

WHITE PAPER

Expert Panel Discussion on Bioabsorbable Stent Technologies

Virtual Roundtable Summary

Drs. Jeffrey Moses, Robert Byrne, Elizabeth Holper and Michael Rinaldi participated in a virtual panel discussion to share their perspectives on the latest Bioabsorbable Stent technologies available in the U.S.

Boston Scientific sponsored the virtual roundtable discussion and provided support for its participants.

To better understand the differences among stents featuring bioabsorbable technologies, four leading interventional cardiologists convened for a virtual roundtable to discuss the clinical implications of the two currently available stents: SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Boston Scientific) that features a bioabsorbable polymer and the Absorb™ GT1 Bioresorbable Vascular Scaffold System (BVS) (Abbott), a fully bioresorbable scaffold (BRS).

The experts agreed that bioresorbable devices are important advancements in interventional cardiology and the future of these technologies is bright. But they also noted that the Absorb BVS is a first generation technology that has some limitations. Specifically, Absorb BVS has thicker struts than those of traditional metallic stents and requires additional delivery considerations, including more extensive vessel prep and post-dilatation. Moreover, it is not indicated for implantation in vessels smaller than 2.5 mm and the instructions for use strongly recommends online QCA or intravascular ultrasound for any vessel visually assessed at ≤ 2.75 mm.¹

Because of these limitations, panelists agreed that imaging—specifically intravascular ultrasound (IVUS) or optical coherence tomography (OCT)—may be necessary, especially at first, for proper implantation of Absorb BVS. In addition, proper pre-and post-dilation are recommended for adequate implantation. Time, equipment and financial cost are involved in the additional imaging requirements of this first-generation bioresorbable stent.

“The importance of careful technique and sizing the vessel appropriately and pre- and post-dilating thoughtfully leads to the need for a higher incidence of intravascular ultrasound, which has its own cost implications,” said Michael Rinaldi, a cardiologist and medical director of Clinical Research at Sanger Heart & Vascular Institute in Charlotte, North Carolina. “Most people do not use intravascular ultrasound routinely; whereas for this device, at least in the learning curve, it’s encouraged that people use intravascular ultrasound liberally.”

The learning curve of physicians is often a consideration with the development of new technologies. But in the case of Absorb BVS, the scaffold structure—greater in both thickness and width—adds a significant layer of difficulty and necessitates additional education, care, and steps that include an emphasis on more rigorous vessel preparation and post-dilatation procedures.

“When implanting these [fully bioresorbable] stents, a different implantation protocol is necessary, than with conventional drug-eluting stents,” said Robert Byrne, a cardiologist at Deutsches Herzzentrum in Munich. “For me, there’s no doubt that from a mechanistic point of view, looking at the non-clinical data, thicker stent struts are associated with delay in endothelialization and healing in comparison with thinner-strut stents.”

When considering which stent technology is most appropriate for patients, factors such as age, bleeding risk, vessel health, potential need for future bypass surgery and vessel placement were noted as key considerations for stent selection. For extensive vessel reconstruction, distal disease and younger patients who may need future treatment, a BRS product may be useful. However, the thicker struts of Absorb BVS make it more difficult to deliver and place - especially in smaller vessels.

According to the panel, trading full absorbability for the thicker strut is simply not advantageous for most patients. In general, the panel described the SYNERGY Stent as a “workhorse” stent,

with broad applications that can be implanted using the same techniques currently used by interventional cardiologists to place drug-eluting stents.

“The pro for the [SYNERGY] bioabsorbable polymer stent is that it’s a very familiar technology,” said Jeffrey Moses, Director of the Center for Interventional Vascular Therapy at New York-Presbyterian Hospital Columbia University Medical Center. “There is really no difference in techniques that need to be employed in the acute situation. As a matter of fact, the SYNERGY Stent, right now in terms of just the features of deliverability ... is probably the best in class we have in the U.S. So it has the potential, obviously, advantage of more rapid healing with the dissolution of the polymer and the drug absorption in a pretty concomitant way over, say, three to four months.”

In addition to the thinner struts and healing benefits, the SYNERGY Stent may provide advantages in terms of dual antiplatelet therapy (DAPT) duration. In general, 2016 U.S. guidelines recommend a minimum of 6 months of DAPT, depending on the patient classification.* There was discussion that DAPT duration for 12 months or longer following Absorb BVS implantation may be beneficial.

“There are folks that we think we can't maintain even 6 months of dual antiplatelet therapy as per our current guideline recommendation. We would probably lean more toward a bioabsorbable polymer-based technology in those folks,” said Elizabeth Holper, Chief Quality Officer and Medical Director of Interventional Cardiology Research at The Heart Hospital Baylor in Plano, Texas. “Currently, with fully bioabsorbable, we are minimally keeping those patients on for 12 months.”

Technology continues to advance and next generation bioresorbable scaffolds are in development. The Absorb BVS is certainly an addition to the standard array of devices, but it does not replace current gold standard DES options, such as the SYNERGY Stent. The over-expansion of Absorb BVS is limited to 0.5 mm to reduce the risk of scaffold fracture. This limits the usefulness of the current bioresorbable stent technology for physicians in certain clinical scenarios.

“When you look at conventional thin-strut bioabsorbable polymer stents, I think the real advantage here is that they have enabled us more and more, over the course of the last ten years, to tackle complex lesion morphology, and complex patients, with a great deal of success,” said Dr. Byrne. “The advent of current-generation DES has been instrumental, I think, in pushing the boundaries of interventional cardiology when it comes to myocardial revascularization.”

Future innovations in bioresorbable technology is expected to provide scaffolds with thinner stent struts that are less cumbersome to implant. These next-generation fully bioresorbable scaffolds will be additional tools for physicians to use in specific cases. But the SYNERGY stent remains the “workhorse” bioabsorbable-polymer option that offers physicians efficiency and ease of use as well as unparalleled safety and healing for the majority of patients undergoing PCI.

[Click here](#) for information on the indications, safety and warnings for the SYNERGY Stent System.

1. Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System Instructions for Use. EL2108074. Abbott 2016.

* Currently, all drug-eluting stents available in the U.S. have 12-month DAPT duration labeling. The SYNERGY Stent labeling states that DAPT should be given daily for 12 months in patients who are not at high risk of bleeding. For more information, see the product directions for use.