

Procedural safety and short-term outcome in Asian men treated with magnesium bio-resorbable scaffold

Background: Bioresorbable scaffold offer the advantages of reduced long-term complications such as stent fracture, late stent thrombosis and in-stent restenosis as well as the return of normal vasomotor function and late lumen gain with plaque regression.

Objective: Identify safety and outcomes of patients undergoing percutaneous coronary intervention (PCI) with magnesium BRS.

Materials and methods: This was a prospective, observational single centre study conducted in UiTM Sungai Buloh from 1st November 2016 to 14th February 2017.

Results: 7 patients were enrolled. The mean age was 46±9. All patients were male. Ethnicity breakdown showed 5 Malays, 1 Chinese, and 1 Indian. Cardiovascular risk assessment revealed 85.7% diabetes mellitus, 42.9% smokers, 28.6% hypertension and 28.6% dyslipidaemia. Target vessels treated were 6 left anterior descending (LAD) and 1 right coronary artery (RCA). Out of the 7 patients, 28.6% were type A lesions, 42.8% were type B, and 28.5% were type C. Among those lesions, 3 involved LAD-D1 bifurcations, and 2 were total occlusions. The lesions were prepared with semi-compliant balloons in 5 cases and non-compliant balloons in 2 cases. The balloon-to-stent ratios were 1:1 (n=1), 0.92:1 (n=1), 0.85:1 (n=4) and 0.83:1 (n=1). The magnesium BRS diameters used were 3.5 mm (n=4) and 3.0 mm (n=3) with length of 15 mm (n=1), 20 mm (n=4) and 25 mm (n=2). Post-dilatation in one patient was carried out with non-compliant balloon of equal diameter to the stent, while the rest had upsizing with +0.5 mm larger non-compliant balloon. Procedural outcome was 100% successful. At three-month follow-up, there were no symptoms, MACE or TLR.

Conclusion: We demonstrated safety and good short-term outcome in the use of magnesium BRS in our cohort, including stenting of total occlusions as well as bifurcation lesions. A larger cohort and longer-term outcome would better delineate the safety and efficacy of this new technology in treating coronary artery disease.

Keywords: Magnesium based bioresorbable scaffold (BRS), Magnesium BRS, Magmaris bioresorbable scaffold, Asian short-term outcome, Procedural safety

Introduction

Invasive coronary angiography remains the gold standard investigation for high definition coronary artery anatomy assessment [1]. The forefront of coronary artery disease treatment was the Vineberg procedure [2-5], even before the advent of coronary angiography [6-8]. Treatments of coronary stenosis have evolved

from the use of balloon angioplasty in 1977 to the use of bare-metal stent (BMS) in 1986 [9-15]. Issues with recurrence of restenosis at the site of implantation lead to the advent of paclitaxel and sirolimus coating drug eluting stents (DES), with the former being less favoured due to higher complication rates such as late in-stent thrombosis (IST) [16-23].

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The treatment of coronary stenosis escalated with percutaneous coronary intervention (PCI) being favoured over bypass surgery in most cases with low SYNTAX (Taxus drug-eluting stent versus coronary artery bypass surgery for the treatment of narrowed arteries) scores [24-28]. With greater usage, issues with DES emerged such as late in-stent thrombosis (IST) and in-stent restenosis (ISR) [29]. Polymers coating the stents that are necessary for drug delivery are now known to be a cause of localised vessel inflammation, risking inadequate healing and stent thrombosis [30-33]. The loss of vasomotor function associated with inadequate healing is also associated with the permanent nature of the metal scaffold and this is more evident with sirolimus-eluting stents [34-38]. These issues gave rise to the need to treat coronary stenosis without leaving a permanent 'cage' to the vessel [39].

