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Intracoronary imaging-guided versus angiography-guided optimization of bioresorbable scaffolds

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Abstract

Aim: This study aimed to understand if intracoronary imaging-guided optimization is useful for improving the acute success of scaffold deployment versus angiography-guided optimization. **Methods:** The 162 patients randomized to bioresorbable scaffold implant were allocated 1:1 to either an imaging-guided or angiography-guided optimization strategy, with each arm having a final optical coherence tomography acquisition, performed blind to the operator in the angiography arm. Further optimization was guided by prespecified criteria (underexpansion, presence of significant malapposition, edge dissection and any residual stenosis) in the imaging-guided arm. Minimal scaffolding area was the primary end-point. Scaffold expansion, malapposition, an optimal-result composite and target lesion failure at 12 months were secondary endpoints. **Results:** The minimal scaffold area was larger with imaging guidance (7.18 versus 6.37 mm², mean difference 0.81, 95% CI 0.39 to 1.24; $p < 0.001$), and the scaffold expansion index was higher (0.84 versus 0.77; $p < 0.001$). There were increases in imaging guidance-use post-dilatation (75 versus 33%), and in absence of significant acute malapposition (11 versus 43%), as well as in the achievement of optimal-result composite (53 versus 26%) (all $p < 0.001$). Although numerically fewer failed with imaging guidance over 12 months, there was no difference between two groups (imaging guidance, 7.4% vs. 14.8%; $p = 0.21$). **Conclusion:** In addition to finding scaffold dimensions larger by intracoronary imaging, there was less malapposition and a higher rate of an optimal acute result with intracoronary imaging than with angiography. There was no powering for clinical outcomes in the study. These data advance the use of intracoronary imaging to improve the use of bioresorbable scaffolding.

Keywords: Bioresorbable scaffold, Optical coherence tomography, Intracoronary imaging, Percutaneous coronary intervention, Malapposition

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1. Introduction

Bioresorbable vascular scaffolds were introduced with the aim of providing temporary mechanical support and drug delivery to a treated coronary segment and then resorbing over the following years, restoring the

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vessel to its natural state and avoiding the permanent metallic cage left by a drug-eluting stent (Onuma and Serruys, 2011; Serruys *et al.*, 2015). The concept was attractive, but the clinical results did not match it. Randomised trials and their pooled analyses found a higher rate of scaffold thrombosis and of target lesion failure with the scaffold than with a contemporary metallic stent, and this excess was greatest in the first year and in vessels that were small or inadequately prepared (Ellis *et al.*, 2015; Cassese *et al.*, 2016; Stone *et al.*, 2016; Wykrzykowska *et al.*, 2017).

Much of this excess has been traced to how the scaffold was implanted rather than to the device alone. The polymer struts are thicker and mechanically weaker than those of a metallic stent, so an incompletely expanded or malapposed scaffold is both more likely and more consequential, and the analyses of scaffold thrombosis have repeatedly identified underexpansion, malapposition and incomplete lesion coverage as the mechanisms (Puricel *et al.*, 2016; Sotomi *et al.*, 2017). This recognition gave rise to a dedicated implantation technique, emphasising adequate lesion preparation, correct sizing and high-pressure post-dilatation, whose careful application improved outcomes (Ortega-Paz *et al.*, 2017; Gori *et al.*, 2014).

The difficulty is that angiography, which guides most procedures, cannot reliably show the very findings that matter here. It renders the lumen as a silhouette and cannot resolve the apposition of individual struts, the true dimensions of the expanded scaffold or a small edge dissection (Raber *et al.*, 2018). Optical coherence tomography, by contrast, resolves these features at a scale of micrometres and can therefore detect underexpansion, malapposition and dissection during the procedure, when they can still be corrected, and in trials of metallic stents imaging guidance has improved both the acute result and, more recently, clinical outcomes (Ali *et al.*, 2016; Zhang *et al.*, 2018; Ali *et al.*, 2023; Lee *et al.*, 2023). Whether it does the same for the bioresorbable scaffold, whose implantation is more demanding and whose margin for error is smaller, is the question addressed here.

