The Absorb BVS: Bench Testing

Vladimír Džavík MD
Professor of Medicine
University of Toronto
Toronto, Canada
The ABSORB bioresorbable vascular scaffold in coronary bifurcations: insights from bench testing.

Vladimír Džavík MD, FACC¹ and Antonio Colombo MD, FACC²

¹Peter Munk Cardiac Centre, University Health Network, Toronto, Ontario, Canada

²San Raffaele Scientific Institute and EMO-GVM Centro Cuore Columbus, Milan, Italy

JACC Cardiovasc Intervent in press
STUDY AIMS

• 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 in order to gain an understanding as to whether or not the Absorb BVS could be utilized in coronary bifurcations in the clinical setting.
BACKGROUND

- Bioresorbable vascular scaffolds (eg. Absorb BVS, a poly-L-lactic acid (PPLA) polymer) are a promising new technology that theoretically can eliminate the late and very late stent thrombosis observed after deployment of metallic DES.

- Trials of the Absorb BVS have excluded those with planned treatment of lesions with a side-branch ≥2 mm in diameter.

- Bifurcation techniques have been discouraged, since the BVS can unravel when deployed beyond recommended diameter limits.

- With up to 20% of patients undergoing PCI requiring treatment of bifurcation lesions, the generalizability of the Absorb BVS to an all-comer PCI population is unclear.

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METHODS

• Procedures performed in a synthetic arterial model comprised of a poly-vinyl alcohol vessel resting in a bifurcated silicone soft plate groove with a 75° bifurcation angle

• The vessel lumen diameter was 3.0 mm in the main vessel and 2.5 mm in the side-branch

• The model immersed in an aqueous bath heated to 37˚C

• Guidewires, balloons and BVS were introduced and deployed via a 6 French vascular sheath inserted into the proximal segment of the bifurcation

• Balanced middle-weight (BMW) guidewires (Abbott Vascular, Santa Clara, CA) were utilized for all procedures and NC Trek balloon catheters were utilized for postdilation.
METHODS

• Bifurcation techniques
  – provisional stenting with a FKB, modified T-stenting with a FKB, double crush and mini-crush, and culotte.

• Assessment of the techniques
  – All procedures were assessed by visual means and digital photographs were taken
  – The two single-stent procedures were assessed by scanning electron microscopy (SEM). The two-stent procedures were assessed by micro CT
EXPERIMENTAL SET-UP

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Main vessel stent procedure after distal recrossing of the BVS struts and a FKB with a 3.0x20 mm NC Trek balloon in the main vessel, and a 2.5x20 mm NC Trek balloon in the side-branch, both inflated to 8 atm.
The Fractal Law
Finet’s Principle

Finet’s Law: $D_{PMV} = 0.678(D_{DMV} + D_{SB})$

Based on IVUS observations of 27 patients with normal coronary arteries observed on angiography performed prior to valve replacement.


The hypothesis was that this would also apply to inflated balloons in an enclosed tube such as an atherosclerotic coronary artery.

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The Fractal Law
Finet’s Principle

Finet’s Law: \( D_{PMV} = 0.678(D_{DMV} + D_{SB}) \)


- 3.0 mm NC Trek + 2.5 mm NC Trek
  - 8 atm: \( 0.678(2.83 \text{ mm} + 2.38 \text{ mm}) = 3.53 \text{ mm} \)
  - 6 atm: \( 0.678(2.73 \text{ mm} + 2.30 \text{ mm}) = 3.41 \text{ mm} \)

- 2.75 mm NC Trek + 2.5 mm NC Trek
  - 8 atm: \( 0.678(2.58 \text{ mm} + 2.38 \text{ mm}) = 3.36 \text{ mm} \)
T-stenting after deployment of a 2.5x18 mm BVS and at 12 atm through the dilated main vessel BVS struts, and after a FKB with 3.0x20 and 2.5x20 mm balloons, both inflated to 8 atmospheres.

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T-STENTING FKB at 10 ATM

10 atm: 0.678(2.91 mm + 2.45 mm) = 3.63 mm
DOUBLE CRUSH – FKB at 8 ATM

Through MV lumen

Through SB lumen

Through MV struts into SB

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MINI-CRUSH FKB at 8 ATM

Through SB lumen

Through MV lumen

Through SB lumen

Through SB lumen
CULOTTTE – FKB at 8 ATM

Bulky neocarina – likely distal recrossing prior to FKB

SB torn during processing for micro CT

Through MV lumen

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A ‘hug’ balloon inflation with minimal protrusion of the SB balloon into the main vessel BVS
CONCLUSIONS

• We have demonstrated the feasibility of PCI of bifurcation lesions with the ABSORB BVS utilizing modern bifurcation techniques in a phantom model of a coronary bifurcation.

• Our current recommendations are to utilize provisional stenting in the majority of cases, with sequential non-compliant balloon inflations in the side-branch and then main vessel, reserving FKB only for cases in which it is absolutely deemed necessary.

• If crossover to a two-stent technique is necessary, T or TAP stenting with a metal DES is preferable.

• If a planned two stent technique is deemed necessary, in a high angle bifurcation such as in our model (≥75°), a BVS deployed in the side-branch followed by a BVS in the main vessel should be feasible.

• In narrower angle bifurcations, a mini-step crush or culotte should be considered, deploying metal DES in the side-branch.
CONCLUSIONS

• Although planned bifurcation techniques such as crush and culotte utilizing the BVS platform in both the main vessel and side-branch appear feasible, their use requires careful evaluation in fractal models with different bifurcation angles, and clinically should be limited to patients with large caliber main vessels.

• As disrupted BVS struts cannot be visualized by angiography, we recommend intravascular imaging, preferably with OCT, or alternatively with intravascular ultrasound, of the main vessel in particular, whenever dilation of the BVS struts, POT or FKB have been performed, or two BVS have been deployed, to ensure the integrity of the final result.
CONCLUSIONS

• Intervention of bifurcation lesions utilizing the ABSORB BVS utilizing modern bifurcation techniques appears feasible in a coronary bifurcation model

• FKB can be performed without disrupting the rings of the main vessel BVS providing that the combined balloon diameter is maintained below the upper diameter limit of the BVS

• Crush and culotte to the BVS platform appear feasible but warrant careful clinical evaluation.
2-D OCT through SB and DMV
3-D OCT at the carina

V. Džavík MD, T. Muramatsu, N. Crooks, S Nakatani, Y. Onuma. Eurointervention (in press)
Figure 5

Downstream flythrough view

Pullback from DMV

Pullback from SB

V. Džavík MD, T. Muramatsu, N. Crooks, S Nakatani, Y. Onuma (manuscript under review)
Thank you for your attention!