Optical coherence tomography guidance for percutaneous coronary intervention with bioresorbable scaffolds

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ABSTRACT

Background: The effect of optical coherence tomography (OCT) guidance on the implantation strategy during all phases of percutaneous coronary intervention (PCI) with bioresorbable vascular scaffolds (BVSs) in a real-world scenario has been poorly investigated.
Methods: Consecutive patients undergoing BVS implantation at our institution were included in this registry. Frequency-domain OCT pullbacks were performed at the operator's discretion during all phases of BVS implantation procedures to optimize preparation of lesions, confirm BVS size, and optimize expansion and apposition of scaffolds.
Results: Between September 2012 and July 2015, 203 BVSs were implanted in 101 consecutive patients at our institution (2.01 BVSs/patient). In 66 patients, the procedure was performed under OCT guidance. In the OCT subgroup, 66 (77.6%) of the 85 treated lesions were complex (B2/C AHA/ACC type). Overall, 147 OCT pullbacks were performed and 72/147 (49.0%) pullbacks indicated the need for changing strategy. After angiography-only-guided optimisation of BVS in 27 (31.8%) lesions, an OCT examination prompted performance of a second post-expansion. This resulted in an increase in the minimal scaffold area (5.5 to 6.3 mm^2, $p = 0.004$) and a decrease in the incomplete scaffold apposition area (1.1 to 0.6 mm^2, $p = 0.082$), with no new stent fractures. When the population was divided according to the time of BVS implantation, an initial learning adaptation became evident, with the number of OCT-guided changes in strategy significantly decreasing between the initial and final time periods ($p = 0.017$).
Conclusions: OCT guidance for BVS implantation significantly affects the procedural strategy, with favourable effects on acute results and the learning curve.

1. Introduction

Bioresorbable vascular scaffolds (BVSs) represent a revolutionary concept in interventional cardiology, and their use is rapidly increasing [1]. This technology has the potential to induce true anatomical and functional vascular restoration after coronary revascularisation. The scaffold loses mechanical integrity after 6–12 months and is completely reabsorbed in 3–5 years [2,3]. Initial experience with BVSs showed a good safety and efficacy profile at 5 years in small and selected groups [4]. The ABSORB III randomized trial recently reported non-inferiority for target lesion failure at 1 year when comparing the Absorb BVS with its metallic counterpart [4,5]. Two angiographic studies (ABSORB China and ABSORB Japan) reported equivalent in-segment lumen loss at 12 and 13 months [6,7]. However, recent "real-world" registries, including patients with greater lesion complexity, reported that the rate of scaffold thrombosis (ST) was not trivial, requiring further investigations [8,9]. Optical coherence tomography (OCT) has been proposed as the gold standard imaging technique for the optimisation of bioresorbable scaffolds [10–13]. The use of near-infrared light, rather than ultrasound, allows OCT to have unprecedented axial resolution (up to 10 to 15 μm). OCT provides information on intravascular anatomy that greatly exceeds the level of detail obtained with intravascular ultrasound. Moreover, the lack of shadowing observed beyond polymer struts with OCT indicates that it is the best imaging technique to

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optimize BVS implantation and identify scaffold failure (e.g., stent malapposition, edge dissection, tissue protrusion and thrombus) [14].

We performed a retrospective study of consecutive patients receiving OCT-guided BVS implantation. This study aimed to evaluate the effect of OCT guidance in modification of the implantation strategy during BVS deployment and determine how OCT information changes the BVS stenting approach over time.