The question has not been made obsolete by the withdrawal of the first widely used scaffold from the market. The lesson drawn from that experience was not that the concept was unsound but that the device was unforgiving of imperfect implantation, and a new generation of scaffolds, with thinner struts and, in some cases, a magnesium rather than a polymer backbone, is now in development with the explicit aim of retaining the benefits of resorption while reducing the penalty for a suboptimal result. For these devices the quality of implantation will remain decisive, and the means of ensuring it, in particular whether intracoronary imaging should guide the procedure, is therefore a question whose answer will carry forward to the scaffolds that follow.

This randomised trial compared intracoronary imaging-guided with angiography-guided optimization of bioresorbable scaffold implantation. In patients undergoing scaffold implantation, all of whom underwent a final optical coherence tomography acquisition, it tested whether guiding the optimization by the imaging produced a larger minimal scaffold area than guiding it by angiography alone, and it compared the scaffold expansion, the malapposition, the achievement of an optimal acute result and the clinical outcomes between the two strategies.

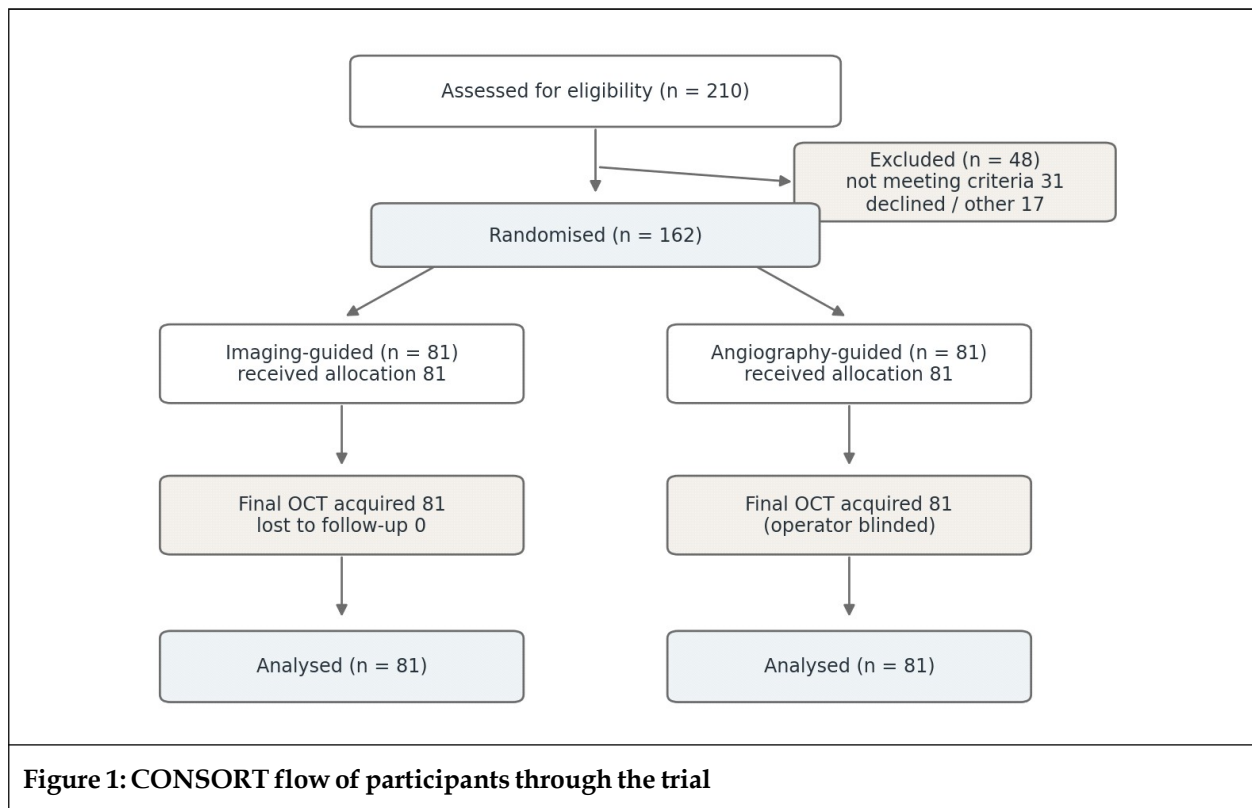
2. Materials and methods

2.1. Trial design and registration

A single-centre, randomised, assessor-blinded trial of intracoronary imaging-guided versus angiography-guided optimum bioresorbable scaffolding implantation in a tertiary care interventional cardiology department. The trial was registered in a public clinical trials registry and designed and reported using The Consolidated Standards of Reporting Trials guidelines (Schulz *et al.*, 2010).

2.2. Eligibility criteria and study population

Participants were eligible adults undergoing Percutaneous Coronary Intervention (PCI) with implantation of a bioresorbable scaffold (BRS) for a de novo native coronary lesion. If the lesions were in a vessel too large or too small for the available scaffolds, if they were heavily calcified where it was unlikely that the scaffolds could be delivered, if they were bifurcation requiring two-scaffold approach, or if they happened in the context of ST-elevation myocardial infarction, with a significant amount of thrombus, the lesions were excluded. The flow of participants through the trial is shown in Figure 1.



2.3. Randomisation, allocation concealment and blinding

After successful scaffold implantation, participants were randomly assigned in a 1:1 ratio to imaging-guided or angiography-guided optimization by a computer-generated sequence concealed until allocation. All participants underwent a final optical coherence tomography acquisition. In the imaging-guided arm the operator reviewed the acquisition and optimised accordingly, whereas in the angiography-guided arm the operator was blinded to it and optimised on the angiogram alone, so that the two arms differed only in whether the imaging informed the decision. The analysts who measured the imaging were blinded to the allocation.

