Bioresorbable Vascular Scaffolds for the Treatment of Chronic Total Occlusions

An International Multicenter Registry

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Background—There are only limited studies reporting clinical outcomes after bioresorbable vascular scaffold (BVS; Absorb; Abbott Vascular, Santa Clara, CA) implantation for coronary chronic total occlusions (CTO). The aim of this study was to evaluate the real-world feasibility and safety of BVS implantation for the treatment of CTO.

Methods and Results—We retrospectively evaluated CTO cases treated with BVS from a multicenter registry. The primary end point was target lesion failure defined as a composite of cardiac death, target vessel myocardial infarction, and clinically driven target lesion revascularization. From September 2012 to November 2015, 65 patients with CTO were successfully treated with BVS. The mean age of patients was 60.8±11.0 years; 89.2% were male and 40.0% diabetic. The mean ejection fraction was 57.7±10.8%. The mean reference vessel diameter and CTO lesion length were 3.0±0.4 and 20.2±3.0 mm, respectively. The mean number of BVS deployed per patient was 1.8±0.7, of which mean diameter and total length were 3.0±0.4 and 47.6±19.9 mm, respectively. Postdilatation with noncompliant balloons (mean diameter 3.3±0.3 mm) was performed at high pressures (18.6±5.3 atm) in all cases. Intravascular ultrasound (n=34) or optical coherence tomography (n=31) was performed in all cases. During the follow-up period (median: 453 days, 25th and 75th percentiles: 230 and 703), there were no occurrences of target lesion failure or scaffold thrombosis.

Conclusions—BVS implantation for the treatment of CTO seems feasible and safe. Appropriate lesion preparation, high-pressure postdilatation, and the use of intravascular imaging are recommended to obtain the best possible final result. **(*Circ Cardiovasc Interv*. 2017;10:e004265. DOI: 10.1161/CIRCINTERVENTIONS.116.004265.)**

Key Words: bioresorbable vascular scaffolds ■ chronic total occlusion ■ intravascular imaging ■ lesion preparation ■ postdilatation

Chronic total occlusions (CTO) are challenging lesions for percutaneous coronary intervention (PCI); however, innovations in PCI techniques and devices have contributed to increased procedural successes.[1,2] Although favorable 3-year outcome data have been reported after the implantation of newer generation drug-eluting stents (DES),[3] CTO PCI generally requires long segment of stenting for diffusely diseased vessels, which is a known risk factor for restenosis and stent thrombosis.[4–6]

The everolimus-eluting bioresorbable vascular scaffold (BVS; Absorb; Abbott Vascular, Santa Clara, CA) is a relatively new device, which provides temporary radial force and drug delivery with complete resorption over time, providing the potential advantages of restoring normal vessel physiology[7,8] and may preserve the option for future bypass grafting.

The aim of this study was to evaluate the real-world feasibility and safety of BVS implantation for CTO lesions from an international multicenter registry.

Methods

Study Population

This was a retrospective, international multicenter registry, which enrolled 65 CTO cases treated with BVS from 5 centers (Heart of England NHS Trust, Birmingham, United Kingdom; Cheng Hsin General Hospital, Taipei, Taiwan; Siriraj Hospital, Bangkok, Thailand; EMO-GVM Centro Cuore Columbus, Milan, Italy; and San Raffaele Scientific Institute, Milan, Italy). The indications for

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WHAT IS KNOWN

- Bioresorbable vascular scaffold (BVS) (Absorb; Abbott Vascular, Santa Clara, CA) has been used in clinical practice across the globe, and evaluation of its safety and efficacy has been continued in various clinical settings.
- For simple stenotic lesions, low rates of adverse cardiac events at short to midterm follow-up after BVS implantation have been established.
- There are limited data available in regards to clinical outcomes after BVS implantation for chronic total occlusions.

WHAT THE STUDY ADDS

- There were no occurrences of target lesion failure defined as a composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization, and scaffold thrombosis after BVS implantation for chronic total occlusions.
- Intravascular imaging–guided lesion preparation and postdilatation are recommended to obtain the best possible final result in BVS implantation for chronic total occlusions.
- Intravascular imaging facilitates detection of issues related to BVS implantation technique.

CTO PCI were symptomatic angina and ischemia on noninvasive functional test(s). All patients provided informed consent for both the procedure and subsequent data collection and analysis. The relevant review boards in each institute approved the study protocol.