The first polymer bioresorbable scaffold (BRS) Absorb (Abbott Vascular, Santa Clara, CA) was introduced in 2011 [40]. Patients treated with Absorb were compared to a conventional DES (Xience) and found to have twice the risk of definite or probable scaffold thrombosis at one year [41,42]. Subgroup analysis in ABSORB-III illustrated that Absorb implanted in smaller vessel diameter (<2.63 mm) had a higher 1-year rate of device thrombosis compared to Xience (2.3% *vs.* 0.9%; relative risk ratio: 2.65) [43]. The Absorb stents were bulky and less able to negotiate difficult tortuosity found in many coronaries due to its inherent polymer design [44]. This led to the development of metallic based absorbable stent.

Second-generation magnesium BRS, Magmaris was released last year by Biotronik with early promising results in European patients. The magnesium alloy scaffold is coated with sirolimus eluting drug and bioabsorbable poly-L- lactide (PLLA) polymer matrix coating [45-54].

Materials and Methods

This was a prospective, single centre observational study conducted in Universiti Teknologi MARA Medical Centre (PPUiTM), Malaysia from 1st November 2016 to 14th February 2017. All patients who underwent percutaneous coronary intervention (PCI) with magnesium based BRS were recruited. Percutaneous coronary intervention was performed according to standard practices. Consent was obtained from all patients prior to procedure.

Data collected were patient demographics, anthropometry, cardiovascular risk factors, laboratory results, echocardiography, coronary angiographic

findings, Syntax score, procedural details and procedural outcome. The primary end points recorded at 30 and 90 days were symptoms, target lesion revascularization (TLR), target lesion failure (TLF) and mortality. Target lesion failure is defined as composite of cardiac death not clearly attributed to a vessel other than the target vessel, target vessel myocardial infarction (MI) and ischaemia driven target lesion revascularization (TLR).

Results

7 patients were recruited during the study period. The mean age was 46±9 years old and all were men. The gender recruitment was by chance and the Malaysian National Cardiovascular Disease (NCVD) Acute Coronary Syndrome registry illustrated a male dominance of 79.4% in 2013 [55]. Ethnicity breakdown revealed 5 Malays, 1 Chinese and 1 Indian. The mean body mass index (BMI) was 27.8±2.9 kg/m². The indication for revascularization were due to ST-elevation myocardial infarction (STEMI, n=4), unstable angina (UA, n=2) and non-ST elevation myocardial infarction (NSTEMI, n=1). Cardiovascular risk factors illustrated 85.7% diabetes mellitus, 42.9% cigarette smokers, 28.6% hypertension and 28.6% dyslipidaemia. Mean left ventricular ejection fraction (LVEF) by modified Simpsons biplane method was 49±8%. Coronary angiography was performed with a mean SYNTAX score of 16±9 (Min 3, Max 33) (Table 1).

Target vessels treated were 6 left anterior descending (LAD) arteries and 1 right coronary artery (RCA). Out of the 7 patients, 28.6% were type A lesions, 42.8% were type B1, and 28.5% were type C. Among those lesions, 3 involved LAD-D1 bifurcations, and 2 were total occlusions. All patients had non-calcified lesions. The lesions were prepared with semi-compliant balloons in 5 cases and non-compliant balloons in 2 cases. The balloon-to-stent ratios were 1:1 (n=1), 0.92:1 (n=1), 0.85:1 (n=4) and 0.83:1 (n=1). The magnesium BRS diameters used were 3.5 mm (n=4) and 3.0 mm (n=3) with lengths of 15 mm (n=1), 20 mm (n=4) and 25 mm (n=2).

All percutaneous coronary interventions were performed via right radial artery access. Guiding catheters used were 6-French EBU 3.5 (Extra Backup, Medtronic, n=6) and 6-French JR 3.5 (Judkins Right, Terumo, n=1). Mean contrast volume was 204±90 ml and mean radiation dose was 3604±1737 mGy. Three patients had multi-vessel PCI. Post-dilatation in one patient was carried out with non-compliant balloon of equal diameter to the stent, while the rest had upsizing with +0.5 mm larger non-compliant balloon. Magnesium BRS procedural implantation success

Table 1: Patients baseline parameters.