2.4. Scaffold implantation and prespecified optimization criteria

Pre and post scaffold dilatation were performed as recommended in both arms and high pressure post dilatation was performed routinely as part of preparation of lesion. The prespecified criteria used for the final acquisition in the imaging-guided arm led to further optimization: scaffold underexpansion (defined as an index of minimal scaffold area < 4.5 square millimetres or an index of expansion < 80%); significant malapposition; significant edge dissection; and significant residual stenosis at a scaffold edge (Prati *et al.*, 2012). Optimization was done by further post dilatation or in cases where it was needed, additional scaffold.

2.5. Optical coherence tomography acquisition and analysis

Optical coherence tomography was performed after intracoronary nitroglycerin with a frequency-domain system and an automated pullback. The scaffolded segment was analysed at intervals across its length in a core laboratory by analysts blinded to the allocation, and the minimal scaffold area, the reference areas, the expansion index, the extent of malapposition and the presence of edge dissection were measured according to consensus methodology.

2.6. Endpoint definitions

The primary end point was minimal scaffold area of the final acquisition. Secondary end points were MIA and scaffold expansion index, minimal scaffold diameter, the incidence of significant acute malapposition, significant edge dissection, and an optimal result composite, which comprised the presence of MIA ≥ 4.5 square millimetres combined with scaffold expansion index $\geq 80\%$, and absence of significant acute malapposition or significant edge dissection. Target lesion failure included cardiac death, target-vessel myocardial infarction and target-lesion revascularisation, which was a clinical endpoint.

2.7. Sample size and statistical analysis

Analyses were conducted using the intention-to-treat approach. Continuous endpoints were compared using the t test and presented as mean difference with 95% confidence interval and categorical endpoints using the chi-squared or Fisher exact test and presented as the relative risk. The clinical endpoint was analysed by the Kaplan-Meier method and the log-rank test. Two-sided P-values < 0.05 were considered significant. A sample size of the order of 160 was required to detect a difference of approximately half a square millimetre (mm) in Minimal Scaffold Area (MSA) between the arms with a two-sided alpha of 0.05 and a power of 80% and to allow for image that could not be analysed for the primary imaging endpoint. So, the trial was also designed with the primary imaging endpoint, and lacked the power to detect clinical outcomes as secondary outcomes.

