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Editorial

A fresh look at bioresorbable scaffold technology: Intuition pumps

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ABSTRACT

Bioresorbable scaffolds (BRS) are a new enticing treatment option in coronary interventions. Absorb BVS™ Is the most widely used and researched polymer based BRS, eluting everolimus. However currently it has several technical limitations; low radial support, larger strut size, poor visualization, poor deliverability and complex implantation technique. Magnesium based BRS are an alternate but they are also limited not only by lower radial support and poor visualization but also earlier bio-absorption. Material processing: blow-molding, annealing, polymer orientation, change in composition and use of higher molecular weight polymer, as well new polymers like tyrosine or salicyclate analogs and even hybrid (polymer and metallic) combined with intelligent cell design has led to evolution of BRS technology. Newer BRS has higher radial strength, lower strut thickness, improved visualization, ease of scaffold implantation as also optimal bio-resorption time.

1. Introduction

Since the time immemorial humanity has been searching for therapies that increase life-span but at the same time are least invasive and toxic to the body. Coronary artery disease (CAD) due to coronary atherosclerosis has become the leading cause of mortality and morbidity world-wide. Ever since the first successful coronary artery bypass procedure was performed by Rene Favaloro in 1968, it has become a standard of care in patients with significant coronary atherosclerosis. However, this being a major surgery and a highly invasive procedure, angioplasty was developed as a relatively non-invasive substitute. Earlier, plain balloon angioplasty while less invasive was also less efficacious; limited by immediate vascular recoil and long term re-stenosis. Stents were developed in an attempt to provide temporary scaffold to tide over the problem of acute recoil. However, since the development of stents physicians and patients have been concerned at the prospect of a metal prosthesis left permanently in the body. Philosophically, "*The scaffolding must be removed once the house is built*." Indeed, there is a persisting risk of late and very late stent thrombosis after drug eluting stents (DES) implantation, which can result from delayed stent endothelialization, or hypersensitivity reactions to one of the stent components leading to poor intimal healing and providing a substrate for eventual stent thrombosis.[1] In this context the perfect human scaffold is one that is easily put in, does its job, and then disappears with no residual effects. This simple disappearing act may have several potential benefits in long term; restoration of physiologic vasomotion, late expansive remodeling, reduced risk of stent thrombosis, avoidance of long term jailing of side branches in bifurcation lesions, avoidance of long-term dual-antiplatelet use, improved availability of graftable (previously scaffolded) segments of coronary artery and improved imaging with computed tomography or magnetic resonance imaging. Thus bio-resorbable scaffolds seem ideal prosthesis to be implanted in the coronaries, however, the reality is that they still have a long way to go before they become the ideal 'disappearing' lscenery, a proposition that is aesthetically irresistible. While good in concept the major limitation of current generation scaffolds is that they are no-where close to technical characteristics of current generation DES.[2]

2. Challenges with current generation of scaffolds

2.1. Polymer scaffolds

With the evolution of DES technology several mechanical characteristics were determined which had an impact not only on the technical aspects of device delivery but even more importantly on long and short term outcomes.

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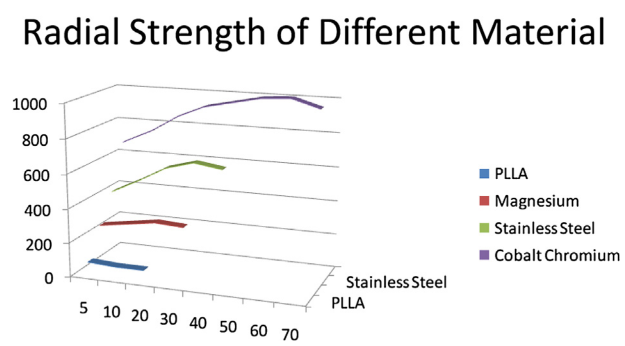

Fig. 1. Radial Strength of BRS and DES.

2.2. Visualization of the scaffold for implantation

Polymeric scaffolds are radiolucent, and thus it may be very difficult to visualize them accurately during fluoroscopy or angiography. Radio-opaque markers embedded near both edges of the angioplasty balloon on which scaffold is mounted help in localizing but they are generally small and still difficult to visualize under X-ray or even enhanced angiography such as stent boost. Thus for really optimal assessment of procedural result, PCI with BRS requires additional visualization technique. Optical coherence tomography (OCT) has a far greater surface resolution than both angiography and intra-vascular ultrasound (IVUS) and can be superior in post-deployment assessment.

