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# Resorbable Magnesium Scaffold in Coronary Bifurcations: Report of In Vitro Experiments – Is There a Role for Magnesium and In Vitro Testing?

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When introduced in the clinical practice of interventional cardiology, bioresorbable vascular scaffolds (BVS) were initially indicated for only a limited number of indications: uncomplicated, so-called simple lesions with no calcifications and no tortuosity. After the first promising results with the first generation of BVS (the polymer-based Absorb), indications were extended to more complex lesions [1,2]. Chronic total occlusions (CTO) and bifurcation lesions have known inferior results, directly during the procedure and in the long term, specifically in terms of restenosis. For these lesions, there is a need for another concept of stenting. Moreover, the characteristics of these BVS in CTO lesions should avoid full metal jackets and avoid lifelong side branch obstruction by overhanging struts in bifurcation lesions. Restoring normal vascular endothelial function seems, at least theoretically, to be a better solution for these kinds of difficult-to-treat lesions.

So in daily practice, these lesions were also targeted. Most operators were initially reluctant to treat bifurcation lesions because of strut thickness, lower flexibility, and higher fragility of the resorbable stents. Experts even discouraged the use of the magnesium resorbable stent (MRS) in these situations [3]. Nevertheless, procedures were performed, and there were speculations and publications about the best methodology, in which avoiding culotte stenting because of the load of material was the most frequently heard comment [4].

After the withdrawal of the BVS from the market, mainly because of higher incidence of late stent thrombosis, which was probably related to the degradation process three years after implantation, the concept of BVS seemed to be relegated to history. But the concept still holds the promise of restoring normal vascular motion, freeing arteries and side branches of the metal load. Now other scaffold concepts have published results that are as good as those of drug-eluting stents (DES). They show low stent thrombosis rates, even over a longer period of time. One of those scaffolds is the MRS, a different concept from the polymer-based ones. They contain relatively thick struts but with better radial strength, albeit not comparable with metal (alloy) based stents. The BIOSOLVE studies and the Magmaris registry demonstrated promising follow-up data with low late stent thrombosis and acceptable restenosis rates, comparable with today's modern DES [5]. In these patients, the treated lesions were relatively simple; complex lesions were not specifically studied.

In this issue of the journal, Toth et al. describe the results of what seems to be the logical next step: to study more complex – bifurcation – types of lesions [6]. These lesions are more demanding for stents because, depending on the technique used, struts have to cross struts and, frequently stents have to bend more than 90 degrees. Furthermore, with proximal optimizing therapy (POT), with post-dilatation, and with kissing dilatation techniques, stents are exposed to high forces. This all might lead to deformation and even fracturing of stent struts. The choice for an in vitro model in this phase of clinical experience with the MRS stent seems a logical one with advantages and disadvantages [7,8]. From earlier in vitro work with the DES in similar models, it is known that the conditions are controllable, stable, and reproducible. Thus, a comparison between different methods of stenting will most likely lead to unambiguous results. And the number of experiments can be limited. On the other hand, in vitro situations do not have the great variability in anatomic lesions as in vivo, the cross sections are circular, there are regular diameters, etc. No calcifications, no elastic recoil, and no second bends are encountered, and the continuous movement in different planes due to a beating heart in 3 dimensions is absent.

In this in vitro study, it is the aim of the authors to understand basic mechanical behavior of the MRS, and the results give better insight into the technology and will undoubtedly be of importance for future clinical applications. Three modalities are used in the experimental setting, fluoroscopy optical coherence tomography and

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micro-computed tomography – a logical approach because the results from these combined methods can give almost complete insight into the behavior of the stents and their struts in bifurcation lesions. Fluoroscopy was used to control positioning and deployment, OCT [9] to check malposition, and μCT analysis to monitor connector and strut fractures.

Five types of bifurcation stenting were investigated and described in great detail in the manuscript. Nonetheless only the relatively "simple" bifurcation lesions were tested. Overlapping of struts and crushing were almost completely avoided, probably because today's struts are still too thick and fragile. This is an understandable argument, but we are left with unanswered questions concerning what the behavior of struts will be when crushed. The in vitro model should specifically help us gain information about stents and struts' behavior in more complex situations because in daily practice, such a precise wiring of struts is not always possible, as described in tests #4 and #5 in the article. Overlapping of more than one strut or crushing might be unavoidable in the clinical situation, although the intention and probably the best way to do it is to keep the bifurcation stenting as simple as possible.

With the above limitations to the simple approach, the results of this very well-conducted and precisely described study were very good.

The figure of 4.3% malposition, seen with OCT overall in the carina of a bifurcation, is excellent, and one broken connector and one single broken strut diagnosed with micro CT, both in situations with outspoken overstretching due to the technique used, is very acceptable.

Even though this is a descriptive in vitro study conducted in well-controlled circumstances, it is hard to compare these results with the in vitro studies performed with DES, unfortunately, because of differences in design. Nor is it possible to directly translate these results to daily clinical practice.

However, when trying to compare the current data with other in vitro studies, the conclusion that the results are at least comparable seems warranted. More data of more complex methods of bifurcation stenting should be gathered before we can translate the results to daily practice.

On the other hand, the data suggest a reluctant attitude in the approach of more complex lesions in daily practice, as the more stretch is seen in the clinical situation, the greater the risk of fracture.

Overall, Toth et al. have performed a well-designed and excellently executed study that helps us to understand the mechanisms of stenting with this particular magnesium stent material and gives future directions for further research. In my opinion, the in vitro model is essential to understand complex stenting procedures, and the magnesium stent still holds promise.

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