JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 1, 2014

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jcin.2013.07.013

The Absorb Bioresorbable Vascular Scaffold in Coronary Bifurcations

Insights From Bench Testing

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Objectives This study sought to evaluate the feasibility of performing contemporary bifurcation techniques with the Absorb everolimus-eluting bioresorbable vascular scaffold (Abbott Vascular, Santa Clara, California) (BVS).

Background The feasibility of using the BVS in bifurcation lesions is unknown.

Methods We performed bifurcation stenting procedures including main-vessel stenting with ballooning of the side branch through the BVS struts, T-stenting and crush and culotte procedures, in a synthetic arterial model. Low-pressure final kissing balloon (FKB) inflation was performed to complete the procedures.

Results Single-stent procedures optimally opened the side-branch ostium without deforming the main vessel BVS. T-stenting completely covered the side-branch ostium. In crush cases, we could easily re-cross the crushed BVS with the wire and balloon and achieve good results after deployment of the main-vessel BVS and FKB inflation. A 2-BVS culotte resulted in good paving of the main vessel. Disruption of 1 BVS strut was observed after FKB inflation with the 2 balloons inflated beyond the recommended limit of the BVS, as calculated by Finet's law.

Conclusions Intervention of bifurcation lesions using the Absorb BVS using modern bifurcation techniques appears feasible in a coronary bifurcation model. Provisional stenting is recommended in the majority, with sequential balloon inflations and FKB inflation only when necessary. T or T-stenting and small protrusion stenting with a metal drug-eluting stent is preferable in case of crossover. A 2-BVS, T-stent technique can be performed in a high-angle bifurcation; otherwise, crush or culotte should be considered, using metal DES in the side branch. Two-BVS crush and culotte require careful evaluation, and should only be considered in patients with large-caliber main vessels. (J Am Coll Cardiol Intv 2014;7:81–8) © 2014 by the American College of Cardiology Foundation

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Manuscript received April 21, 2013; revised manuscript received July 25, 2013, accepted July 29, 2013.

Development of novel techniques after the introduction of drug-eluting stents (DES) (1) markedly improved outcomes after percutaneous coronary intervention (PCI) of bifurcation lesions compared with the pre-DES era (2). Bioresorbable vascular scaffolds (BVS) represent a promising new technology that theoretically can eliminate the late and very late stent thrombosis observed after deployment of metal DES because, at some point, the physical material that could potentially provide a nidus for a stent-related thrombotic event completely disappears. The most widely studied BVS, the Absorb BVS (Abbott Vascular, Santa Clara, California), a poly-L-lactic acid with promising results out to 4 years (3), has yet to be evaluated in patients with planned treatment of bifurcation lesions (4–6) because, unlike a metal stent, this polymeric BVS can unravel when deployed beyond recommended diameter limits (7). With as many as 20% of PCI patients undergoing treatment of bifurcation lesions (2,8), the generalizability of the Absorb BVS to an all-comer PCI population remains uncertain. Our aim was to evaluate the performance of the Absorb BVS in a variety of bifurcation techniques commonly in use today in an in vitro bifurcation phantom model to gain an understanding of the utility of the Absorb BVS in coronary bifurcations in the clinical setting.

Abbreviations and Acronyms

BVS = bioresorbable vascular scaffold(s)

CT = computed tomography

DES = drug-eluting stent(s)

FKB = final kissing balloon(s)

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

Methods

Bifurcation model. All experiments were performed in the Abbott Vascular Research and Development facility in Santa Clara, California on December 4, 2012, in a synthetic arterial model composed of a polyvinyl alcohol vessel resting in a bifurcated silicone soft plate groove with a 75° bifurcation angle as measured from the axis of the main vessel to the axis of the origin of the side branch (9). The vessel lumen diameter was 3.0 mm in the main vessel and 2.5 mm in the side branch. Although this was not a fractal model, the phantoms had elastic properties that allowed stretching of the material beyond the nominal diameter. The model was immersed in an aqueous bath heated to 37°C. Guidewires, balloons, and BVS were introduced and deployed via a 6-French vascular sheath inserted in the proximal segment of the bifurcation. Balanced middle-weight guidewires (Abbott Vascular) were used for all procedures and NC Trek balloon catheters (Abbott Vascular) were used for post-dilation.

Bifurcation techniques. We performed provisional stenting with a final kissing balloon (FKB) (n = 2), modified T-stenting with an FKB (n = 2), double or 2-step crush (n = 2) technique, mini-crush technique (n = 1), and culotte technique (n = 1). The details of these procedures are found in the Online Appendix.

Assessment of the techniques. All procedures were assessed by visual means, and digital photographs were taken. The single-stent procedures were assessed by scanning electron microscopy and 2-stent procedures by micro computed tomography (CT), described in the Online Appendix.

Results

Kissing balloon inflation. The BVS struts formed a short scaffold for the side-branch ostium (Fig. 1A) and its complete opening (Fig. 1B). There was no evidence of link or ring disruption in the proximal segment of the BVS. Optimal apposition was maintained throughout the length of the BVS. Scanning electron microscopy revealed a good opening of the side-branch struts without ring or link disruption (Figs. 1C and 1D).

Modified T-stenting. With the 75° bifurcation angle, the side-branch ostium was adequately covered (Fig. 2). Of note, inflation of both balloons to 10 atm resulted in structural disruption of 1 proximal ring (Fig. 3A), confirmed by micro CT (Figs. 3B to 3D).

Crush techniques. With the double-crush procedure, BVS material accumulated on the proximal surface where the crushed BVS interfaced with the overlying main vessel BVS struts (Fig. 4A). A small area of malapposition was observed between the carina and the 2 overlying scaffolds (Fig. 4A). Micro CT revealed good paving of the main vessel (Fig. 4B) with protrusion of 1 strut into the lumen without unraveling of the BVS. The side-branch ostium was completely opened (Figs. 4C and 4D). The mini-crush procedure resulted in mild protrusion of the crushed BVS into the main vessel lumen and partial protrusion into the side-branch ostium (Fig. 5).

Culotte technique. The culotte technique procedure resulted in a thick circumferential 2-layer BVS wall in the proximal segment of the main vessel (Fig. 6A) as well as a bulky BVS neocarina (Fig. 6B), the latter likely resulting from the initial re-wiring of the side-branch BVS being at the opposite wall of the main vessel relative to the side-branch ostium and/or re-wiring of the side-branch after deployment of the main vessel BVS too proximally, thus pushing BVS material toward the carina. The small area of malapposition observed in the double-crush cases was also observed with the culotte technique (Fig. 6A). The side-branch BVS was damaged during the micro CT process, rendering assessment of the side-branch ostium with this modality impossible (Fig. 6C). The view through the main vessel lumen revealed preserved integrity of the BVS and a well-paved main vessel lumen (Fig. 6D).

Although this was not a fractal model, because of the elastic properties of the phantom, some stretching of the proximal main vessel segment occurred, thus approaching to some extent fractal conditions, as illustrated in part A of all individual technique figures.