3. Results

3.1. Trial population and lesion complexity

Of the patients assessed, 162 were randomised, 81 to imaging-guided and 81 to angiography-guided optimization, and all were followed and analysed, as shown in Figure 1. The two arms were well balanced in their clinical and lesion characteristics, as expected after randomisation, and these are given in Table 1.

Table 1: Baseline clinical and lesion characteristics by treatment arm

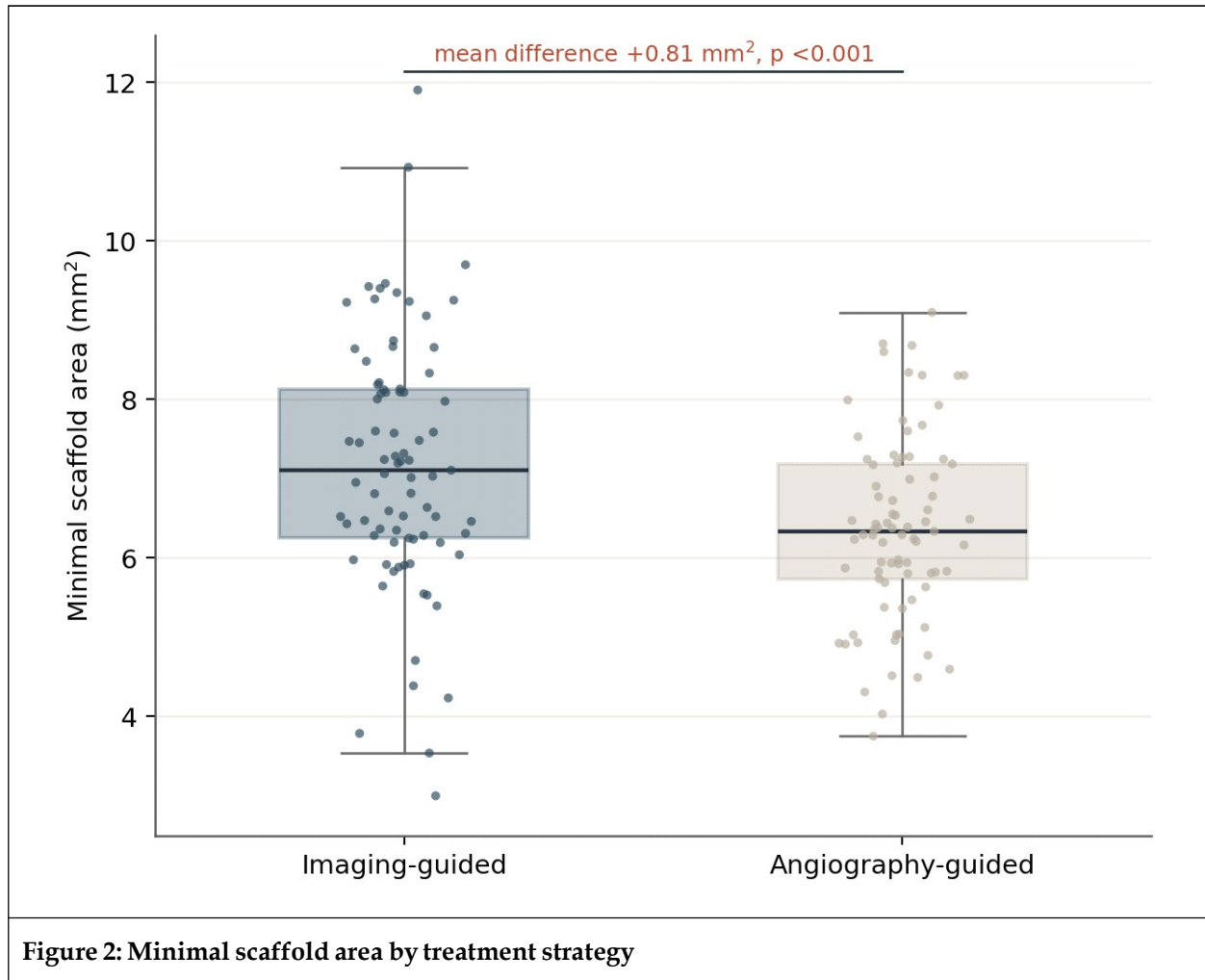
Characteristic	Imaging-guided (n = 81)	Angiography-guided (n = 81)
Age (years)	61.3 ± 10.5	59.6 ± 9.7
Male sex	57 (70%)	60 (74%)
Diabetes mellitus	25 (31%)	30 (37%)
Hypertension	50 (62%)	49 (60%)
Acute coronary syndrome	28 (35%)	34 (42%)
LAD lesion	40 (49%)	36 (44%)
Lesion length (mm)	17.8 ± 6.4	16.4 ± 5.4
Reference vessel diameter (mm)	2.9 ± 0.4	3.0 ± 0.4
Moderate/severe calcification	24 (30%)	28 (35%)
Type B2/C lesion	38 (47%)	47 (58%)