Patient	Age	BMI	Sex	Indication	HTN	DM	Dyslipidemia	Smoker	eGFR	Creatinine	LVEF
1	59	28.1	M	UA	N	Y	Y	N	81	89	54
2	37	25.7	M	STEMI	N	Y	N	Y	111	73	59
3	53	32.4	M	STEMI	Y	Y	Y	N	93	80	45
4	55	27.6	M	UA	Y	Y	N	N	76	95	54
5	45	23.7	M	STEMI	N	Y	N	N	90	85	38
6	43	26.4	M	STEMI	N	Y	N	Y	88	87	42
7	35	30.6	M	NSTEMI	N	N	N	Y	99	82	51

(Y: Yes; N: No; BMI: Body Mass Index; M: Male; HTN: Hypertension; DM: Diabetes Mellitus; eGFR: estimated glomerular filtration rate in mL/min/1.73 m², LVEF: Left Ventricular Ejection Fraction in %)

rate was 100% with no complications or technical difficulties. There was no residual stenosis at the stented segments in all patients (Table 2).

Post procedure, all patients were discharged the following day and planned for 12 months of dual antiplatelet therapy with 75 mg of aspirin and 75 mg of clopidogrel daily. At 30-days and 90-days post procedure, there were no symptoms, target lesion revascularisation (TLR), target lesion failure (TLF) or mortality (Table 3).

Discussion

First-generation magnesium BRS (DREAMS I)

Drug eluting absorbable metal scaffold (DREAMS) was based on absorbable metal stent (AMS-2, Biotronik

platform, which consists of magnesium scaffold backbone, degradable polymer and paclitaxel elution. It has a strut thickness of 125 µm and uses platinum radio-opaque markers. DREAMS provide scaffolding and paclitaxel release up to 3 months. In comparison to Taxus (Boston Scientific), DREAMS illustrated comparable in vitro elution and late lumen loss, but with lower inflammatory scores. that demonstrated TLF of 6.8% at 12 months, which comprised of 2.3% target-vessel myocardial infarction (TV-MI), 4.5% clinically driven target lesion revascularization (cd-TLR) and no cardiac deaths [57,58].

Second-generation magnesium BRS (DREAMS II, Magmaris)

Magmaris scaffold backbone is comprised of

Table 2: Patient Coronary Characteristics (LAD=left anterior descending, RCA=right coronary artery).

Patient	Target Vessel	SYNTAX Score	Proximal Reference Diameter, mm	Distal Reference Diameter, mm	Lesion Length, mm	Lesion Stenosis, %	Bifurcation, Medina	Total Occlusion	Lesion Type
1	LAD	14	4.0	3.4	12	70	1,1,1	N	B1
2	RCA	3	3.5	3.0	20	60	N	Y	C
3	LAD	16	3.5	3.5	10	80	N	N	B1
4	LAD	19	3.5	3.0	14	70	N	N	A
5	LAD	10	4.0	3.5	8	70	N	N	A
6	LAD	33	3.0	2.75	20	90	1,1,1	Y	C
7	LAD	19	3.0	3.0	8	95	1,1,1	N	B1

Table 3: Patients PCI Procedural Information.

Patient	Guiding Catheter	SC	NC	Pre-dilatation Balloon Diameter, mm	BRS Diameter, mm	BRS length, mm	Post-dilatation NC Balloon Diameter	Radiation, mGy	Fluoro Time, min	Contrast, ml
1	6Fr EBU3.5	Y	N	3.5	3.5	20	4.0	3758	33	110
2	6Fr JR3.5	Y	N	3.0	3.0	25	3.5	2644	13	100
3	6Fr EBU3.5	Y	N	3.0	3.5	20	4.0	3170	25	210
4	6Fr EBU3.5	Y	N	3.0	3.5	20	3.5	5057*	27	270*
5	6Fr EBU3.5	N	Y	3.0	3.5	20	4.0	1375	16	150
6	6Fr EBU3.5	N	Y	2.5	3.0	25	3.5	2633*	22	240*
7	6Fr EBU3.5	Y	N	2.75	3.0	15	3.5	6597*	84	350*