Definitions of Lesion and Procedure

A CTO was defined as a completely occluded vessel with Thrombolysis In Myocardial Infarction flow grade 0 through the affected segment of >3 months estimated duration. The lesion complexities were evaluated based on the morphology of the entry point, proximal tortuosity, vessel angulation (>45°), the presence of a bifurcation or bridging collaterals at the CTO, and calcification graded by fluoroscopy. The Multicenter CTO Registry of Japan score was calculated for all lesions.[9] Because of the limitations in the available device sizes, the target vessel diameter was between 2.5 to 4.0 mm.

The decision on whether to perform an anterograde or retrograde approach was made by the operator. Predilatation with appropriately sized balloons (usually 1:1 with vessel diameter) was performed in all cases, and there was a low threshold for using scoring/cutting balloons or rotational atherectomy if required. After BVS implantation, postdilatation with noncompliant balloons (maximum 0.5 mm diameter greater than scaffold size) was performed. All procedures were guided by intravascular imaging for the evaluation of lesion morphology, selection of scaffold size, and postdilatation balloon diameter (Figure 1). Procedural success was defined as an achievement of <30% in-scaffold residual stenosis and Thrombolysis In Myocardial Infarction flow grade >2 after BVS implantation.

Intravascular Ultrasound and Optical Coherence Tomographic Imaging

Intravascular ultrasound (IVUS) was performed using an automatic pullback of 0.5 mm/s using the various catheters available at each of the centers (ViewIT, Terumo Corporation, Tokyo, Japan; iLab, Boston Scientific, Natick, MA; Revolution, Volcano Corporation, San Diego, CA). The examined region included the treated segment and the adjacent proximal and distal 5 mm. We analyzed plaque morphologies, the diameter and area of the vessel, lumen, and scaffold in the manner previously described.[10] All analyses were conducted by well-experienced operators at each institute.

Optical coherence tomography (OCT) was performed with the C7 Dragonfly (St. Jude Medical, St. Paul, MN) intracoronary imaging catheter and the ILUMIEN PCI Optimization System (St. Jude Medical). All of the OCT images were reviewed at New Tokyo Hospital and independently analyzed by well-experienced operators according to the definitions previously described[10] using the LightLab Imaging workstation (St. Jude Medical). The analysis of continuous cross sections was performed at each 1-mm longitudinal interval within the treated segment. Incomplete scaffold apposition (ISA) was defined as a clear separation between the abluminal side of the strut and the vessel wall with a distance larger than the strut thickness.[11] The presence of calcification with arc >180°, thrombi, edge dissections, and scaffold disruptions were also analyzed.

Follow-Up and Antiplatelet Therapy

Clinical follow-up was performed on all subjects either by clinic visit or telephone interview. Follow-up angiography was performed by either physician's request or the presence of symptoms warranting repeat angiography (Figure 2). Patients received dual antiplatelet therapy before the procedure with an aim to continue this for at least 12 months after BVS implantation. The decision to use ticagrelor or prasugrel as a substitute for clopidogrel was dependent on the discharging physician.

Clinical Outcomes

The primary outcome was device-oriented end point defined as target lesion failure (TLF), which was a composite of cardiac death, target vessel myocardial infarction, and clinically driven target lesion revascularization (TLR). Secondary outcomes included all-cause mortality, clinically driven target vessel revascularization, and scaffold thrombosis (ST). TLR was defined as repeat revascularization for the site where BVSs were previously implanted for CTO lesion or in the adjacent 5 mm. Target vessel revascularization was defined as repeat PCI in the target vessel. Periprocedural and follow-up myocardial infarction was defined as a creatinine kinase elevation >3× the upper limit of normal accompanied by an increase in troponin level >5× upper limit of normal at the time of postprocedure and follow-up.[12] ST was defined according to the Academic Research Consortium definitions for definite or probable stent thrombosis.[13]

Statistical Analysis

Categorical data are presented as frequencies and continuous variables are expressed as mean±SD or median with 25th and 75th percentiles. Cumulative rate of incidences were determined by Kaplan–Meier analysis. All analyses were conducted using SPSS software version 21.0 (IBM Corp, Armonk, NY).

Results

Study Population and Baseline Characteristics

Between January 2012 and November 2015, 65 CTO cases treated with BVS were enrolled (Thailand, 34 cases; Taiwan, 9 cases; Italy, 19 cases; and United Kingdom, 3 cases). The baseline characteristics of patients are shown in Table 1. The mean age of the population was 60.8±11.0 years; 89.2% were male; 40.0% had a previous history of diabetes mellitus and 16.9% previous myocardial infarction. The mean ejection fraction of the cohort was 57.7±10.8%. The most common dual antiplatelet therapy regimen was aspirin and clopidogrel in 70.8%; with ticagrelor (16.9%) or prasugrel (12.3%) used in the remainder.