2.3. Deliverability of scaffold

Larger strut size and plastic physical properties contribute to limited maneuverability of polymer based scaffolds so much so that there may be crossing issues especially in distal lesions, tortuous lesions or side-branches.

2.4. Scaffold implantation

Classic metallic stent can directly dilate a stenosed artery and expand significantly beyond its rated expansion diameter. Thus if metallic stent is under-sized it can be further dilated (upto 1.5 mm more) to reach full expansion enabling perfect apposition to the vessel wall. Polymeric scaffolds have a larger strut size and an plastic nature which prevent proper expansion (maximum 0.5 mm), limiting its ability to appose to the vessel wall. Furthermore, their technique of implantation is also different; optimal bed preparation (using 1:1 NC balloon, cutting balloon, rotablation or even laser), use of imaging (IVUS or OCT) for appropriate sizing, proper positioning of device, gradual inflation of device to achieve the target expansion, and finally, confirmation of full apposition by OCT.

2.5. Radial strength

The process of stenting involves compression of atherosclerosis plaques and sealing of dissections. This requires a sufficient radial force, the more the better. Poly-L-lactic acid (PLLA) is the most commonly used polymer in BRS is broken down via depolymerization and hydrolysis. The smaller chains are then metabolized by phagocytes into soluble monomers that are metabolized into pyruvate (a bio-chemical substance metabolized by body). Unfortunately, though completely bio-resorbable the radial strength of PLLA is much lower than the metallic prosthesis.[3] Fig. 1 Further, not only radial strength but tendency to elastic recoil is also higher. In practice this translates into higher strut thickness to compensate for inherent radial weakness in the basic material. Thus practically all bio-resorbable stents which use this technology have higher strut thickness.[4] Fig. 2 Finally, the physical characteristics of PLLA scaffold are such that there are higher chances of acute mal-apposition requiring more aggressive optimization but despite this the procedure success rate is somewhat lower.[5]

2.6. Strut thickness

Increased strut thickness provides increased radial support and prevents elastic recoil but reduces deliverability as also acutely decreasing neo-intimal area and causing flow disturbances, PLLA based BRS have a higher strut thickness which is responsible not only for poor deliverability but also higher neo-intimal volumes, leading possibly to flow limitations. Higher strut thickness is also co-relative of poor long term outcomes: restenosis and stent thrombosis. Thus the challenge is to have adequate radial support but still a low strut thickness.

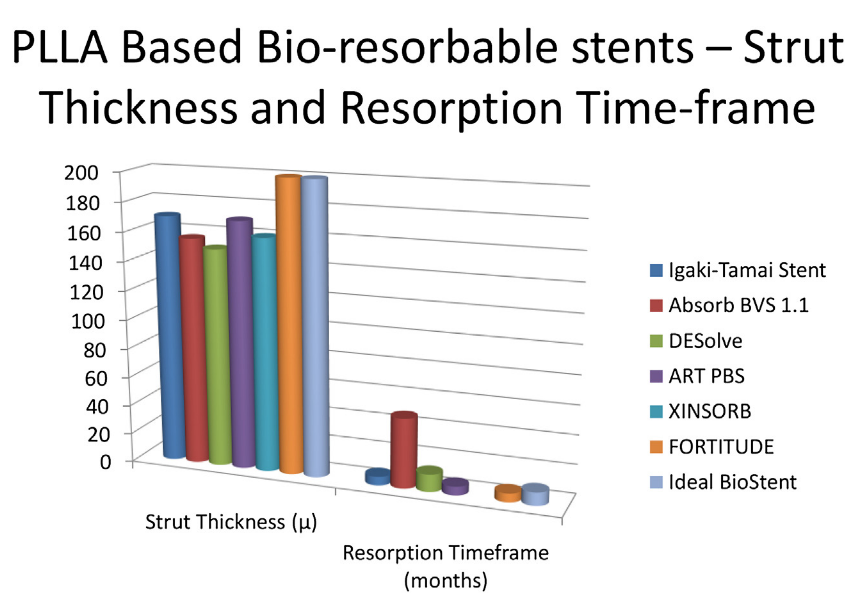

Fig. 2. PLLA based BRS – Strut thickness and resorption time-frame.