(SC: Semi-compliant; NC: Non-compliant; EBU: Extra Back-up Guiding Catheter; JR: Judkins Right Guiding Catheter; Patients 4, 6 and 7 had multi-vessel PCI)

magnesium alloy and 95% of magnesium is absorbed at 12 months. The scaffold has a strut thickness of 150 µm and is laser-polished, giving rise to its very smooth surface. Aiding visualization and placement are two radiopaque tantalum markers at the scaffold edges. It is available in two diameters of 3.0 mm and 3.5 mm, and three lengths of 15 mm, 20 mm and 25 mm. Its polymer coating and drug is identical to Orsiro DES (Biotronik), which comprised of sirolimus with bioabsorbable poly-L-lactide (PLLA) polymer matrix coating [59]. BIOSOLVE-II was a multicentre, non-randomized, first-in-man trial with a total of 123 patients implanted with Magmaris. Long-term safety showed target lesion failure (TLF) of 3.3% at six months, which comprised of 0.8% cardiac death, 0.8% target vessel MI and 1.7% clinical driven TLR. Of note, no stent thrombosis was observed at 12 months [60-62]. BIOSOLVE-II and BIOSOLVE-III pooled 24 months outcome revealed TLF of 3.3%, 3.4% and 5.9% at 6, 12 and 24 months, respectively. Throughout the 24-month period, there was no definite or probable scaffold thrombosis [60-62].

Magnesium metabolism

Magnesium is the fourth most abundant cation in the body. It is a prominent intracellular cation required for the function of hundreds of enzyme systems. Magnesium blood serum concentration is 1.7-2.6 mg/dl and its level is regulated by the intestines, kidneys and bones [63-65]. Magnesium scaffold interacts with water to form magnesium hydroxide and hydrogen. One Magmaris BRS has approximately 8.5 mg of magnesium and 95% is resorbed over 12 months. After resorption of magnesium BRS scaffold, intravascular ultrasound (IVUS) and optical coherence tomography

(OCT) have shown that the scaffold space was replaced with calcium apatite complex and accompanied by a phosphorous compound [66].

Magnesium and endothelium

Magnesium promotes re-endothelialisation via increasing migration and proliferation of endothelial cells. The role of magnesium in prevention of thrombosis is through reduction of cleavage of ultra-large von Willebrand Factor (vWF), hence reducing platelet adhesion and aggregation. Reduction of free radicals and nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) both reduces local inflammation at the scaffold [67-69].

Magnesium and vascular smooth muscle

Magnesium promotes vasodilatation via attenuation of vasoconstrictor action and inhibition of calcium transport. Magnesium act pharmacologically as non-competitive antagonist of N-methyl-D-aspartate (NMDA) receptor by virtue of their role as endogenous voltage-sensitive blockers of the ion channel. It also reduces neointima formation by reducing extracellular matrix (ECM) synthesis and cellular migration [70,71].

Advantages of polymer BRS

The absence of residual metallic foreign body reduces long-term complications such as stent fracture, late stent thrombosis and in-stent restenosis. Late lumen gain is seen with plaque regression. Absence of scaffold allows restoration of physiological vasomotor function and reduction of dual antiplatelet therapy duration [60-62]. Late advantages are ability for future non-invasive cardiac imaging with modalities like multi-slice computed tomography (MSCT) and cardiac magnetic resonance imaging (CMR) (Figure 2).