3.2. Minimal scaffold area (primary endpoint)

The minimal scaffold area, the primary endpoint, was larger with imaging-guided than with angiography-guided optimization (7.18 versus 6.37 square millimetres, mean difference 0.81, 95% CI 0.39 to 1.24; $p < 0.001$), as shown in Figure 2. The distribution of the minimal scaffold area was shifted upward across the imaging-guided arm, not merely at the mean, indicating that the benefit was general rather than confined to a few lesions.

3.3. Scaffold expansion, malapposition and optimal-result achievement

The larger scaffold area was accompanied by better expansion and less malapposition. The scaffold expansion index was higher with imaging guidance, the in-scaffold minimal lumen area was larger, and significant acute malapposition was less than a third as frequent as with angiography guidance (the expansion index was 0.84 versus 0.77, and malapposition occurred in 11 versus 43%). Achieving these results required more intervention: additional post-dilatation was performed roughly twice as often, and at a higher pressure, in the imaging-guided arm, and the procedure was correspondingly longer. The optimal-result composite was



achieved about twice as often with imaging guidance. Significant edge dissection did not differ between the arms. These endpoints are given in Table 2.

Table 2: Procedural and optical coherence tomography endpoints by treatment arm				
Endpoint	Imaging-guided	Angiography-guided	Difference/RR	p
Minimal scaffold area (mm ²)	7.18 ± 1.59	6.37 ± 1.17	+0.81 (+0.39, +1.24)	<0.001
In-scaffold minimal lumen area (mm ²)	6.76 ± 1.44	5.64 ± 1.39	+1.11 (+0.68, +1.55)	<0.001
Scaffold expansion index	0.84 ± 0.08	0.77 ± 0.11	+0.07 (+0.04, +0.10)	<0.001
Minimal scaffold diameter (mm)	2.84 ± 0.43	2.69 ± 0.38	+0.14 (+0.02, +0.27)	0.027
Maximal post-dilatation pressure (atm)	18.20 ± 2.93	15.09 ± 3.25	+3.10 (+2.15, +4.06)	<0.001
Procedure duration (min)	82.76 ± 18.89	68.70 ± 15.18	+14.06 (+8.79, +19.34)	<0.001
Additional post-dilatation	61 (75%)	27 (33%)	2.26	<0.001
Significant acute malapposition	9 (11%)	35 (43%)	0.26	<0.001
Significant edge dissection	12 (15%)	9 (11%)	1.33	0.640
Optimal scaffold result	43 (53%)	21 (26%)	2.05	<0.001

3.4. Target lesion failure and scaffold thrombosis at 12 months

At 12 months, target lesion failure had occurred in 7.4% of the imaging-guided arm and 14.8% of the angiography-guided arm, a difference that was not statistically significant (log-rank $p < 0.122$), as shown in Figure 3. The individual components, and scaffold thrombosis, were numerically lower in the imaging-guided arm but the numbers were small, consistent with a trial sized for the imaging endpoint rather than for clinical outcomes. The clinical outcomes are given in Table 3.