2. Methods

Between September 2012 and September 2015, a total of 203 BVSs were implanted in 101 consecutive patients (2.01 BVSs/patient) at our institution. Of these, 66 (65.3%) patients underwent at least one OCT evaluation for a total of 147 pullbacks. Frequency-domain OCT pullbacks were performed using DragonFly or Dragonfly 2 catheters and the C7 system (n = 20 patients) or the Ilumien Optis system (n = 46 patients) (St. Jude Medical, Minneapolis, MN). Intracoronary nitrates were administered before each OCT pullback. Before BVS implantation, baseline OCT pullbacks were mainly performed after pre-dilatation with non-compliant balloons, attempting to achieve a 1:1 balloon/vessel ratio. Dedicated tools (e.g., cutting balloon, scoring balloon, Rotablator) were used at the operator's discretion. Complete expansion of the balloon, checked in multiple views, was considered as a satisfactory lesion preparation result. Scaffolds were sized according to the angiographic results after lesion preparation by either quantitative coronary angiography or operator (with established skills and case-load) judgement. This was achieved by matching the mean reference vessel diameter and sized so that no post-dilatation beyond 0.5 mm above the scaffold size would be needed (as per the manufacturer's recommendation). At this stage, OCT was used to collect information on lesion characteristics (e.g., plaque calcification and eccentricity, wall disruption, lumen size, lesion length, relationship with branches) that were useful for confirming optimal lesion preparation and the size and length of the BVS (pre-BVS, Phase 1). When OCT was performed at this stage, further pre-dilatation was performed in case of identification of an inadequate/insufficient vessel response to balloon inflation (with residual area stenosis >30%) and/or permanence of severely calcified plaques (involving more than two quadrants for at least three consecutive frames) possibly preventing the scaffold from crossing the lesion. Moreover, when OCT was used at this stage, the size of the BVS to implant was decided according to the OCT measurements, confirming or not the angiography-based decision. Scaffolds were deployed using slow balloon inflation (2 atm every 5 s). This was consistently followed by post-dilatation with shorter non-compliant balloons, including OPN NC balloons (SIS Medical AG, Winterthur Switzerland) when pressures higher than 30 atm were required (Fig. 1) [15,16]. Attention was paid to avoid reaching a maximal balloon diameter beyond the recommended rupture point of the BVS (0.5 mm above the scaffold nominal diameter). After angiography-guided BVS optimisation, OCT was used to confirm optimal scaffold expansion/apposition and lesion coverage, and to guide further post-dilatation or further scaffold/stent deployment (post-BVS, Phase 2) (Fig. 2). Further OCT-guided post-dilatation was performed in case of scaffold underexpansion, with an in-stent minimal lumen area (MLA) >90% of the average reference lumen area as a final target whenever possible. Further OCT-guided post-dilatation was also performed in the presence of considerable malapposition, which was defined as a distance between the strut and vessel wall greater than 200 μm in at least three contiguous frames [17,18]. Further scaffold deployment was performed in case of scaffold-induced vessel wall dissection with a clear endoluminal flap (in at least three consecutive frames) at OCT analysis.

All implanted BVS were Absorb BVS 1.1 (Abbott Vascular, Santa Clara, CA). Bioresorbable scaffolds were not used in the following cases: coronary bifurcations intended to be treated with a two-stent strategy; and aorto-ostial lesions, with a reference vessel diameter <2.5 mm or >4.0 mm. The reasons why OCT was not used in 35/101 patients who were treated with BVSs include a low estimated glomerular filtration rate (eGFR < 30 ml/min/1.73 m^2), the presence of straightforward type A/B1 short lesions or temporary unavailability of the OCT system. Our population was then divided into two groups according to the time of OCT-guided BVS implantation. Group 1 included all of the patients in the early phase (n = 33) of our experience with BVS implantation procedures and Group 2 included all of the patients who were subsequently treated (n = 33). This subgroup analysis allowed assessment of whether the information acquired with OCT in the early phase (Group 1) was eventually used to modify the procedural strategy in Group 2, making routine OCT assessment redundant. OCT-induced changes in strategy were as follows: further lesion pre-dilatation, a change in scaffold diameter and length (different from the angiography-guided decision), further scaffold post-dilatation, and further stent/scaffold implantation. The indication for percutaneous intervention was based on angiography and fractional flow reserve was used in case of uncertainty.

OCT analysis was confirmed by off-line assessment in all cases. Acquisition and quantitative analysis methods of OCT have been previously published by our group and others, and are available as online-only material (see Supplementary file) [13]. All patients provided signed informed consent for BVS deployment and OCT guidance. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.1. Statistical analysis

Continuous variables are reported as mean and standard deviation, and categorical variables as number and percentage. Comparison between groups for continuous variables was performed by the unpaired t test (in case of parametric distribution) or the