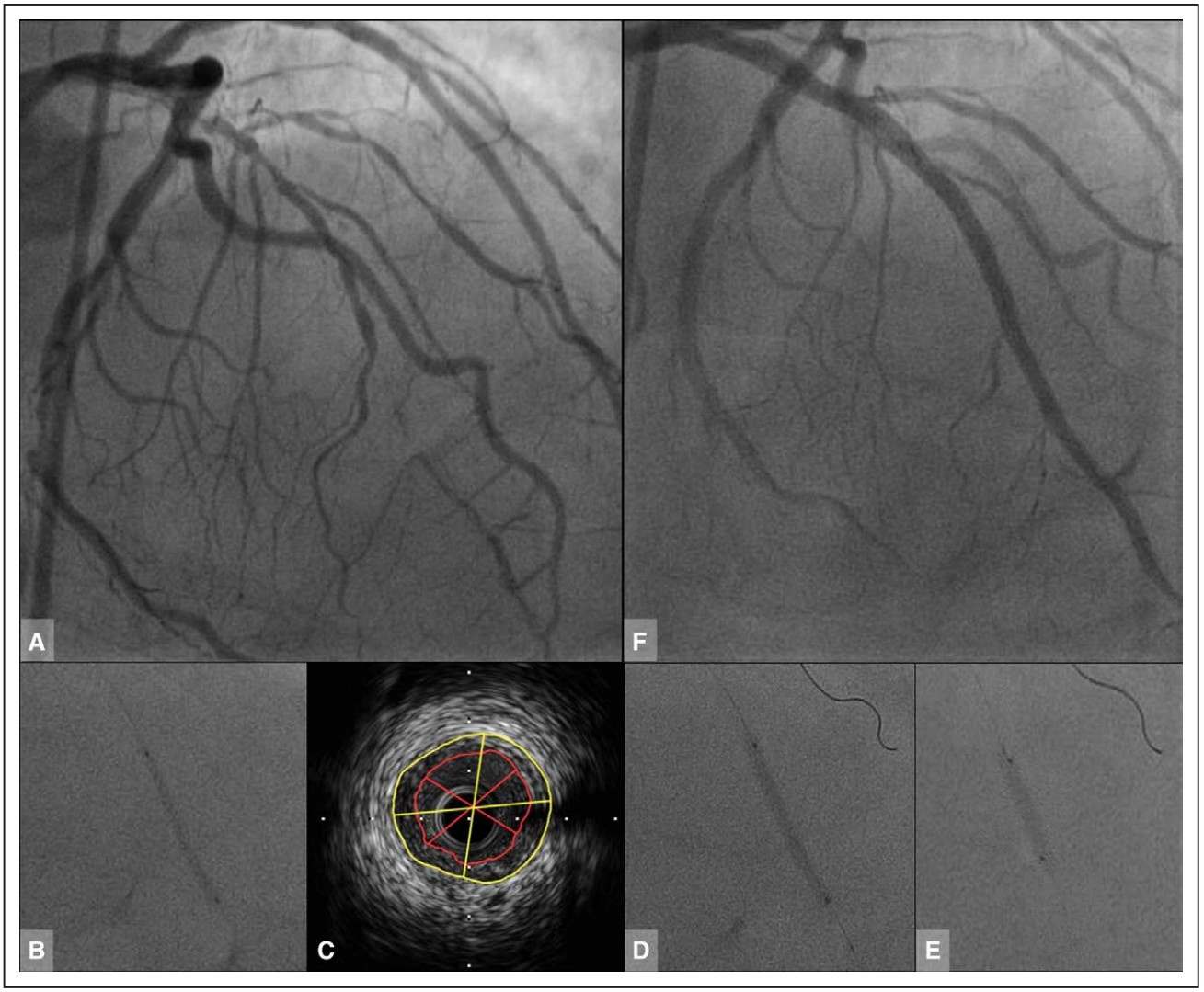

Figure 1. Representative case of BVS implantation for LAD CTO. **A**, Angiography before PCI of LAD CTO; (**B**) predilatation with 2.0 mm semicompliant balloon for CTO lesion; (**C**) IVUS evaluation before BVS implantation; (**D**) BVS (2.5/28 mm) implantation for CTO lesion; (**E**) postdilatation with 3.0 mm noncompliant balloon after 2.5 mm BVS implantation for CTO lesion according to the IVUS evaluation; and (**F**) final angiography after revascularization with BVS. BVS indicates bioresorbable vascular scaffold; CTO, chronic total occlusion; IVUS, intravascular ultrasound; LAD, left anterior descending artery; and PCI, percutaneous coronary intervention.