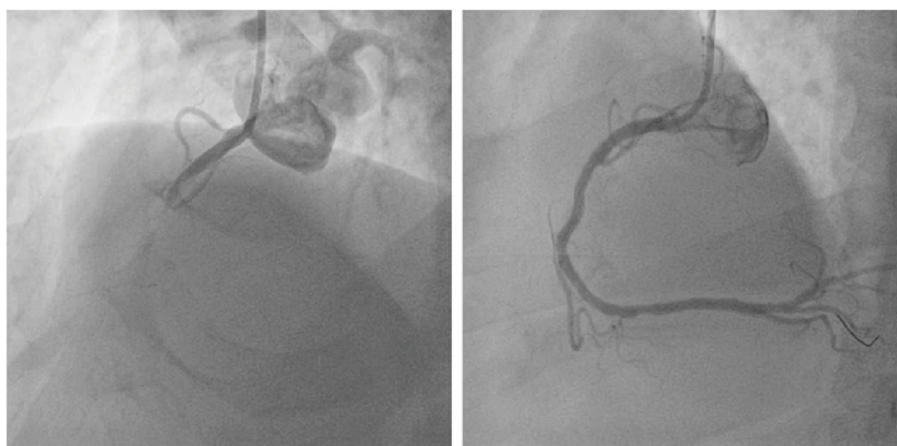


Figure 1: A 37-year-old gentleman with inferior myocardial infarction (7 days post MI with Streptokinase). Treated with Magmaris 3.0/25 and post-dilated with 3.5 NC.

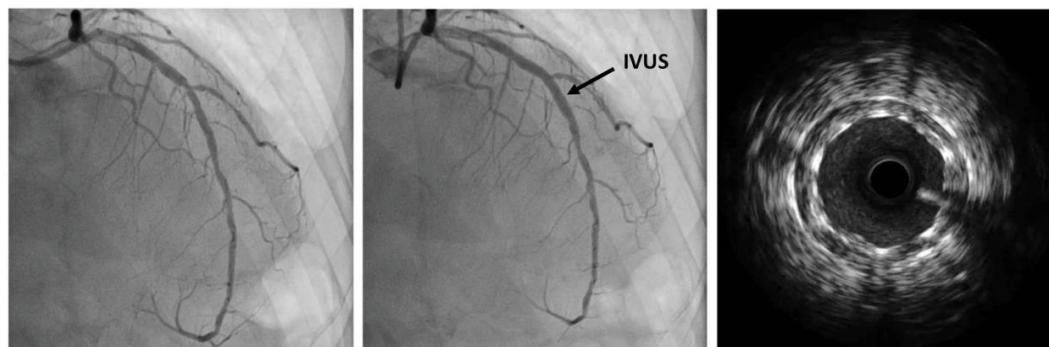


Figure 2: A 60-year-old gentleman with unstable angina. Treated with Magmaris 3.5/20 and post-dilated with 4.0 NC balloon. Intravascular Ultrasound (IVUS) showed good scaffold apposition and no edge dissection or thrombus.

Limitations of polymer BRS

There are several limitations of polymer based BRS. Polymer scaffold struts are thicker, for instance 157 μm in Absorb PLLA-EES and 165 μm in DeSolve PLLA-NOV. Thicker struts makes the scaffold less deliverable and its polymer nature makes it slow to expand during implantation [72]. Apart from being prone to fractures, polymer BRS also has limited use in bifurcations, calcified, long or diffusely disease lesions. It also requires refrigeration during storage. PLLA scaffold has cautionary use in small vessels. However, it was observed that Absorb implanted in vessels bigger than 2.63 mm had no difference in device thrombosis at 1-year compared to Xience (0.8% *vs.* 0.6%; relative risk ratio: 1.28) [43].