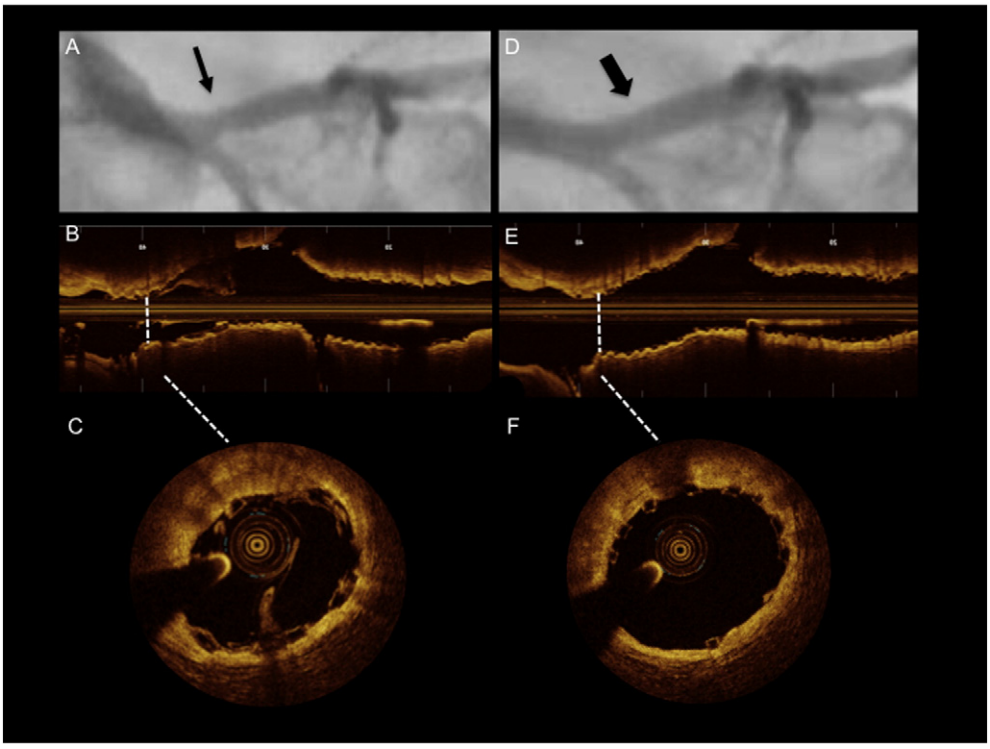

Fig. 1. BVS optimisation with HPPD. (A) Angiographic result after 3.0 × 28 mm Absorb BVS deployment and post-dilatation with a 3.5 mm NC balloon at 16 atm. A narrowing of the proximal segment of the scaffold is visible (thin arrow). OCT long (B) and cross-sectional (C) views confirming scaffold under-expansion (MLA 4.53 mm^2). (D) Good final angiographic result after HPPD with a 3.5 × 8.0 mm NC balloon expanded at 28 atm (thick arrow). OCT long (E) and cross-sectional (F) views showed optimal scaffold expansion (MLA 7.71 mm^2). BVS = bioresorbable vascular scaffold; HPPD = high-pressure post-dilatation; LAD = left anterior descending artery; OCT = optical coherence tomography.