Lesion Characteristics

Lesion characteristics are described in Table 2. Left anterior descending artery CTO was the most common (46.2%), followed by right coronary artery (40.0%) and left circumflex artery (12.3%). One left main trunk CTO case was treated with BVS, which involved a 10 mm in-stent CTO lesion at the midshaft of the left main trunk. On lesion complexities, ≈65% of cases were evaluated as Multicenter CTO Registry of Japan score ≥2 (difficult). The majority of cases (81.5%) had Rentrop grade 3 collateral flow. The mean reference vessel diameter and CTO lesion length on visual estimation were 3.0±0.4 and 20.2±3.0 mm, respectively.

Procedural Characteristics

Procedural characteristics are summarized in Table 3. Procedural success was achieved in all cases. The mean number of BVS implanted per patient was 1.8±0.7, with mean scaffold diameter and total scaffold length of 3.0±0.4 and 47.6±19.9 mm, respectively. Of note, predilatation and postdilatation based on careful lesion evaluation by intravascular imaging were performed in all cases. For postdilatation, noncompliant balloons (3.3±0.3 mm) were inflated at high pressures (18.6±5.3 atm) to achieve appropriate apposition. Either IVUS (52.3%) or OCT (47.7%) was performed in all cases. Seventeen cases (26.2%) required additional DES implantation for stenotic lesions adjacent to CTO lesions.

IVUS Findings

IVUS was performed in 34 cases (IVUS findings were summarized in Table I in the Data Supplement). The final minimal scaffold area (MSA) was 7.74±3.21 mm^2, and final minimal vessel area was 12.32±4.02 mm^2.

OCT Findings

OCT was performed in 31 cases (OCT findings were shown in Table II in the Data Supplement). The final MSA and mean

