

# Bioresorbable magnesium scaffold in the treatment of simple coronary bifurcation lesions: The BIFSORB pilot II study

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## Abstract

**Objectives:** To evaluate the feasibility, safety, and healing response of a magnesium-based bioresorbable scaffold (BRS) in the treatment of simple bifurcation lesions using the single stent provisional technique.

**Background:** BRS may hold potential advantages in the treatment of coronary bifurcation lesions, however low radial strength and expansion capacity has been an issue with polymer-based scaffolds. The magnesium BRS may prove suitable for bifurcation treatment as its mechanical properties are closer to those of permanent metallic drug-eluting stents.

**Methods:** The study was a proof-of-concept study with planned inclusion of 20 patients with stable angina pectoris and a bifurcation lesion involving a large side branch (SB) > 2.5 mm with less than 50% diameter stenosis. Procedure and healing response were evaluated by optical coherence tomography (OCT). The main endpoints were a composite clinical safety endpoint and an OCT healing index at 1 month (range: 0–98).

**Results:** Eleven patients were included in the study. The study was prematurely terminated due to scaffold fractures and embolization of scaffold fragments in three cases requiring bailout stenting with drug-eluting stents. One patient underwent bypass surgery at 3 months due to stenosis proximal to the study segment. All SB were patent for 1 month. One-month OCT evaluation showed strut coverage of 96.9% and no malapposition. Scaffold fractures and uncovered jailing struts resulted in a less favorable mean OCT healing index score of  $10.4 \pm 9.0$ .

**Conclusions:** Implanting a magnesium scaffold by the provisional technique in nontrue bifurcation lesions was associated with scaffold fracture, embolization of scaffold fragments, and a high need for bailout stenting.

## KEYWORDS

bifurcation lesions, bioresorbable scaffolds, optical coherence tomography, strut fracture

**Abbreviations:** BRS, bioresorbable scaffold; CABG, coronary artery bypass graft; DES, drug-eluting stent; LAD, left anterior descending artery; MI, myocardial infarction; Mini-KBPD, mini-kissing postdilatation; MV, main vessel; OCT, optical coherence tomography; PLLA, poly-L-lactic acid; POT, proximal optimization technique; SB, side branch; ST, stent thrombosis.

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## 1 | INTRODUCTION

Stenting coronary bifurcation lesions can be challenging and are associated with an increased rate of complications such as acute closure of the side branch (SB), restenosis, and stent thrombosis (ST) when compared to treatment of simple lesions.<sup>1-3</sup> Bioresorbable scaffolds (BRS) are of particular interest for bifurcation stenting using the provisional technique as jailing struts in front of the SB may disappear over time.<sup>4</sup> First generation polymer-based BRS had low radial strength, low expansion capacity, inferior deliverability, and was associated with increased rates of scaffold thrombosis and myocardial infarction (MI) compared with permanent drug-eluting stents (DES).<sup>5-8</sup>

The Magmaris BRS (Biotronik AG) is a commercially available magnesium-based BRS. In single-arm studies, Magmaris was proven safe and effective in the treatment of patients with stable coronary artery disease.<sup>9,10</sup> The recent BIOSOLVE-IV-registry confirmed a good safety profile when implanted in simple lesions.<sup>11</sup> As the mechanical properties of the Magmaris BRS are closer to permanent metallic DES than poly-L-lactic acid (PLLA) scaffolds, Magmaris BRS could prove suitable for bifurcation treatment. A bench study evaluating safety parameters for postdilatation, SB dilatation, and mini-kissing postdilatation (mini-KBPD)<sup>12</sup> found the Magmaris BRS to be more resistant to strut fractures and that systematic postdilatation could help avoid excess recoil compared with the PLLA Absorb BRS (discontinued; Abbott).<sup>13</sup> Bifurcation treatment with Magmaris BRS was also evaluated in rabbits and deemed feasible.<sup>14</sup> Furthermore, a bench study indicated that the Magmaris BRS was less thrombogenic than other BRS possibly lowering the risk of scaffold thrombosis.<sup>15</sup> Based on these findings and favorable case reports<sup>16</sup> we designed a pilot study to evaluate the safety and feasibility of provisional bifurcation stenting using the Magmaris BRS in lesions with little or no SB stenosis.

