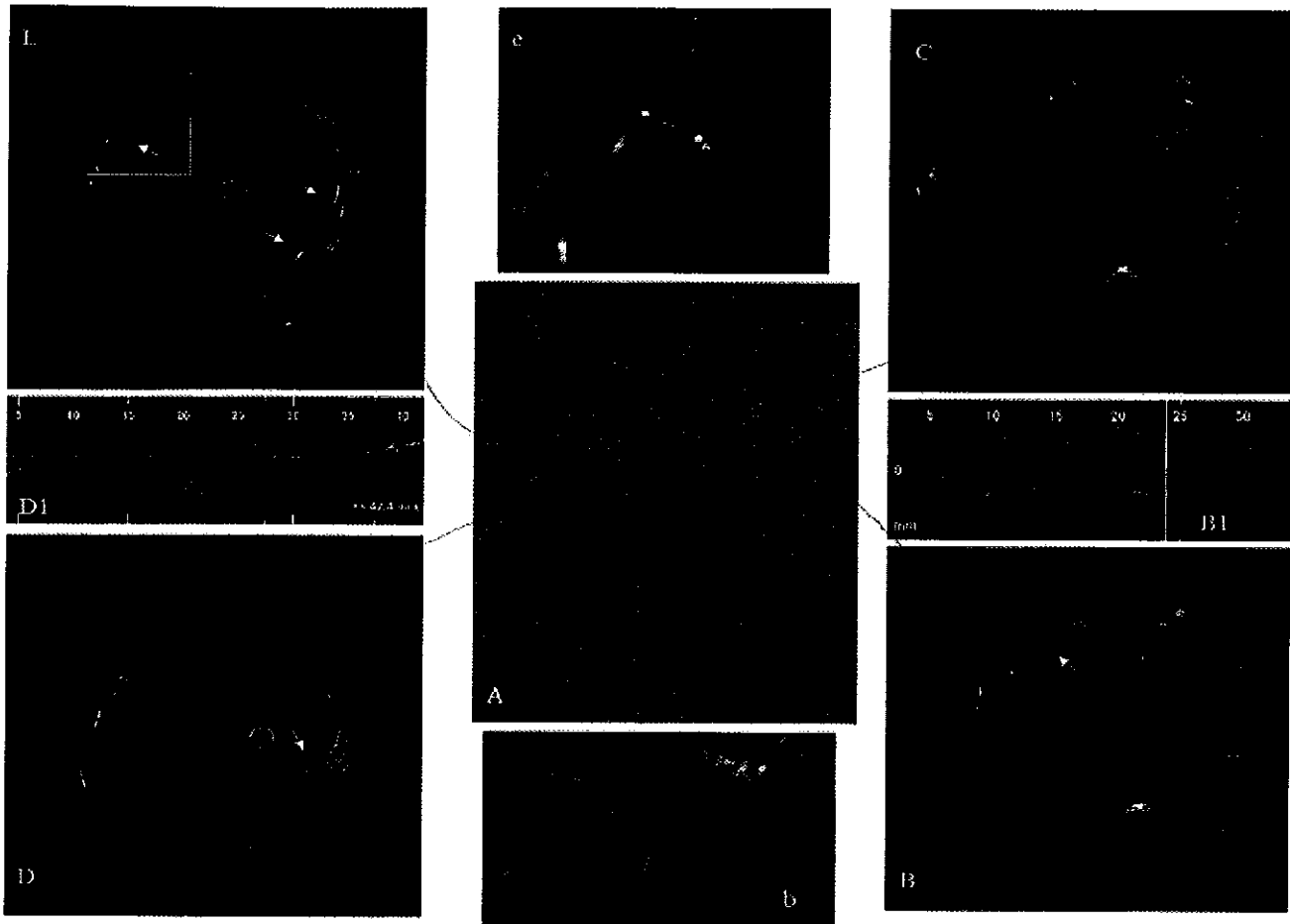


Fig. 3. Panel A is the final angiographic result. Optical coherence tomography (OCT) was performed in both the left circumflex (LCx) and first obtuse marginal (OM1) branches using the ImageWire employing a nonocclusive technique with motorized pullback at 3 mm/s during continuous iso-osmolar contrast injection. Panels B, C, D, E, b, and e are OCT cross-sectional images. Panels B1 and D1 are longitudinal images of the OM1 and the LCx, respectively, with the distal end corresponding on

the left, progressing to proximal end on the right. White arrow indicates areas of maximal strut-vessel wall separation. Higher magnification maximal strut separation of the proximal LCx is shown in Panel e (distance = 160 μm) and of the side branch origin in Panel b (distance = 150 μm). Blue arrow in Panel C indicates the guide wire placed in the distal left circumflex coronary artery. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

side branch restenosis in 30 patients at 6 month follow up [8,9].