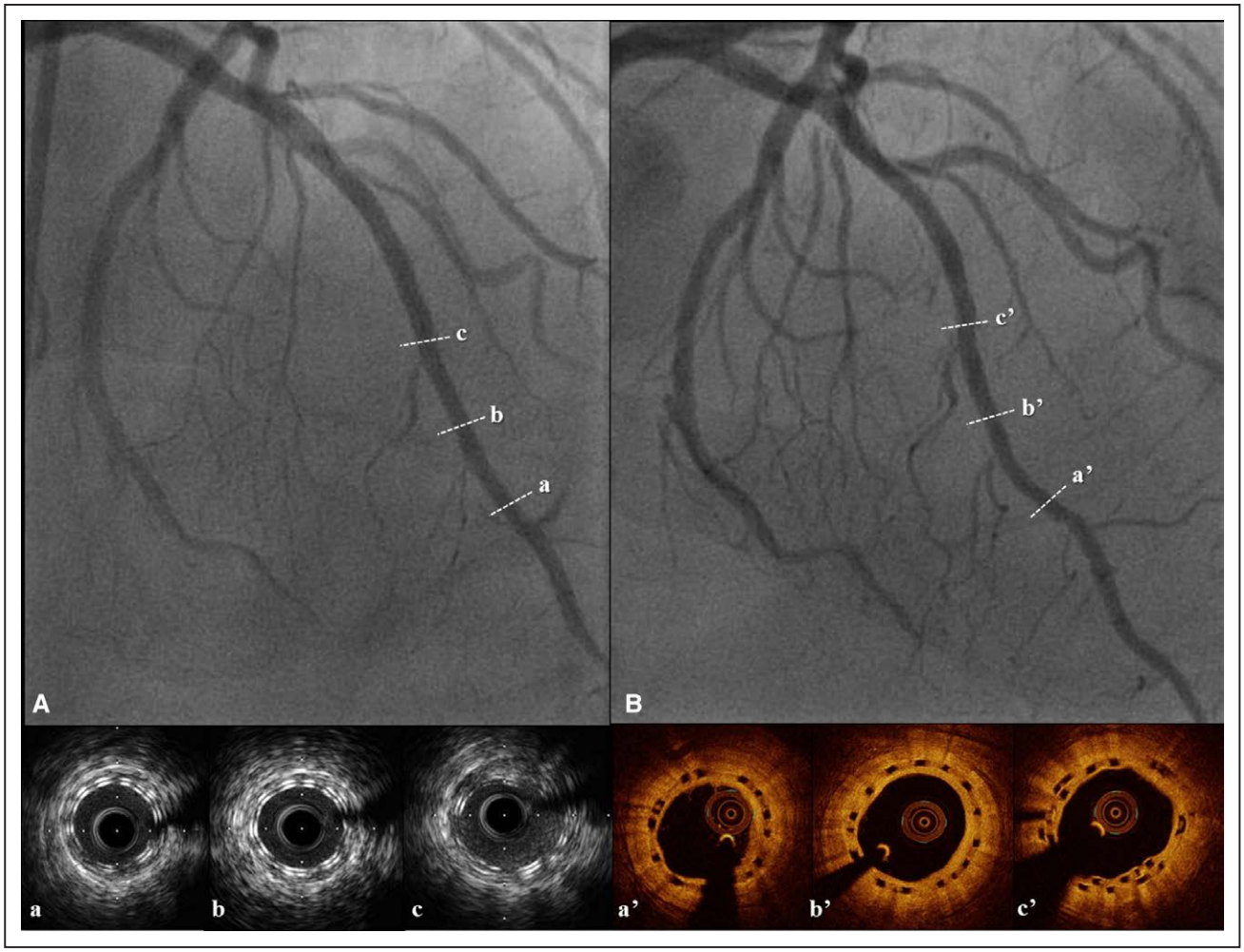

Figure 2. Angiographic and intravascular images after BVS implantation for LAD CTO at initial PCI and 18-month follow-up (the same case in Figure 1). **A**, Angiography after revascularization for LAD CTO with BVS. a–c, Short-axial views of IVUS images at each of the lesions indicated with white dashed line in Figure 2A. **B**, Angiography at 18-month follow-up of LAD CTO treated with BVS. a'–c', Short-axial views of OCT images at each of the lesions indicated with a white dashed line in Figure 2B. BVS indicates bioresorbable vascular scaffold; CTO, chronic total occlusion; IVUS, intravascular ultrasound; LAD, left anterior descending artery; and PCI, percutaneous coronary intervention.

scaffold area were 4.89±1.92 and 6.19±1.66 mm^2, respectively. Final OCT pullback revealed ISA in 3 cases (9.7%), scaffold disruption in 3 cases (9.7%), and edge dissections in 9 cases (29.0%).

Clinical Outcomes

The median follow-up period was 453 days (25th and 75th percentiles: 230 and 703), and 22 cases (33.8%) underwent follow-up angiography. There were no in-hospital adverse events. During the follow-up period, there were no occurrences of TLF. Four cases of target vessel revascularization were documented during the follow-up period (Kaplan–Meier curves for target vessel revascularization are shown in Figure I in the Data Supplement). There were no documented cases of significant intrascaffold restenosis, which required revascularization either clinically or angiographically. There were no incidences of definite/probable ST during the follow-up period. Only 1 patient discontinued dual antiplatelet therapy prematurely (within 12 months) because of a gastric ulcer.

Discussion

The main findings of this study are BVS implantation for the treatment of CTO seems feasible and safe with no evidence of TLF or stent thrombosis during the median follow-up of 453 days.

The main PCI principles that were followed in all 65 CTO cases were (1) meticulous lesion preparation for appropriate expansion of BVS, (2) postdilatation with an appropriately sized noncompliant balloons to maximize the chance of adequate apposition, and (3) careful lesion evaluation with intravascular imaging during all steps of the procedure.

In previous nonrandomized studies of BVS implantation for CTO, predilatation was performed in all cases; however, intravascular imaging guidance was lower (0%–60%) and the postdilatation was also lower (<60%).[14–16] They reported TLR rates ranging from 2.9% to 6.0% without any ST during the follow-up period (median: 3–12 months). From these limited data, it is difficult to evaluate an impact of intravascular imaging on the clinical outcomes because of small number of cases and short-term follow-up. However, intravascular

Table 1. Baseline Clinical Characteristics

	n=65
Age, y	60.8±11.0
Male, n (%)	58 (89.2)
Hypertension, n (%)	44 (67.8)
Dyslipidemia, n (%)	40 (61.5)
Diabetes, n (%)	26 (40.0)
Insulin-dependent diabetes mellitus, n (%)	2 (3.1)
Chronic kidney disease (eGFR<60), n (%)	26 (40.1)
Peripheral arterial disease, n (%)	6 (9.2)
Previous MI, n (%)	11 (16.9)
Previous PCI, n (%)	35 (53.8)
Previous CABG, n (%)	4 (6.2)
Previous cardiac surgery, n (%)	2 (3.1)
Previous stroke, n (%)	20 (30.8)
LVEF, %	57.7±10.8
DAPT regimen, n (%)	
Aspirin/clopidogrel	46 (70.8)
Aspirin/prasugrel	8 (12.3)
Aspirin/ticagrelor	11 (16.9)