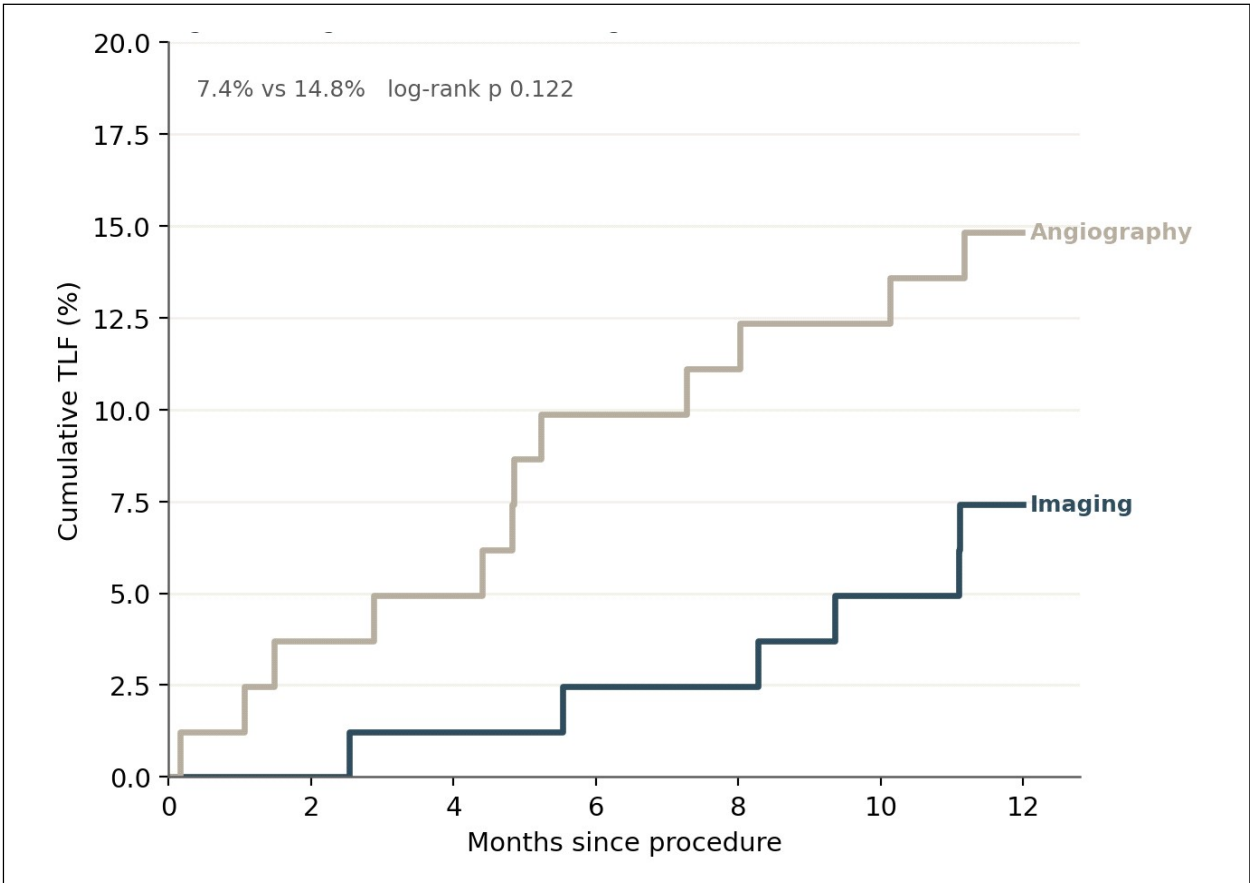


Figure 3: Cumulative incidence of target lesion failure through 12 months

Table 3: Clinical outcomes at 12 months by treatment arm				
Outcome	Imaging-guided (n = 81)	Angiography-guided (n = 81)	RR	p
Target lesion failure	6 (7.4%)	12 (14.8%)	0.50	0.210
Cardiac death	2 (2.5%)	3 (3.7%)	0.67	1.000
Target-vessel MI	4 (4.9%)	10 (12.3%)	0.40	0.160
Target-lesion revascularisation	6 (7.4%)	7 (8.6%)	0.86	1.000
Scaffold thrombosis	1 (1.2%)	4 (4.9%)	0.25	0.367