## 2 | MATERIALS AND METHODS

The study was a single-arm, proof-of-concept study with the planned enrollment of 20 patients. Patients were included at Aarhus University Hospital. Inclusion criteria were stable angina pectoris, stabilized non-ST-elevation MI or silent angina pectoris, age above 18 years, and a de novo bifurcation lesion with the main vessel (MV)  $\leq 4.0$  mm and an SB diameter  $\geq 2.5$  mm with diameter stenosis  $< 50\%$ . Exclusion criteria were ST-elevation MI within 48 h, expected survival  $< 1$  year, severe heart failure (NYHA  $> III$ ), S-creatinine  $> 120$   $\mu\text{mol/L}$ , allergy to planned medications, planned use of more than three stents in the target lesion, severe tortuosity or calcification as identified with optical coherence tomography (OCT). The study was approved by the Central Denmark Region Ethics Committee for Biomedical Research and the Danish Data Protection Agency. All patients provided written informed consent. The study adhered to the Declaration of Helsinki.

## 2.1 | Endpoints

The main endpoint was clinical safety at 1 month (procedural MI, non-procedural MI, restenosis causing ischemia, or cardiac death). The second main endpoint was an OCT healing index (range: 0–98, lower is better) of adverse vessel wall features including SB ostial area late loss, strut fracture, uncovered non-SB apposed struts, uncovered stent struts in front of the SB, uncovered stent struts on acquired or persistent malapposed struts, persistent malapposition, maximal neointimal thickness, and cumulated extra stent lumen gain at 1 month. The OCT healing index scoring system is explained in detail in the Supporting Information Material.

## 2.2 | Study device

The Magmaris BRS is based on a magnesium alloy that gradually degrades to amorphous calcium. It is the first metallic BRS. The surface is coated with PLLA-polymer eluting sirolimus. The process is relatively fast and 95% of the magnesium is resorbed after 12 months. The platform has in-phase sinusoidal hoops with two connectors per hoop linking the valleys and peaks. Strut thickness is 150  $\mu\text{m}$ .<sup>17</sup>

## 2.3 | Study procedure

The MV and SB were wired, and predilatation was performed with noncompliant balloon or scoring balloon. OCT was performed after predilatation to exclude severely calcified lesions, assess plaque preparation, and estimate optimal scaffold length and diameter. It was decided by integrating angiographic and OCT findings if the lesion was suitable for Magmaris implantation in terms of the limited presence of calcium and reference size in both proximal and distal MV segments within the formal limits of the device. If applicable, the procedure proceeded with scaffold implantation with mandatory jailing of the SB, postdilatation, and proximal optimization technique (POT). A final OCT was performed to evaluate treatment results when the procedure was finalized. In case of severe ostial pinching or thrombolysis in myocardial infarction flow  $< III$ , mini-KBPD<sup>12</sup> was performed after OCT confirmed rewiring.