Values are n (%) or mean±SD. CABG indicates coronary artery bypass grafting; DAPT, dual antiplatelet therapy; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; MI, myocardial infarction; and PCI, percutaneous coronary intervention.

imaging–guided PCI is associated with better clinical outcomes when compared with angiography alone,[17–20] and its use and importance in BVS implantation, especially in complex lesions, have been recognized widely.[21]

First, intravascular imaging provides morphological information and precise vessel size in complex lesion, which is difficult to evaluate sufficiently with angiography alone. Appropriate lesion preparation based on these evaluation could facilitate adequate expansion of BVS. Furthermore, there are some discrepancies of vessel sizing between angiography and imaging modalities such as IVUS and OCT.[22,23] Precise vessel sizing is mandatory for device selection because BVS has limitation of overexpansion.[24] In our study, following meticulous lesion preparation involving additional rotational atherectomy in 3 cases, BVS were successfully delivered and deployed in all of the 65 cases.

Second, intravascular imaging facilitates operator to select an appropriate balloon size for postdilatation and to detect complications related to device implantation. It is indicated that suboptimal BVS implantation such as ISA, underexpansion, and disruption (fracture) may increase the risk of TLR and ST[25] and are well known for PCI with DES.[26,27] The differences in the physiological properties of BVS and DES such as strut thickness and bioabsorption should be taken into account; however, high-pressure postdilatation with appropriate size of noncompliant balloon would be recommended for the best possible results while minimizing the risk of scaffold fracture and edge dissections. In our cases guided by IVUS (34 cases), a final MSA of 7.74±3.21 mm^2 and minimal vessel area of 12.32±4.02 mm^2 were achieved. In cases guided by OCT (31 cases), the final MSA was 4.89±1.92 mm^2 and minimal lumen area 5.69±1.37 mm^2. These results are acceptable when compared with previous studies of BVS implantation in 2.5 to 3.0 mm vessels with relatively simple lesions,[28,29] and it has been reported that those lumen dimensions in previous study had been preserved with low cardiac events at 5-year follow-up.[30] Furthermore, both the MSA and minimal lumen area evaluated with OCT in our study were larger when compared with those reported in the previous study of BVS implantation for CTO (MSA, 4.49±1.20 mm^2; minimal lumen area, 5.23±1.29 mm^2).[31] These results may indicate that the scaffolds were appropriately embedded in the CTO lesion. After imaging-guided postdilatation in our study, ISA (3 cases), disruption (3 cases), and scaffold edge dissections (12 cases) were detected; all of the ISAs were focal, in the calcified segment, or at the scaffold edge. Therefore, the operators had judged that it was difficult to achieve complete apposition of those struts even with additional postdilatation. Disruptions were detected at

Table 2. Lesion Characteristics

	n=65
CTO vessel, n (%)	
LMT	1 (1.5)
RCA	26 (40.0)
LAD	30 (46.2)
LCx	8 (12.3)
CTO location, n (%)	
Proximal	29 (44.6)
Middle	31 (47.7)
Distal	5 (7.7)
CTO lesion characteristics, n (%)	
Blunt-type entry point	26 (40.1)
Calcification	21 (32.3)
Tortuosity	6 (9.2)
Bent	13 (20.0)
Bifurcation	23 (35.4)
Bridge collateral	32 (49.2)
J-CTO score ≥2, n (%)	42 (64.6)
Vessel diameter by visual estimation, mm	2.97±0.36
CTO length by visual estimation, mm	20.15±2.97
Collaterals Rentrop grade >2, n (%)	53 (81.5)
In-stent CTO, n (%)	2 (3.1)
No. of diseased vessels, n (%)	
Single-vessel disease	31 (47.7)
2 vessel disease	22 (33.8)
3 vessel disease	12 (18.5)

Values are n (%) or mean±SD. CTO indicates chronic total occlusion; J-CTO, Multicenter CTO Registry of Japan; LAD, left anterior descending artery; LCx, left circumflex artery; LMT, left main trunk; and RCA, right coronary artery.