Intravascular ultrasound (IVUS), the gold standard for assessment of luminal and total vessel size, was not used in this case. This may have led to underestimation of the balloon diameter for final postdilatation. However, our goal was to assess stent strut apposition in this bifurcation lesion. OCT provides cross-sectional images with powerful resolution (10–20 μm) than IVUS [10], allowing optimal assessment of stent strut apposition and of irregularity in struts distribution [11–13], with fewer artifacts [12,13]. Although extensive literature, which had established the clinical usefulness of IVUS, is still lacking for OCT, and this technique is currently limited by its penetration depth (1–3 mm) and the need for a blood cleared environment to obtain

image production, it appears a powerful imaging tool for the characterization of stent deployment in PCI.

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REFERENCES

1. Iakovou I, Schmidt T, Bonizzoni E, Ge L, Sangiorgi G, Stankovic G, Airoldi F, Chieffo A, Montorfano M, Carlino M, Michev I, Corvaja N, Briguori C, Gerckens U, Grube E, Colombo A. Incidence predictors and outcome of thrombosis after successful implantation of drug-eluting stents. *JAMA* 2005;293:2126–2130.

2. Ge L, Arnoldi F, Iakovou I, Cosgrave J, Iassen M, Sangiori GM, Montofano M, Chieffo A, Carlino M, Corvaja N, Colombo A. Clinical and angiographic outcome after implantation of drug-eluting stents in bifurcation lesions with the crush stent technique. importance of final kissing balloon post-dilation. *J Am Coll Cardiol* 2005;46:613–620.
3. Kaplan AV, Davis HR. Tryton side-branch stent. new device technical report. *Eurointervention* 2006;2:270–271.
4. Medina A, Surez De Lezo J, Pan M. A new classification of coronary bifurcation lesions. *Rev Esp Cardiol* 2006;59:183–184.
5. Tanigawa J, Barlis P, Di Mario C. Intravascular optical coherence tomography: Optimisation of image acquisition and quantitative assessment of stent strut apposition. *Eurointervention* 2007;3:128–136.
6. Sudhir K. Abbott vascular drug eluting stent program. Presented at FDA Panel Meeting December 12, 2008. Available at: http://www.fda.gov/ohrms/dockets/ac/06/slides/2006-4253oph2_18_Sudhir.pdf (accessed April 2, 2008).
7. Iakovou I, Ge L, Colombo A. Contemporary stent treatment of coronary bifurcations. *J Am Coll Cardiol* 2005;46:1446–1455.
8. Kaplan AV, Ramcharitar S, Louvard Y, Müller R, Davis HR, Morice M-C, Serruys PWJC, Grube E. Tryton I (First-In-Man) Study: Acute and 30 day outcome. Preliminary report. *Euro-Intervention* 2007;3:54–59.
9. Onuma Y, Müller R, Ramcharitar S, Van Geuns RJ, Louvard Y, More MA, Morice MC, Davis R, Kaplan AV, Lefèvre T, Grube E, Serruys P. Tryton I. First-In-Man (FIM) Study: Six month clinical and angiographic outcome, analysis with new quantitative coronary angiography dedicated for bifurcation lesions. *Eurointervention* 2008;3:546–552.
10. Low AF, Tearney GJ, Bouma BE, Jang IK. Technology insight: Optical coherence tomography—Current status and future development. *Nat Clin Pract Cardiovasc Med* 2006;3:154–162.
11. Diaz-Sandoval LJ, Bouma BE, Tearney GJ, Jang IK. Optical coherence tomography as a tool for percutaneous coronary interventions. *Catheter Cardiovasc Interv* 2005;65:492–496.
12. Bouma BE, Tearney GJ, Yabushita H, Shishkov M, Kauffman CR, DeJoseph Gauthier D, MacNeill BD, Houser SL, Aretz HT, Halpern EF, Jang IK. Evaluation of intracoronary stenting by intravascular optical coherence Tomography. *Heart* 2003;89:317–320.
13. Grube E, Gerckens U, Buellesfeld L, Fitzgerald PJ. Images in cardiovascular medicine. Intracoronary imaging with optical coherence tomography: A new high-resolution technology providing striking visualization in the coronary artery. *Circulation* 2002;106:2409–2410.