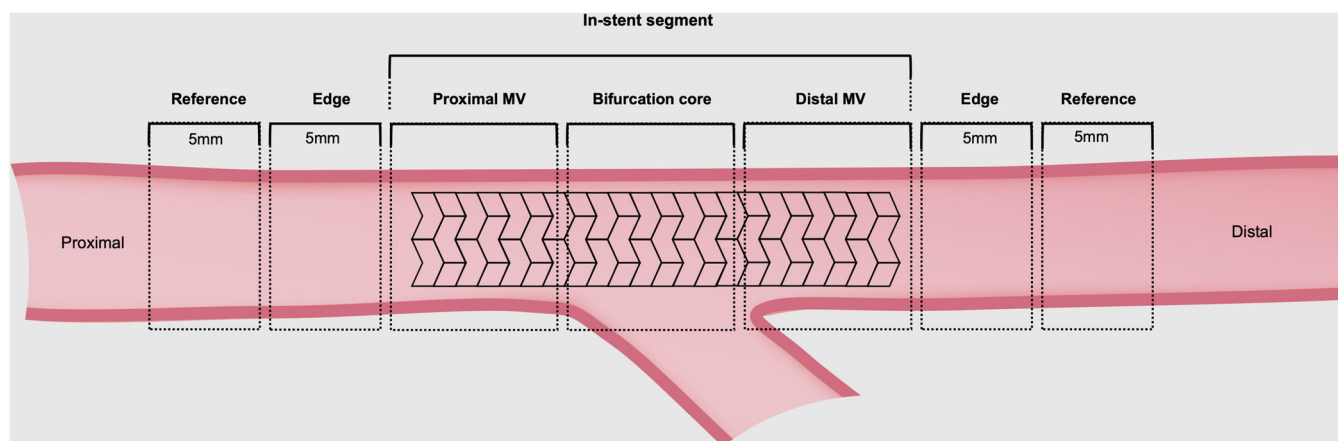
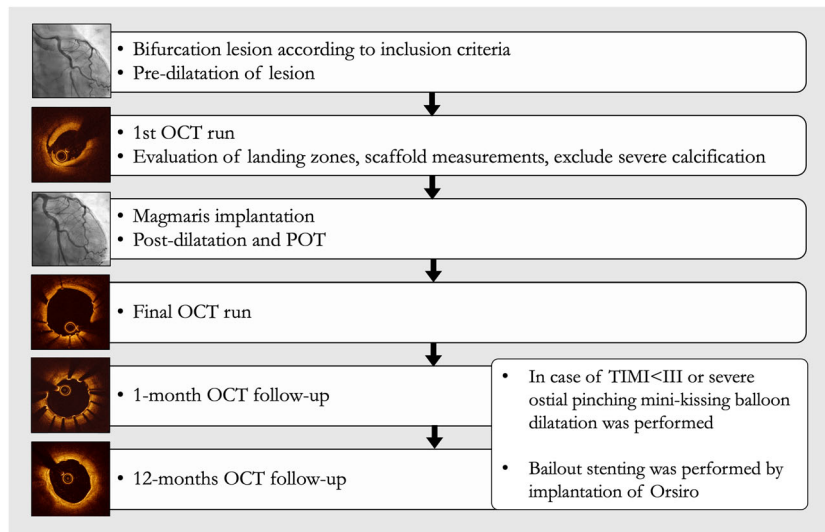
Bailout stenting was performed by implantation of an Orsiro DES (Biotronik) and at the operators' discretion. Proximal postdilatation of the BRS was mandatory and dilatation beyond expansion limits of the scaffold was not allowed.

The study procedure flowchart is shown in Figure 1.

OCT scans were performed using the OPTIS OCT system (Abbott). A pullback speed of 36 mm/s (75 mm normal resolution) was used for the pullback after predilatation while the 18 mm/s (54 mm high resolution) pullback was used after scaffold implantation. In the case of guidewire shadow covering the SB ostium, wires were manipulated, and a new OCT pullback was performed.

Follow-up angiography with OCT was performed at 1 and 12 months to evaluate the scaffold properties and the healing response.

**FIGURE 1** Study procedure flowchart. OCT, optical coherence tomography; POT, proximal optimization technique [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 2** Segmental model of the different segments for OCT analysis. MV, main vessel; OCT, optical coherence tomography [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

Angiographic images were analyzed with two-dimensional (2D) quantitative coronary angiography using QAngio XA (Medis Medical Imaging Systems bv.).

## 2.4 | OCT analysis

Baseline scans were matched with 1- and 12-month scans on frame level and rotation based on stent edges, calcified plaques, and SB. All scans were calibrated before analysis. Frames were analyzed every 0.6 mm except for the bifurcation segment where all frames were analyzed (0.1–0.2 mm). Each pullback was divided into seven segments (Figure 2). Lumen, stent struts, and stent were contoured semi-automatically. In the bifurcation, segment struts were marked as opposite the SB or toward the SB. Analysis was performed in QCU-CMS. On follow-up, strut coverage was evaluated by visual assessment. The SB ostial area was measured using the Cut-plane analysis (QAngioOCT). QAngioOCT was also used for 3D reconstructions and to check all pullbacks for the presence of