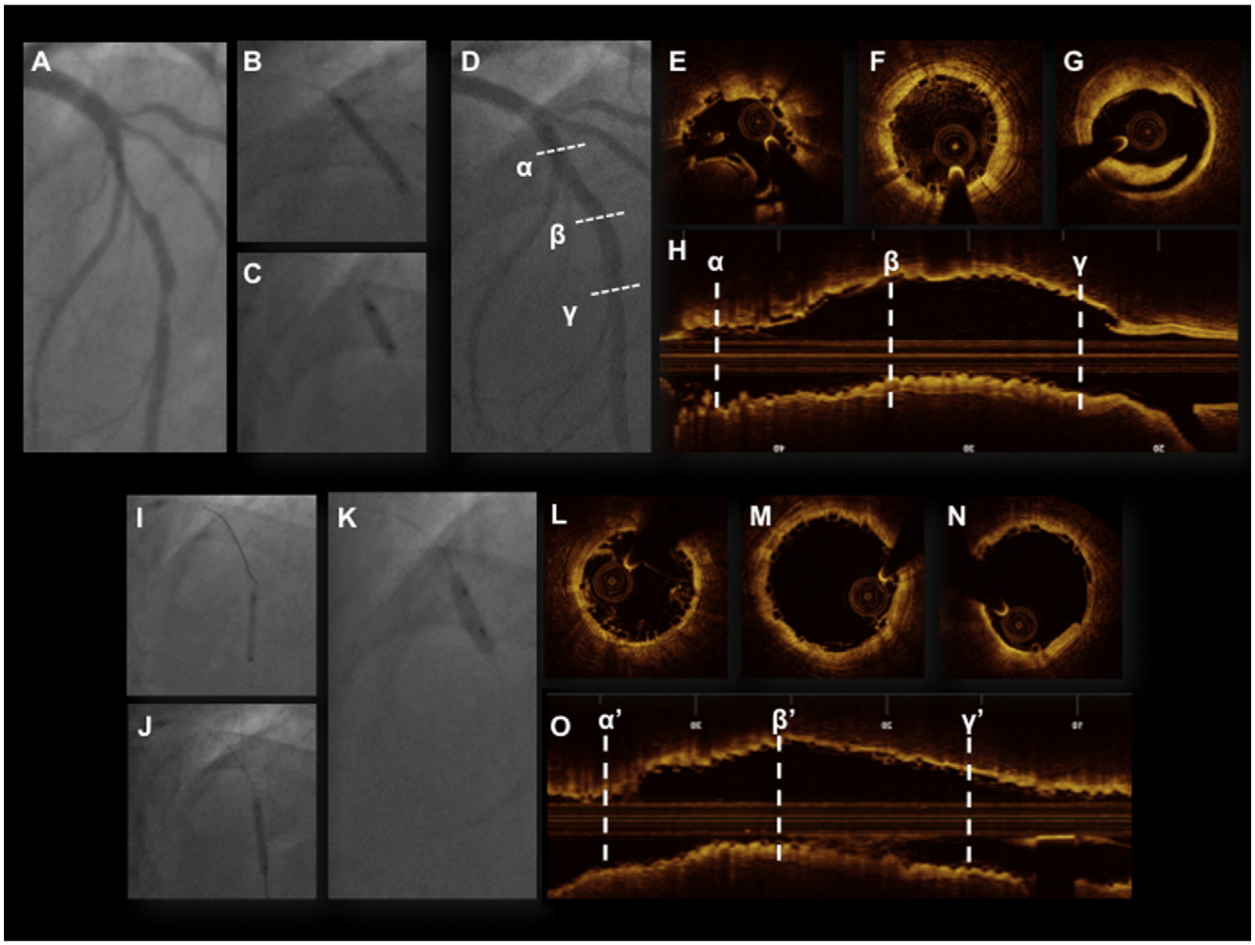

Fig. 2. Example of OCT-guided changes of strategy during BVS implantation. (A) Angiographic view of two severe stenoses in the mid-LAD. (B) 3.0 × 28 mm Absorb BVS implantation and (C) angiography-guided scaffold optimisation with a 3.0 × 8.0 mm NC balloon at 18 atm. (D) Final angiography showing good result in all scaffolded segments (α,β,γ). OCT cross-sections show clear underexpansion of the proximal segment (despite good angiographic appearance) (E), good struts apposition in the mid-segment (F) and evident luminal dissection at the distal edge (G). (H) The longitudinal view emphasizes the localisation of the various cross-sections (α,β,γ). (I) Further 2.5 × 18 mm Absorb BVS deployment (buddy wire technique) covering the edge dissection, post-dilated with a 3.0 × 20 NC balloon (J). (K) Further post-dilatation of the proximal segment of the first BVS (with a 3.5 × 8.0 mm NC balloon at 20 atm). OCT cross-sections showing improved scaffold expansion in the proximal segment (L), well apposed scaffold in the mid-segment (M) and well apposed distal BVS (N). (O) The longitudinal view emphasizes the uniform dilatation of the scaffolded segments (α′,β′γ′).

Mann–Whitney *U* test (in case of non-parametric distribution), as appropriate. Categorical variables were compared using Pearson's χ^2 test. The p threshold value for statistical significance was set at 0.05. Statistical analyses were performed using the SPSS statistical software package version 20.0 (IBM Corporation, Somers, NY).

3. Results

3.1. Patient and lesion characteristics

Overall, we implanted 203 Absorb BVS in 101 patients. OCT was performed in 66 (65.3%) patients undergoing BVS implantation. Reasons for exclusion from OCT use were as follows: eGFR <30 ml/min/1.73 m^2 (42.9%), the presence of straightforward type A/B1 short lesions (34.3%) and temporary unavailability of the OCT system (22.8%). In the population of patients who had OCT performed, the mean age was 58 ± 12 years and 66.7% were male patients. Almost all of the patients had a stable clinical presentation (n = 63, 95.4%) and 30.3% of them were diabetic. A total of 85 lesions were treated (1.3 lesions/patient) and 66 (77.6%) were defined as B2 and/or C according to the AHA/ACC classification. Patient and lesion characteristics are shown in Tables 1 and 2.

3.2. Preparation of lesions

Pre-dilatation was performed in 84 (98.8%) lesions using non-compliant balloons in 75% of patients (mean pressure, 16 ± 4.0 atm). Rotablator and scoring/cutting balloon catheters were used in 2.4% and 15.3% of lesions, respectively, because of the presence of heavy calcification or persistent indentation of the pre-dilatation balloon. Of the 147 total OCT pullbacks performed, 59 (40.1%) were performed before BVS insertion (pre-BVS, Phase 1) in 87.9% of patients. Fifteen (10.2%) pullbacks indicated the need for further pre-dilatation. Seven (4.8%) pullbacks prompted the selection of a different scaffold diameter and 17 (11.6%) suggested a different length (Table 2 and Fig. 3).

3.3. Scaffold deployment and optimisation

The mean scaffold diameter and length were 3.1 ± 0.4 mm and 23.1 ± 5.3 mm, respectively. Angiography-guided post-dilatation was performed in 84 (98.8%) lesions with a mean balloon diameter of 3.3 ± 0.4 mm and balloon pressure of 20.6 ± 6.0 atm. High-pressure post-dilatation (>24 atm) was performed in 41.2% of lesions. After angiographic optimisation of the result with high-pressure post dilatation, 88 (59.9%) OCT pullbacks were finally performed in 98.5% of patients to evaluate eventual sub-optimal stenting results (e.g., underexpansion, malapposition, fracture and/or edge dissections) (post-BVS, Phase 2). Twenty-seven (18.4%) pullbacks suggested the need for a second post-dilatation for scaffold apposition/expansion optimisation, while six (4.1%) pullbacks indicated the need for further BVS/stent implantation for incomplete lesion coverage and/or edge dissection. The mean balloon diameter for the additional OCT guided post-

dilatations was 3.6 ± 0.6 mm and mean balloon pressure was 21.1 ± 7.2 atm (Table 2 and Fig. 3).