Table 3. Procedural Characteristics

	n=65
No. of implanted BVS per patient, n	1.8±0.7
Patient treated with 1 BVS, n (%)	24 (36.9)
Patient treated with 2 BVSs, n (%)	31 (47.7)
Patient treated with ≥3 BVSs, n (%)	10 (15.4)
BVS diameter per stent, mm	3.0±0.4
BVS total length per patient, mm	47.6±19.9
Predilatation balloon diameter, mm	2.6±0.5
Rotational atherectomy, n	3 (4.6)
Postdilatation balloon diameter, mm	3.3±0.3
Max pressure for postdilatation, atm	18.6±5.3
IVUS, n (%)	34 (52.3)
OCT, n (%)	31 (47.7)
Antegrade approach, n (%)	53 (81.5)
Retrograde approach, n (%)	12 (18.5)
Double injection, n (%)	51 (78.5)
DES implantation in non-CTO lesions, n (%)	17 (26.2)
Complete revascularization, n (%)	52 (80.0)

Values are n (%) or mean±SD. BVS indicates bioresorbable vascular scaffold; CTO, chronic total occlusion; DES, drug-eluting stent; IVUS, intravascular ultrasound; and OCT, optical coherence tomography.

just 2 or 3 struts (boxes), and they were not protruding into the lumen. All of the edge dissections were small and focal intimal tear (nonextending longitudinally) with Thrombolysis In Myocardial Infarction 3 flow; therefore, the operators had judged that bail out stenting was not necessary. None of these findings on IVUS and OCT translated into clinical end points. The impact of these findings on clinical outcomes remains unclear,[32] and appropriateness of additional procedure to fix them remains controversial.[33,34] However, at least, intravascular imaging evaluation enables operators to consider additional intervention and careful follow-up of these patients.

There are specific factors which should be taken into account while implanting BVS for the treatment of CTO (1) long scaffold implantation and (2) subintimal space BVS implantation.

First, treatment of CTO lesions generally requires implantation of multiple long stents. Our team has reported 1-year clinical outcomes of full plastic jackets which were relatively acceptable when compared with nonfull plastic jackets and full metal jackets.[35] Furthermore, the feasibility of BVS implantation in diffuse lesion has been reported in comparison with everolimus-eluting stent.[36,37] In our study, ≈2 BVSs with an average of 47.6±19.9 mm length were implanted for each CTO lesion. Although careful attention should be made to minimize overlap, implanting ≥2 BVSs may be clinically acceptable even in CTO PCI.

Secondary, CTO PCI often requires subintimal wiring and stenting, and, therefore, the feasibility of BVS implantation in the subintimal space should also be evaluated because of the different mechanisms of vessel healing and the less radial force provided by the scaffold when compared with metallic stents. Our team reported a case in which a BVS was implanted in the subintimal space and remained patent after 12-month follow-up with OCT without evidence of scaffold recoiling or thrombus.[38] In our current study, scaffold implantation in the subintimal space was not evaluated, and, therefore, we cannot comment on this, and further studies are warranted.

Study Limitations

Our study has several limitations. First, this study was a nonrandomized registry, and, therefore, the PCI strategy was not standardized and was dependent on the individual operator's skills and decision. Second, although CTO lesions were treated with BVS, the DESs were deployed for adjacent stenotic lesions. Therefore, clinical outcomes may have been affected by concomitant DES implantation. Third, this study used only BVS; therefore, the results of this study cannot be extrapolated to other bioresorbable scaffolds. Fourth, the angiographic follow-up was not performed in all cases, and, therefore, the event rate may have been underestimated, nevertheless clinically we had no TLF. Final, this study was conducted with a relatively small number of cases and short-term follow-up. Further larger randomized investigations with longer-term follow-up are required to confirm the efficacy of BVS implantation for the treatment of CTO.

Conclusions

BVS implantation for CTO after appropriate lesion preparation and postdilatation seems feasible and safe. Careful lesion evaluation with intravascular imaging is recommended to obtain the best possible final result.

Disclosures

None.

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Bioresorbable Vascular Scaffolds for the Treatment of Chronic Total Occlusions: An International Multicenter Registry

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SUPPLEMENTAL MATERIAL

Supplemental Tables

Supplemental Table 1. IVUS findings

IVUS findings	N=34
Plaque morphology	
fibrous, n	11 (32.4)
soft, n	2 (5.9)
calcified, n	8 (23.5)
mixed (fibrous/ calcified), n	10 (29.4)
unclassified, n	3 (8.9)
Calcium arch (degree)*	120.0 (80.0-170.0)**
Proximal reference lumen area (mm^2)	9.36±2.41
Proximal reference lumen diameter (mm)	3.02±0.38
Proximal reference vessel area (mm^2)	13.67±3.75
Proximal reference vessel diameter (mm)	3.65±0.58
Distal reference lumen area (mm^2)	6.21±1.69
Distal reference lumen diameter (mm)	2.46±0.30
Distal reference vessel area (mm^2)	9.03±2.96
Distal reference vessel diameter (mm)	2.96±0.48
Initial minimal vessel diameter (mm)	3.28±0.52
Initial maximal vessel diameter (mm)	3.59±0.47
Initial mean vessel diameter (mm)	3.44±0.49
Final minimal scaffold area (mm^2)	7.74±3.21
Final minimal scaffold diameter (mm)	2.71±0.55
Final maximal scaffold diameter (mm)	3.11±0.45
Final minimal vessel area (mm^2)	12.32±4.02
Final minimal vessel diameter (mm)	3.59±0.66
Final maximal vessel diameter (mm)	3.87±0.69
Edge dissection, n	3 (8.9)

Values are n (%) or mean±SD.