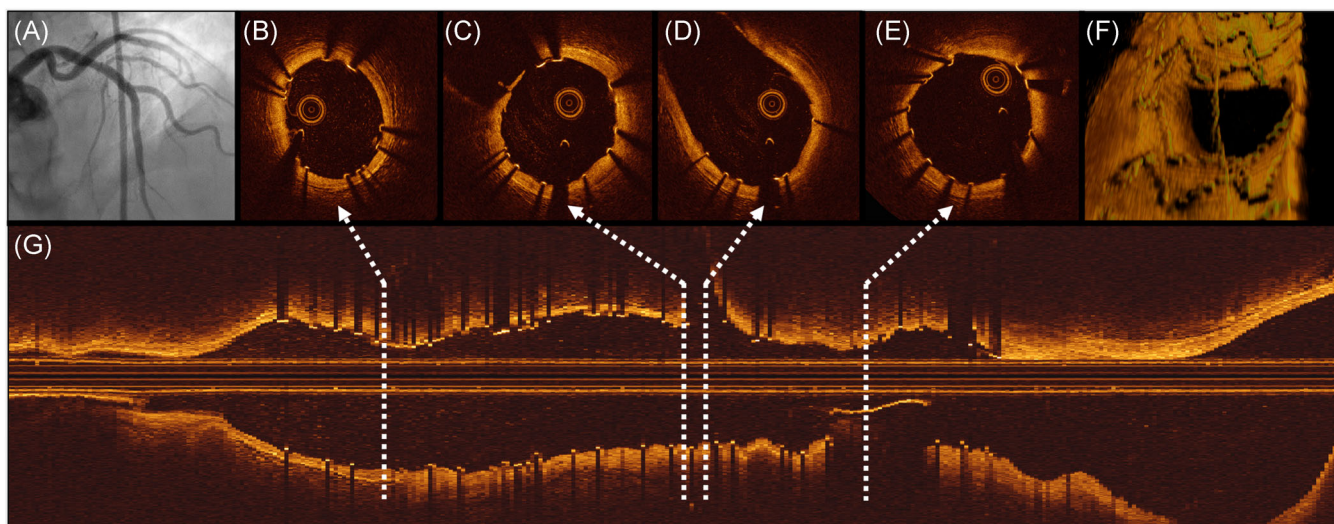
fracture and major cardiac motion artifacts. A figure example is shown in Figure 3.

## 2.5 | Statistics

Data are presented as mean  $\pm$  standard deviation or as counts (%). If following a non-gaussian distribution data are presented as medians and interquartile ranges. Differences were tested by paired *t*-test or by Wilcoxon-signed rank test depending on the distribution. All tests were two-sided and a  $p < 0.05$  was considered significant.

## 3 | RESULTS

A total of 11 patients were included before the investigators stopped enrollment due to safety concerns. Full OCT analysis of baseline and 1 month OCT scans were available for eight patients. Of the eight patients, seven completed 12 months of OCT follow-up.



**FIGURE 3** Patient case setup showing final angiogram and final OCT at baseline. (A) Final angiogram. (B) Cross-section from the distal main vessel. (C) Carina point. (D) Bifurcation core segment with the open side branch. (E) Image from proximal MV. (F) Three-dimensional reconstruction of the side branch ostium. (G) Longitudinal view of the OCT pullback. White lines mark the individual cross-sections. OCT, optical coherence tomography [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

**TABLE 1** Patient baseline characteristics

Baseline characteristics (n = 11)	
Male gender	9 (82%)
Age (years)	66 ± 10
Diabetes	3 (27%)
Family history	4 (36%)
Treatment for hypertension	6 (55%)
Statin treatment	7 (64%)
Current smoker	1 (10%)
BMI (kg/m <sup>2</sup> )	28 ± 5
Previous PCI	3 (27%)
Previous CABG	0 (0%)
Ejection fraction (%)	60 [55; 60]
Angina CCS-class	
1	3 (27%)
2	7 (64%)
3	1 (9%)

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

Of the 11 included patients 9 (82%) were male and 3 (27%) had diabetes. The mean age was 66 ± 10 years. Additional patient characteristics are presented in Table 1. Most lesions were located in the left anterior descending artery (LAD) (63%). Lesions were Medina class 0.1.0 (73%) or 1.1.0 (27%). Procedural and lesion characteristics are presented in Table 2. Drop-out was by patient request.

After 1 month there were no clinical events. One patient underwent coronary artery bypass grafting (CABG) 3 months after the index procedure due to angina caused by ostial LAD stenosis just proximal to the implanted Magmaris stent. There were no cases of MI or cardiac death. We saw no cases of scaffold thrombosis. After 12 months a patient had developed an aneurism just distal to the SB takeoff.

Three cases had OCT verified fractures of the scaffold and received bailout stenting with Orsiro during the baseline procedure. In all three cases, OCT showed a part of the proximal ring of the scaffold was missing and had embolized distally (Figure 4). None of the patients had significant calcifications. All three cases with fractured BRS were predilated using scoring balloons and had subsequently two Magmaris BRS implanted. Nominal diameters were 3.0 or 3.5 mm, and length was 20 mm in five scaffolds and 25 mm in one scaffold. The maximum deployment pressure was 20.7 ± 3.5 atm. The balloons used for POT were 6 [6; 6] mm long and were inflated to a maximum diameter of 4.2 [3.6; 4.2] mm. In all three cases, a DES was implanted from the proximal scaffold edge and distally to the SB takeoff, leaving the distal part of the scaffold, uncovered. One of the fracture cases also had a DES bailout of the distal scaffold edge due to a large edge dissection. After bailout stenting, a scaffold fragment was found in the lumen distally to the scaffold edge in one patient. None of the fractures were visible by angiography.