3.4. Clinically driven changes in OCT strategy

Overall, 72 (49.0%) of 147 OCT pullbacks caused a change in strategy during the BVS implantation procedure (Fig. 4A). When our population was then divided in two groups according to the time of OCT-guided BVS implantation, the number of OCT pullbacks did not differ between the early (Group 1, n = 73, 49.7%) and final experience (Group 2, n = 74, 50.3%). The total number of OCT pullbacks that caused a change in strategy was significantly decreased in the most recently treated group of patients (59.7% in Group 1 vs 40.3% in Group 2, p = 0.017) (Fig. 4B). The lesions treated with overlapping scaffolds and/or with a 2.5-mm-diameter BVS (n = 40), considered as a higher degree of complexity, received more than one OCT pullback in a higher proportion of cases (p = 0.007) compared with the other lesions (n = 45). However, the proportion of changes in strategy prompted by OCT in these lesions was not significantly higher (p = 0.3).

3.5. Effect of OCT-guided post-dilatation

In the 27 lesions (31.8%) with an OCT pullback before and after OCT-guided scaffold optimisation, quantitative OCT analysis showed an increase in the MLA (5.9 ± 1.3 to 6.1 ± 1.2 mm^2, p = 0.37) and minimal scaffold area (5.5 ± 1.8 to 6.3 ± 1.5 mm^2, p = 0.004). The incomplete scaffold apposition area was decreased from 1.1 ± 0.3 to 0.6 ± 0.5 mm^2 (p = 0.08). Qualitative OCT analysis showed a low incidence of dissection (13.3%) and fractures (0.9%) (Tables 2 and 3). No contrast-induced nephropathy event was reported, including patients with an eGFR >31 and <60 ml/min/1.73 m^2.

4. Discussion

The main finding of this study is that OCT guidance significantly affected the procedural strategy during all phases of BVS implantation in a real-world scenario. Half (49.0%) of the OCT pullbacks performed in our series led to a change in strategy. When used before BVS implantation, OCT allowed fine-tuning of the length and size of BVSs that were used or suggested additional lesion preparation. When OCT was used after BVS deployment, the results led to additional expansion in one third of lesions, despite the aggressive systematic angiography-guided post-expansion strategy adopted in all of the patients before the OCT study. OCT use during BVS implantation in this study remained high and relatively constant overtime, with a significant reduction in the rate of OCT-induced changes in strategy in the most recently treated patients. This finding suggests that there is a learning curve in BVS implantation. However, modifications in strategy were still performed 40.3% of the time in the most recently treated patients, which is not trivial. In light of this, our findings also suggest that OCT imaging guidance plays an important role during BVS implantation procedures for experienced operators, and not exclusively in the initial phase of the learning curve. Interestingly, we also found that lesions that received 2.5-mm overlapping scaffolds, considered at a higher degree of complexity, required more than one OCT pullback in a higher proportion of cases compared with the other lesions.

This is the largest cohort of patients to be studied after application of a strategy of active correction of suboptimal BVS deployment as detected with OCT, with imaging performed in two critical phases (before deployment and after optimal angiographic expansion). Our research group applied a similar strategy with OCT after angiographic optimisation in a cohort of 108 patients who underwent percutaneous intervention with second-generation drug-eluting stent (DES)

Table 1
OCT subgroup — patients' characteristics.

	n = 66
Age ± SD	58 (12)
Male n (%)	44 (66.7)
Hypertension n (%)	52 (78.8)
Hyperlipidaemia n (%)	51 (77.3)
Smoking n (%)	12 (18.2)
Diabetes mellitus n (%)	20 (30.3)
IDDM n (%)	11 (16.7)
Family history n (%)	10 (15.2)
Previous PCI n (%)	20 (30.3)
Previous CABG n (%)	6 (9.1)
eGFR (ml/min/1.73 m^2)	87 ± 19
LVEF	55 ± 6
Clinical presentation n (%)	
Stable angina	63 (95.5)
Unstable angina	1 (1.5)
NSTEMI	1 (1.5)
STEMI	1 (1.5)

n = number; IDDM = insulin-dependent diabetes mellitus; PCI = percutaneous coronary intervention; CABG = coronary artery by-pass grafting; eGFR = estimated glomerular filtration rate; LVEF = left ventricular ejection fraction; NSTEMI = non-ST segment elevated myocardial infarction; STEMI = ST segment elevated myocardial infarction.

Table 2
OCT subgroup — lesion/procedural characteristics and OCT analysis.