Advantages of metallic BRS

Magnesium scaffold bio-absorb within 6 to 12 months, and this potentially reduces the duration of dual antiplatelet therapy and late complications of residual metallic cage seen in BMS and DES. Metallic BRS has comparable radial force to stainless steel and cobalt chromium stents. The crimped profile of Absorb was 1.38 ± 0.01 mm, while the Magmaris was 1.44 ± 0.00 mm and in vitro study has demonstrated superior tractability and force transmission of the latter [73]. Intravascular ultrasound (IVUS) sub-analysis in BIOSOLVE II revealed that the loss in minimum lumen area (MLA) at 6 months with Magnesium (-0.83 mm²) is related to a reduction in the minimum scaffold area (-0.79 mm²) rather than neointimal area (0.08 mm²). Comparison in paired patient illustrated scaffold area remain the same between 6 and 12 months [60,61,74-76]. Sirolimus-eluting Magmaris offers radial support for 3 to 6 months and has a degradation time of 9 months [77]. The dissolution of scaffold leads to formation of inorganic salts, which produce electronegative charge with antithrombotic effect [78,79].

Disadvantages of metallic BRS

Several disadvantages of resorbable metallic scaffold are time of degradation, rate of degradation, remaining polymer, biocompatibility, drug elution, scaffolding and radial force, early and late recoil, and poor radio-opacity of scaffold [78,79].

Other Bioresorbable Scaffolds:

Absorbable metal stent

Absorbable metal stent (AMS, Biotronik, Berlin, Germany) was the first metallic bioresorbable scaffold. First generation non-drug eluting AMS was composed of high strength WE43 magnesium alloy with a strut thickness of 165 μm [80]. The radial strength of scaffold is similar to that of metallic stent with low elastic recoil (<8%), high collapse pressure (0.8 Bar) and minimal shortening after inflation (<5%) [81]. Early studies illustrated degradation into inorganic salts within 60 days [82,83]. AMS was an evolution of Lektin Magic stents (Biotronik), which were first evaluated in porcine coronary artery and followed by human lower limb [84].

Igaki-Tamai BRS

This was the first fully bioresorbable stent evaluated in man. Igaki-Tamai scaffold (Kyoto Medical, Japan) was made of PLLA without any drug coating and has a strut thickness of 170 μm . The first-generation scaffold was both thermal self-expanding and balloon expandable. In IVUS analysis, the stent struts mostly disappeared within 3 years. Nishio et al. reported 38% TLR at 10 years follow-up [85]. Igaki-Tamai BRS was challenging to use as it required heated contrast and large 8-French guide catheter. Newer revisions are currently being evaluated.

DESolve BRS

DESolve BRS (Elixir Medical, CA, USA) has a PLLA

scaffold and is coated with novolimus. It has a strut thickness of 150 μm and resorbs in 2 years. The scaffold has sinusoidal ring patterns and good radial strength. Newer generation DESolveNX and DESolve100 have thinner struts (120 μm). 2 year DESolve outcome trial with 126 patients illustrated major adverse cardiac event rate of 3.3% (n=4 of 122) at 6 months and 7.4% (n=9 of 122) at 24 months, including 1 probable stent thrombosis within the first month. Optical coherence tomography analysis during 6-month follow-up, showed full strut coverage in $99\pm 1.7\%$ [86,87].

Fortitude, aptitude and magnitude

Several iterations of sirolimus coated polymer bioresorbable scaffold were developed by Amaranth Medical Inc, Mountain View, CA, USA. The PLLA scaffold is made of multiple layers of high molecular weight semi-crystalline polymers to provide superior flexibility and strength. The structural integrity of the Amaranth scaffold lasts 3 to 6 months. The FORTITUDE (150 μm), APTITUDE (120 μm) and MAGNITUDE (90 μm) scaffolds have various strut thickness. The FORTITUDE was investigated in MEND II and RENASCENT-I studies. Nine-month follow-up in 45 patients showed 2.2% TLF [88-92].

MeRes BRS

MeRes BRS (Meril Life Sciences, Vapi, Gujarat, India) is a merilimus eluting bioresorbable coronary scaffold. The scaffold backbone comprised of PLLA polymer with a top coat of poly (D,L-lactic acid) (PDLLA), which controls the release of drug. Its strut thickness is 100 μm and it has uniquely differentiated triaxial-couplets platinum radio-opaque markers that provide greater visibility during deployment. MeRes-1 clinical trial with angiographic, OCT and IVUS 6-month follow-up, illustrated no TLF and in-scaffold late lumen loss was 0.15 ± 0.23 mm [93].