*Calcium arc was calculated for patient with calcified and mixed plaque (n=18).

**Median with 25th and 75th percentiles

Abbreviation as in Table 3.

Supplemental Table 2. OCT findings

	N=31
Calcification (>180 degrees), n	6 (19.4)
Thrombus, n	4 (12.9)
Proximal reference lumen diameter (mm)	3.31±0.71
Distal reference lumen diameter (mm)	2.29±0.45
Final minimal lumen area (mm^2)	5.69±1.37
Final mean lumen area (mm^2)	7.81±1.87
Final minimal scaffold area (mm^2)	4.89±1.92
Final mean scaffold area (mm^2)	6.19±1.66
Final minimal scaffold diameter (mm)	2.54±0.37
Final maximal scaffold diameter (mm)	3.51±0.31
ISA at CTO lesion, n	3 (9.7)
Proximal edge ISA, n	2 (6.4)
Distal edge ISA, n	1 (3.2)
Scaffold disruption, n	3 (9.7)
Edge dissections, n	9 (29.0)

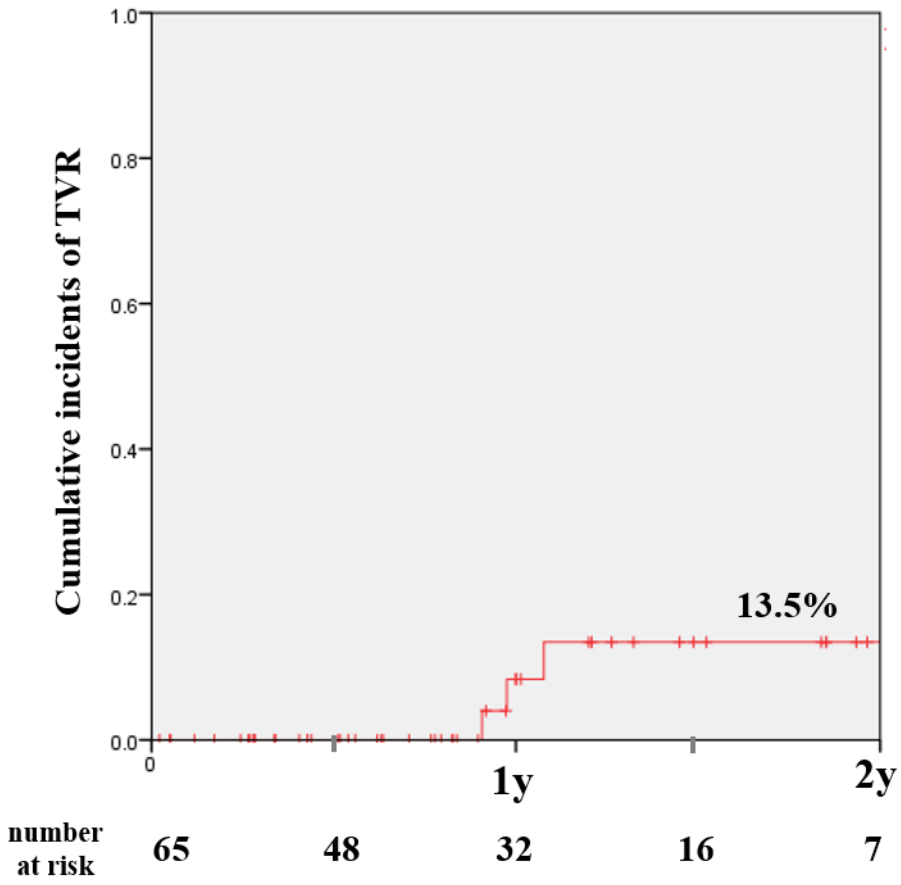
Values are n (%) or mean±SD.

ISA = incomplete scaffold apposition.

Abbreviation as in Table 3.

Supplemental Figure and Figure legend

Supplemental Figure 1.



Supplemental Figure 1. Kaplan-Meier Curve for TVR during follow-up period.

Patients at risk at different times are reported below the graph.

TVR: target vessel revascularization.