Lesion characteristics	n of lesions	85
	n of implanted BVS	118
	CTO, n (%)	6 (7.1)
	Bifurcation involvement, n (%)	32 (37.6)
	In-stent restenosis, n (%)	6 (7.1)
	AHA-ACC lesion classification, n (%)	
	A/B1	19 (22.4)
	B2/C	66 (77.6)
	Treated vessel, n (%)	
	LMCA	1 (1.2)
	LAD/diag	47 (55.2)
	RCA	18 (21.2)
	LCX/OM	18 (21.2)
	Vein graft	1 (1.2)
Procedural characteristics	Pre-dilatation, n (%)	84 (98.8)
	Post-dilatation, n (%)	84 (98.8)
	Very high pressure post-dilatation (>24 atm), n (%)	35 (41.2)
	Rotablator, n (%)	2 (2.4)
	Cutting/scoring balloon, n (%)	13 (15.3)
	Guideliner catheter, n (%)	7 (8.2)
	Mean scaffold diameter (mm) ± SD	3.1 (0.4)
	Mean scaffold length (mm) ± SD	23.1 (5.3)
	Mean balloon diameter for post-dilatation (mm) ± SD	3.3 (0.4)
	Mean balloon pressure for post-dilatation (atm) ± SD	20.6 (6.0)
	Mean balloon diameter for second post-dilatation induced by OCT (mm) ± SD	3.6 (0.6)
	Mean balloon pressure for second post-dilatation induced by OCT (atm) ± SD	21.1 (7.2)
OCT analysis		BVS n = 112[a]
	MLA (mm^2) ± SD	5.9 (1.9)
	MSA (mm^2) ± SD	5.8 (1.8)
	Minimum eccentricity index ± SD	0.8 (0.1)
	Symmetry index ± SD	0.2 (0.1)
	Scaffold with RAS >20% (%)	36 (32.1)
	Malapposed struts (ISA) ± SD	1.9 (2.9)
	Edge dissections (%)	15 (13.3)
	Fractures (%)	1 (0.9)

[a] Six scaffolds did not receive final OCT pullback for measurements; n = number; BVS = bioresorbable vascular scaffold; CTO = chronic total occlusion; LMCA = left main coronary artery; LAD = left anterior descending; Diag = diagonal branch; RCA = right coronary artery; LCX = left circumflex artery; OM = obtuse marginal; SD = standard deviation; OCT = optical coherence tomography; MLA = minimal lumen area; SD = standard deviation; MSA = minimal scaffold area; RAS = residual area stenosis; ISA = incomplete scaffold apposition.

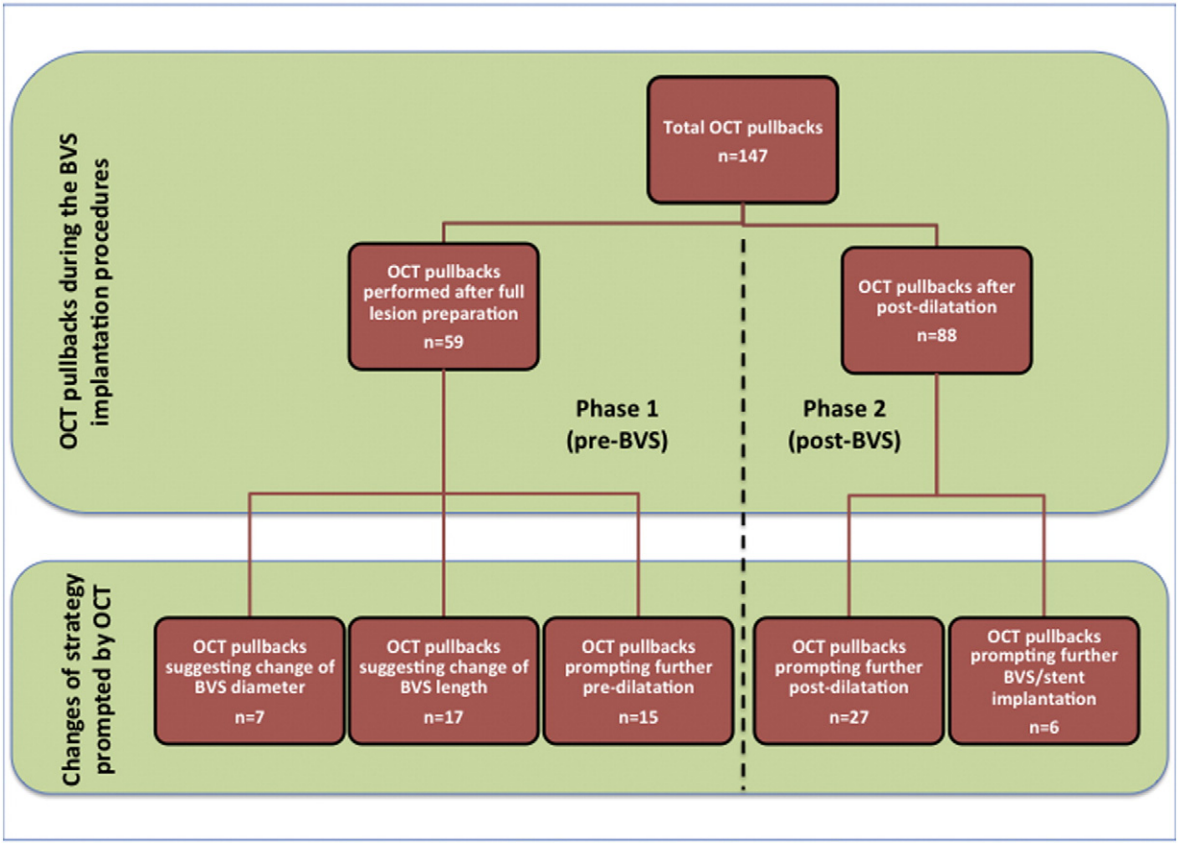

Fig. 3. OCT pullback distribution during BVS implantation procedures and relative changes of strategy.