### 3.1 | Quantitative OCT results

Quantitative OCT results for baseline and 1-month follow-up are presented in Table 3. All stented segments were

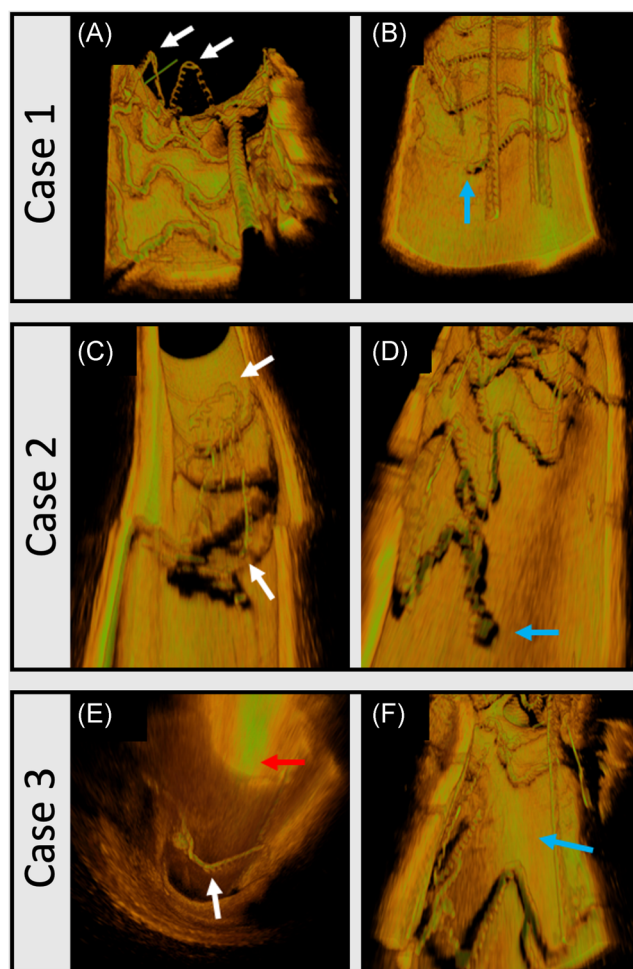
**TABLE 2** Procedural and lesion characteristics

Procedural and lesion characteristics (n = 11)	
Lesion location	
Left anterior descending artery	7 (63.4%)
Circumflex artery	4 (36.4%)
Right coronary artery	0 (0%)
Mean lesion length, mm (visual estimate)	34.5 ± 18.5
Length of stented main vessel (mm)	42.6 ± 22.5
Procedure time (min)	76 ± 24
Fluoroscopy time (min)	20 ± 8
Contrast volume (ml)	215 ± 55
Medication	
ASA	11 (100%)
Ticagrelor	8 (73%)
Clopidogrel	3 (27%)
GPIIb/IIIa inhibitor	1 (9.1%)
Predilatation	
Nominal diameter (mm)	3 [3; 3.5]
Maximum diameter (mm)	3.29 [3.18; 3.68]
Scaffold length (mm)	20 [20; 25]
Scaffold nominal diameter (mm)	3 [3; 3.5]
Maximum deployment pressure (atm)	17.9 ± 4.6
Proximal optimization technique	
Balloon length (mm)	6 [6; 8]
Nominal diameter (mm)	3.75 [3.5; 4.0]
Maximum diameter (mm)	3.9 [3.6; 4.2]

Abbreviation: ASA, acetylsalicylic acid.

analyzed regardless of stent/scaffold type. Malapposition for the entire segment at baseline was  $1.3 \pm 2.1\%$  for patients treated solely with Magmaris versus  $0.9 \pm 0.8\%$  for the bailout stented group. There was no malapposition at the 1-month follow-up. After 1 month, stent strut coverage was  $96.0 \pm 4.2\%$  for the patients with sole Magmaris implantation versus  $98.5 \pm 1.9\%$  for the bailout group. The mean neointima thickness for the entire segment was  $44.5 \pm 15.3 \mu\text{m}$  in the Magmaris group versus  $59.3 \pm 23.5 \mu\text{m}$  in the bailout group.