Mirage BRMS

Mirage Bioresorbable Micro-fiber Scaffold (Manli Cardiology Singapore) is a PLLA-based sirolimus-eluting scaffold. Its strut thickness is either 125 μm or 150 μm if 3.5 mm or larger in diameter. Its scaffold has a helical coil design that provides high flexibility. Prospective, single-blinded, 1:1 randomized trial of Mirage to Absorb (n=60) with 12-month follow-up demonstrated non-statistically significant difference of median in-scaffold late luminal loss of 0.37 mm (IQR: 0.08 to 0.72 mm) and 0.23 mm (IQR: 0.15 to 0.37 mm), respectively [94].

Fantom and ReZolve

The Fantom (Reva Medical Inc, San Diego, CA, USA) is a sirolimus-eluting scaffold with a strut thickness of 125 μm . The device is constructed from desaminotyrosine-derived polycarbonate material. Its characteristic features are complete scaffold visibility under X-ray, single-step continuous inflation and lower crossing profile [95,96]. In Fantom-I trial (n=7), 4 months follow-up median in-stent lumen loss was 0.21 mm. With IVUS, mean lumen area varied from 6.15 ± 0.68 mm² at post procedure to 5.6 ± 0.67 mm² at 4 months (p=0.2), with $3.1\pm 2.0\%$ of neointimal hyperplasia obstruction. Compared to OCT, the 4-month total neointimal hyperplasia area was 1.56 ± 0.28 mm² and 99.1% of all struts were covered with no incomplete strut apposition. No clinical events were observed up to 6 months of follow-up [97]. Fantom-II illustrated 6-month target vessel MI of 1.71% and mean late lumen loss of 0.29 ± 0.38 mm.

The ReZolve is the revision upon REVA scaffold, which has a spiral slide-and-lock mechanism and coated with sirolimus. In the RESTORE (ReZolve sirolimus-eluting bioresorbable coronary scaffold) clinical trial, acute recoil was minimal at 3.8% and at 6 months there were 9% (n=2) focal in-scaffold TLRs [98].

FADES Scaffold

The FADES scaffold (Zorion Medical, Indianapolis, IN, USA) is a fully bioresorbable drug-eluting scaffold. The polymer of the scaffold involves a hybrid material of magnesium that includes rare earth elements and poly(lactic-co-glycolic-acid) (PLGA). Early studies illustrated that the device was completely absorbed with little to no inflammatory response within 60 days [99].

Conclusions

Our experience with Magnesium BRS was challenging visualization of stent post-deployment, which required road-map for post-dilatation due to less radio-opaque scaffold and small tantalum radio-opaque markers. Additionally, it was imperative for good lesion preparation with appropriate balloon type and diameter. Lesion selection was also crucial, as Magnesium BRS (Magmaris) only had diameters of 3.0 mm and 3.5 mm. Meanwhile, there was good tractability of magnesium BRS, not dissimilar to metallic DES.

We demonstrated good procedural success and short-term outcome in the use of Magnesium BRS in our Asian cohort. However, a larger cohort and long-term outcome monitoring would better delineate the safety and efficacy of this BRS.

Executive summary

Background: Bioresorbable scaffold offer the advantages of reduced long-term complications such as stent fracture, late stent thrombosis and in-stent restenosis as well as the return of normal vasomotor function and late lumen gain with plaque regression.

Objective: Identify safety and outcomes of patients undergoing percutaneous coronary intervention (PCI) with magnesium BRS.

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Conclusion: We demonstrated safety and good short-term outcome in the use of magnesium BRS in our cohort, including stenting of total occlusions as well as bifurcation lesions. A larger cohort and longer-term outcome would better delineate the safety and efficacy of this new technology in treating coronary artery disease.

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