implantation. We showed that OCT results prompted further optimisation of the implanted stent in 31% of patients [19]. Similarly, the larger (418 patients), prospective ILUMIEN I study demonstrated that decision-making by physicians was affected by OCT imaging prior to DES implantation in 57% and post-DES implantation and optimisation in 27% of all patients [20]. Similar percentages of strategy changes after OCT (34.7%) were also reported in the multicentre CLI-OPC registry, which was conducted in 670 patients treated with DESs with 12 months of follow-up (OCT group, n = 335) [21]. Unlike in our study and the other two previously mentioned OCT studies lacking a comparison group and a sufficiently long follow-up, a significantly lower 1-year rate of cardiac death or myocardial infarction was observed in the OCT-guided group compared to the angiography-guided group [21].

Our series represents a real-world scenario, where 77.6% of complex lesions were treated. The importance of technical aspects during BVS implantation procedures was highlighted in the large GHOST-EU study [9]. The high reported ST rate (2.1% at 6 months) was attributed to pitfalls in the implantation technique, including poor use of intracoronary imaging guidance (Intravascular Ultrasound and OCT uses were 14.4% and 13.8%, respectively) [9,10,22]. In contrast, real-world, single-centre, consecutive cohorts actively using intravascular imaging and high-pressure post-dilatation reported no ST at mid-term follow-up [13,23].

4.1. Lesion preparation

The importance of accurate lesion preparation during BVS implantation is well recognized and the pivotal role of OCT has been confirmed in our series [24]. Despite performing a default pre-dilatation strategy (98.8%) to achieve full lesion preparation with a 1:1 balloon/vessel ratio in most cases, 10.2% of all OCT pullbacks indicated the need for further pre-dilatation. Meticulous sizing of the scaffold is also a crucial step during BVS implantation, especially taking into account the tendency towards underestimation of vessel size with angiography compared with OCT [25]. Based on the maximum BVS expansion limit of 0.5 mm above its nominal diameter, undersizing the scaffold may translate into malapposition, which could cause BVS failure [26–28]. Therefore, accurate vessel sizing on the basis of the proximal reference in case of tapered vessels is important for achieving good, acute results. In this respect, OCT is a unique tool for accurate vessel/scaffold sizing. In our series, OCT results significantly influenced our decisions, with 16.4% of OCT pullbacks indicating the need for a different scaffold size.

4.2. Post-expansion

High-pressure post-dilatation in achieving better stent expansion and reducing ST is important, as shown after Colombo et al.'s pioneering study on bare metal stents [29,30]. A final MLA <5.0 mm^2 was shown in IVUS studies of first-generation DESs to be associated with a higher risk of late stent failure [28]. OCT has some potential disadvantages over IVUS because it does not measure the external elastic membrane area in most cases, especially in the proximal vessel segments. However, OCT has the major advantage of automatic tracking of the lumen–plaque interphase, which allows longitudinal reconstruction in real time of a lumen profile (Figs. 1 and 2). This is useful for highlighting the segments that need further treatment. OCT also has clear advantages in terms of optimal definition of strut apposition and scaffold disruption. Because of the higher strut thickness and greater recoil, BVS implantation might require more accurate final optimisation than contemporary metallic stents, especially for the treatment of complex lesions. Accordingly, recent studies that reported a high post-dilatation rate (>90%) and pressure (>20 atm) showed a low rate of ST (13,24).