At 12 months follow-up, seven patients had OCT scans. The three patients that received bailout stenting had the stented segment analyzed accordingly. In the remaining four patients, the Magmaris BRS was resorbed and only the tantalum markers were still visible. The mean lumen area for patients without bailout stenting was  $8.7 \pm 1.9$  versus  $9.0 \pm 1.4 \text{ mm}^2$  for patients with bailout stenting. Despite all Magmaris struts being resorbed by



**FIGURE 4** Scaffold fractures. Three-dimensional (3D) reconstructed images of the three cases with scaffold fractures. Horizontally aligned images are from the same case. (A) The white arrows indicate a distally embolized scaffold fragment. By 3D rendering, the entire scaffold can be visualized, and the marked scaffold part is extra. (B) Same case at the proximal scaffold edge. The blue arrow marks a break in the scaffold and a part is missing. (C) Second case with distal embolization of the fragment (marked by white arrows). (D) Same case at the proximal edge of the scaffold. Blue arrow marks a break in the scaffold and a part of the scaffold is missing. (E) Third case; the red arrow marks the OCT catheter. Unflushed blood is trapped between the catheter and the vessel wall. The white arrow marks a scaffold fragment. (F) Same case with fracture. Parts of the scaffold missing in the proximal end (blue arrow). OCT, optical coherence tomography [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

OCT evaluation, neointimal bridging over the SB ostium was seen in one patient (Figure 5).

### 3.2 | OCT healing index

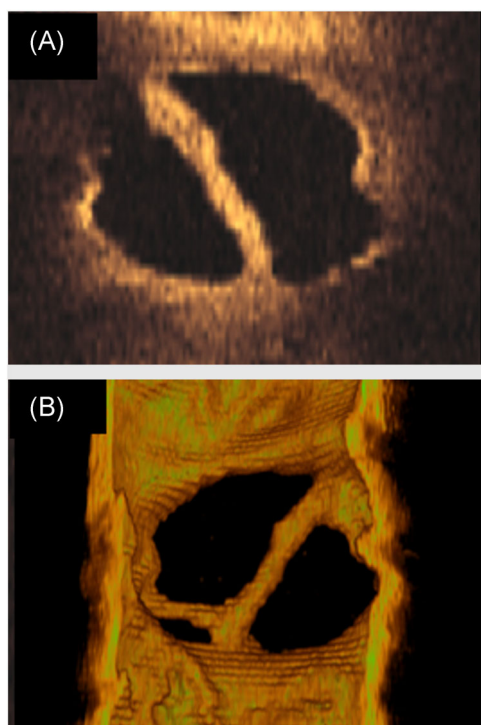
The mean coronary OCT healing index at 1 month was  $10.4 \pm 9.0$ . The main components for high scores were scaffold fracture and uncovered struts in front of SBs.

**TABLE 3** Quantitative OCT results for baseline and 1-month follow-up

OCT analysis (n = 8) Analysis for segments	Distal MV			Bifurcation core			Proximal MV		
	Baseline	Follow-up	p Value	Baseline	Follow-up	p Value	Baseline	Follow-up	p Value
Minimal luminal area (mm <sup>2</sup> )	5.0 ± 1.0	4.1 ± 1.2	0.01	8.6 ± 2.1	7.8 ± 2.6	0.09	8.4 ± 1.5	7.7 ± 1.9	0.06
Mean luminal area (mm <sup>2</sup> )	8.2 ± 1.2	7.5 ± 1.2	0.09	9.7 ± 2.1	9.0 ± 3.1	0.26	10.3 ± 1.6	9.3 ± 2.2	0.05
Mean scaffold area (mm <sup>2</sup> )	8.0 ± 1.2	7.7 ± 1.2	0.37	9.3 ± 2.3	9.2 ± 3.2	0.91	9.8 ± 1.8	9.4 ± 2.4	0.42
Malapposed struts (%)	0 [0; 0.45]	0 [0; 0]	0.25	0.01 [0; 0.03]	0 [0; 0]	0.06	0 [0; 0.32]	0 [0; 0]	0.50
Coverage (%)	-	96.9 ± 3.9	-	-	98.0 ± 2.4	-	-	95.4 ± 6.4	-
Minimal ostial side branch area (mm <sup>2</sup> )	-	-	-	1.74 ± 1.3	2.79 ± 1.1	0.02	-	-	-
Analysis for the entire segment	Baseline	Follow-up							
Mean neointimal thickness (µm)	-	50.1 ± 18.7							
Extra stent lumen (mm <sup>2</sup> )	0.47 ± 0.15	0.27 ± 0.10							
Fracture visible by OCT on patient level (%)	3 (30%)	1 (12.5%)							
Neointimal bridging over side branch by 3D evaluation on patient level	-	2 (25%)							

Note: Pooled for patients with and without bailout stenting.

Abbreviations: MV, main vessel; OCT, optical coherence tomography.



**FIGURE 5** Neointimal bridging at 12-months follow-up. (A) Cut-plane analysis of the side branch ostium from QAngioOCT. (B) 3D reconstruction of the side branch ostium showing neointimal bridging. The scaffold struts seem completely resorbed as no struts or strut shadows can be identified by OCT. 3D, three-dimensional; OCT, optical coherence tomography [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

### 3.3 | SB intervention and analysis

One patient had predilatation of the SB due to pinching after MV predilatation. One patient had mini-KBPD with a 3.5 × 20 mm MV balloon and a 2.5 × 12 mm SB balloon by low-pressure inflation (10 atm) after Magmaris implantation due to a pinched SB. All patients with bailout stenting had kissing balloon inflation performed. In one patient the final angiogram of modest quality indicated possible residual stenosis in the SB ostium. Poor contrast filling also affected the final OCT scan, and the SB ostium was not visualized. The physician decided not to proceed with the mini-kissing technique. The patient had no clinical events and at 12 months the SB was open and without apparent stenosis.

All other studies SB were patent at follow-up. The ostial SB area assessed by cut-plane analysis was 1.4 ± 1.3 mm<sup>2</sup> at baseline for the Magmaris group versus 2.2 ± 0.9 mm<sup>2</sup> for the bailout group. At 1 month, the ostial SB area was 2.7 ± 1.2 mm<sup>2</sup> for the Magmaris group versus 2.9 ± 1.3 mm<sup>2</sup> for the bailout group. After 1 month 24% of jailing struts were uncovered.

### 3.4 | 2D QCA results

Reference diameters in the proximal MV, distal MV, and the SB remained stable from baseline to 1-month follow-up (Table 4). SB ostial diameter stenosis at 1-month follow-up (50 ± 19%) was comparable to the baseline residual stenosis (47 ± 25%; *p* = 0.54).

**TABLE 4** Results of the 2D QCA analysis

2D QCA analysis	Postimplantation	1-month follow-up	p Value
Proximal MV reference diameter (mm)	3.47 ± 0.27	3.18 ± 0.38	0.323
Distal MV reference diameter (mm)	2.87 ± 0.50	2.73 ± 0.18	0.506
Side branch reference diameter (mm)	2.14 ± 0.15	2.23 ± 0.27	0.484
Side branch ostial area stenosis (%)	46.79 ± 25.43	50.12 ± 18.68	0.543

Abbreviations: 2D, two-dimensional; MV, main vessel; QCA, quantitative coronary analysis.

## 4 | DISCUSSION

In this pilot study of treating coronary bifurcation lesions with the Magmaris BRS, the main findings were: (1) the scaffold was feasible to implant and expand (2) three cases presented with scaffold fracture detected by OCT during the procedure, (3) bailout stenting with Orsiro DES in case of fracture was effective and safe, (4) no patient had MI or died, (5) the healing of the scaffold was in general good, (6) ostial SB area improved from baseline to follow-up, (7) the Magmaris BRS was completely resorbed as assessed by OCT at 12 months.

The use of BRS in bifurcations has been low as most clinical trials have excluded bifurcation lesions with an SB > 2.0 mm or SB > 50% diameter stenosis per protocol.<sup>5,10,18-20</sup> Therefore, the experience with BRS in bifurcations is limited despite being theoretically promising. Only one case of bifurcation treatment with the Magmaris BRS has been published<sup>16</sup> but evaluation in bench tests and animal models were promising.<sup>13,14,21,22</sup> Still, the general limitations of BRS such as lower expansion capacity, higher crossing profile, and lower radial strength was evident in the experiments. While bench tests and animal studies bear advantages, the current models do not allow for evaluation in humanlike stenosis. This is a major limitation in the preclinical evaluation as delivery, expansion, device integrity, and degradation is greatly affected by the underlying disease.