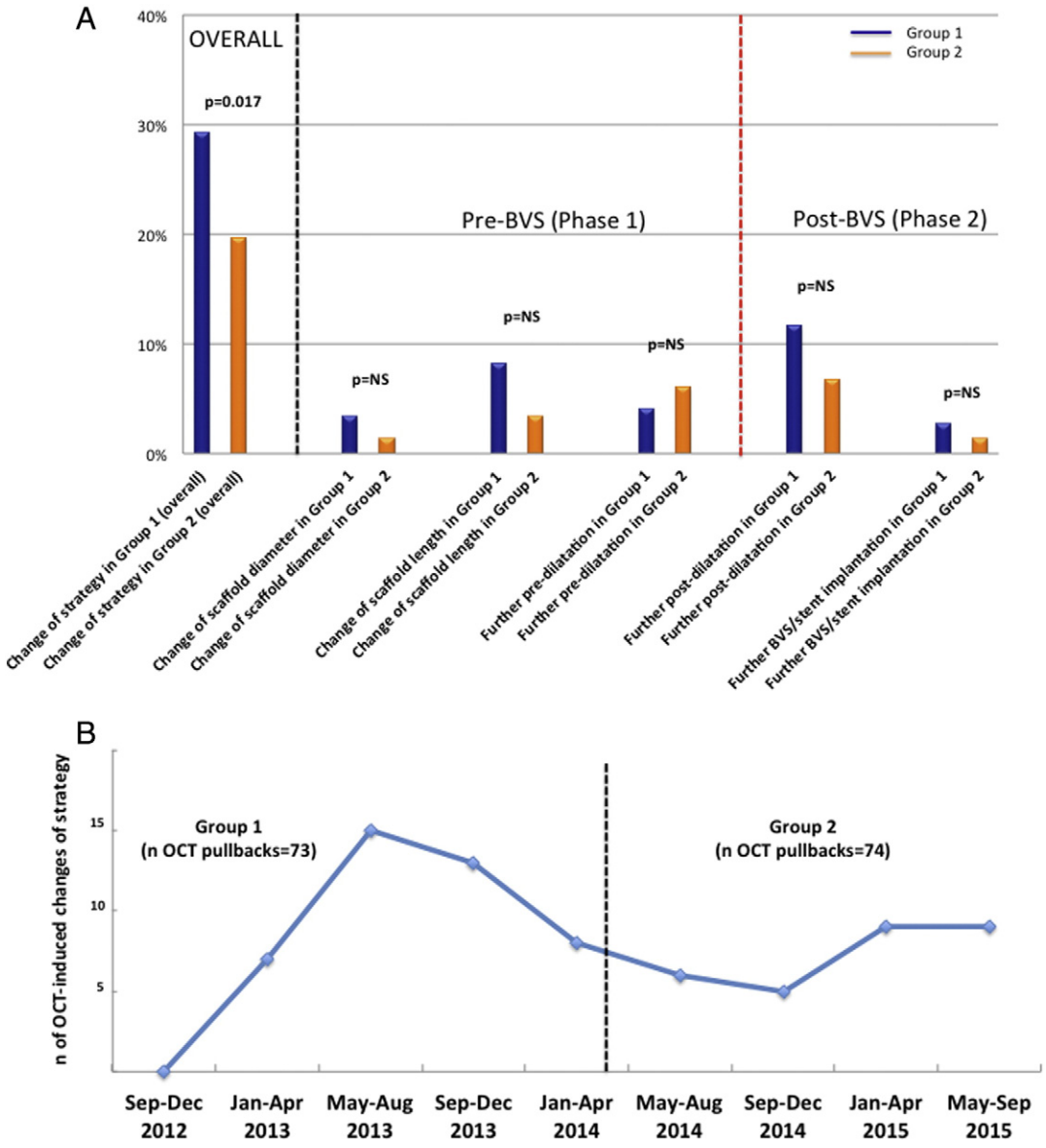

Fig. 4. A. Changes of strategy during BVS implantation procedure phases: group comparison. The number of OCT pullbacks prompting a change of strategy at any procedural step significantly differs between groups. B. Number of OCT-guided changes of strategy over time. The number of OCT pullbacks did not differ between initial (Group 1) and final (Group 2) experience (divided by the dashed line) whereas the total number of OCT pullbacks causing a change of strategy significantly decreased in the second half of the centre experience.

In our series, angiography-guided post-dilatation was almost systematic (98.8%) and was usually performed with high-pressure inflation (20.6 ± 6.0 atm; pressure > 24 atm in 41.2% of cases). However, despite universal application of an aggressive post-expansion strategy with the benefit of frequent use of OCT measurements from pre-deployment pullback to optimize balloon selection, OCT-guided post-dilatation led to an increase in the minimal scaffold area of 0.8 mm^2 (12.7%) and/or corrected malapposition in one third of lesions. Notably, the post-expansion strategy adopted in our series did not lead to any major concerns of safety, with low rates of dissection and fracture of the scaffold.

Table 3
Differences before and after second post-dilatation prompted by OCT.

	After angiographic scaffold optimisation	After second post-dilatation prompted by OCT	p value
MLA (mm^2) ± SD	5.9 ± 1.3	6.1 ± 1.2	0.37
MSA (mm^2) ± SD	5.5 ± 1.8	6.3 ± 1.5	0.004
ISA area (mm^2) ± SD	1.1 ± 0.3	0.6 ± 0.5	0.082
%AS ± SD	27.9 ± 15.6	25.9 ± 13.8	0.184

OCT: optical coherence tomography; MLA: minimal lumen area; SD: standard deviation; MSA: minimal scaffold area; ISA: incomplete scaffold apposition; AS: area stenosis.

4.3. Limitations

OCT was performed at the operator's discretion, with a bias towards the most challenging cases. Therefore, results may have overestimated the clinical usefulness of OCT when BVSs were implanted in simpler lesions. In this registry, no attempt was made to apply absolute and systematic criteria of BVS optimisation. However, we still had the goal of achievement of an area within the BVS matching the proximal and distal references. An MLA within the BVS greater than 90% than the closest reference area was considered as the final target, with greater aggressiveness applied in smaller vessels.

5. Conclusion

Our study shows that OCT guidance during BVS implantation significantly affects the procedural strategy. Use of OCT facilitates accurate

lesion preparation and BVS optimisation, leading to additional interventions in one third of cases after BVS implantation. There is good acute performance of the scaffolds and no safety concerns. Moreover, our findings support the concept that OCT use favourably affects the learning curve.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

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