In clinical use, the fast resorption time of the Magmaris BRS could cause problems with the early loss of radial strength as was shown in a case series with early restenosis due to early collapse of the scaffold.<sup>23-26</sup>

Implantation of the Absorb BRS (discontinued; Abbott) in bifurcations has been explored with mixed results. The GHOST-EU registry included a "less selected" patient population and investigated 333 bifurcation lesions of which 80% were treated by the provisional approach.<sup>8</sup> The study reported increased ST rates of 1.5% at 30 days and 2.5% at 1 year. As early restenosis was reported for Magmaris due to apparent collapse of the scaffold, the present study was focused on evaluating the early healing response, apposition, and resorption of the Magmaris BRS, mandating the 1-month follow-up.

The high ST rates seen in GHOST-EU were believed to be in part related to the low use of intravascular imaging (<23%) and the lack of postdilatation of the MV in 38.7% of cases. This may have led to BRS under-expansion and malapposition, which are known predictors of ST.<sup>27</sup> A small pilot study investigated the DESolve BRS for treatment of bifurcation lesions in 10 patients.<sup>28</sup> All procedures were OCT guided and 1 month OCT follow-up was performed in all patients.

Implantation was feasible and there were no clinical events reported at 6 months. OCT showed improvement in SB ostial area and reduction in malapposition at follow-up.<sup>28</sup>

Since the introduction of BRS, it has become evident that careful selection of lesions and meticulous implantation techniques are of utmost importance. In BIFSORB pilot II we followed present recommendations for BRS implantation with careful predilatation, meticulous sizing of the scaffold by OCT, and sensible care during implantation procedures with no expansion beyond the device limits. Still, we observed three cases of scaffold fracture. All cases of fracture showed that a part of the most proximal ring of the scaffold was missing. In all cases, the fragment embolized distally. The fragments did not cause a buildup of thrombus and none of the patients experienced chest pain during or after the procedures. This might be related to the limited flow disturbance caused by the fragments and because the Magmaris BRS is less thrombogenic than other BRS and DES.<sup>15,29</sup> However, the fact that the scaffolds fractured and that fractured parts were embolized are deeply concerning. There is a potential risk of thrombus formation on embolized struts due to the disturbed blood flow.

All fractures were located in the proximal MV similar to an animal study.<sup>14</sup> A possible explanation for the scaffold fractures could be a collision with the OCT catheter, the POT balloon catheter, or the guiding catheter.<sup>30</sup> Other healing parameters were positive with a low presence of uncovered struts and low rates of malapposition possibly due to the meticulous postdilatation.

It is unknown if the acute fractures of the Magmaris BRS is a safety issue if left untreated. All three cases with fracture and embolized fragments received bail-out stenting and the patients had no symptoms or events during follow-up. Still, the frail stent platform is a safety concern. As the fractures may not be exclusively related to the additional steps in bifurcation stenting, we recommend evaluating implantation of the Magmaris BRS with OCT imaging.

### 4.1 | Limitations

BIFSORB pilot II was a pilot study and thus solely hypothesis-generating. The study was not sufficiently powered to detect less frequent early and late clinical safety endpoints. Still, the sample allowed for the identification of a potential safety issue during a basic and highly controlled bifurcation implantation strategy.

## 5 | CONCLUSION

Treatment of simple coronary bifurcation lesions with the Magmaris BRS was associated with scaffold fractures during implantation and the study was stopped due to safety concerns. Clinical outcome and healing results during 1 and 12 months follow-up were acceptable.

## 6 | IMPACT ON DAILY PRACTICE

The use of the magnesium bioresorbable scaffold, Magmaris, in simple bifurcation lesions was associated with scaffold fracture and distal embolization of scaffold parts. Bailout stenting with drug-eluting stents was effective. Treatment of bifurcation lesions with the Magmaris BRS cannot be recommended.

### CLASSIFICATIONS

Bioresorbable scaffolds, Bifurcation lesions, Strut fracture, Optical coherence tomography.

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### CONFLICT OF INTERESTS

Emil N. Holck: Travelling grant from Biotronik. Institutional research grants from Reva Medical. Evald H. Christiansen: Speaker fees from Abbott, research grants from Biotronik and Abbott, and grants from Biotronik to his institution. Niels R. Holm: Speaker fees from Abbott, Biotronik, Medis medical imaging and Terumo, and institutional research grants from Abbott, Boston Scientific, Medis medical imaging, and Reva Medical. Trine Ø. Barkholt, Omeed Neghabat, and Lene N. Andreasen declares that there are no conflict of interests.

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## SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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