4. Discussion

In this randomised trial, guiding the optimization of bioresorbable scaffold implantation by intracoronary imaging rather than by angiography produced a larger minimal scaffold area, better expansion, markedly less malapposition and a higher rate of an optimal acute result. The clinical outcomes were numerically better with imaging guidance but the trial was not powered to test them.

These findings are what the mechanism of scaffold failure would predict. Because underexpansion and malapposition are the principal correctable causes of scaffold thrombosis and target lesion failure, and because angiography cannot reliably show them, a strategy that reveals them during the procedure and prompts their correction should improve the acute result, and it did. The improvement was not achieved passively: it required nearly twice as much additional post-dilatation, at higher pressure, in the imaging-guided arm, which shows that the imaging changed what the operator did rather than merely describing the result, and it accords with the observation that a final imaging check prompts further optimization in a substantial minority of scaffold procedures that appeared satisfactory on angiography.

The results extend to the bioresorbable scaffold a benefit already established for metallic stents. In trials of drug-eluting stents, imaging guidance has consistently produced larger stent dimensions and less malapposition than angiography, and the larger recent trials have begun to translate this into better clinical outcomes ([Buccheri et al., 2017](#)). The case for imaging is stronger, not weaker, for the bioresorbable scaffold, whose thicker and mechanically weaker struts make underexpansion both more likely and more dangerous and whose margin for error is smaller, so that the acute gains shown here are of particular relevance to a device whose clinical results have been most limited by exactly these problems.

Two practical matters temper how these results should be applied. The first is the cost of the strategy. Imaging guidance required more post-dilatation, more contrast and a longer procedure, and although these are modest for an experienced operator, they are not negligible, and the benefit of imaging must be weighed against them in each case rather than assumed to be worthwhile universally. The second is generalisability. The trial studied a particular scaffold and a particular technique at a single centre, and while the mechanism by which imaging helps is general, the size of the benefit may differ with other devices, other operators and other populations, so that the acute gains shown here should be confirmed for the next-generation scaffolds to which they are most relevant. Neither consideration undermines the central result, but both bear on how it should be translated into practice.

The clinical outcomes should be read with care. The numerically lower rate of target lesion failure with imaging guidance is consistent with the improved acute result and with the direction of the larger stent trials, but the trial was sized for the imaging endpoint and the confidence around the clinical difference is wide, so no conclusion about clinical benefit can be drawn from it. What the trial does establish is that imaging guidance reliably improves the acute mechanical result of scaffold implantation, which is the necessary link in the chain between the technique and any later clinical benefit, and which provides the rationale for a trial powered to test that benefit directly.

The reduction in malapposition deserves particular emphasis, because malapposition is not merely a cosmetic imperfection on the imaging but a mechanism of harm. A strut that stands away from the vessel wall is exposed to flowing blood on both surfaces and delays or prevents the coverage by which the vessel heals over the device, and in the analyses of scaffold thrombosis malapposition, together with underexpansion, is among the findings most consistently present at the site of the event. With the bioresorbable scaffold the concern is compounded, because the struts are thicker and protrude further into the lumen when malapposed, and because the polymer discontinuities that appear as the device resorbs can themselves become malapposed later. A strategy that more than halves the frequency of significant malapposition at the time of implantation therefore addresses one of the principal mechanisms by which these devices fail, which is the strongest reason to expect that the acute benefit shown here would, in an adequately powered trial, translate into a clinical one.

The choice of optical coherence tomography as the guiding modality shaped what could be seen and corrected. Its resolution is several times finer than that of intravascular ultrasound, and it detects malapposition and edge dissection more readily, which is an advantage when these are the findings that guide optimization; the trade-off is a shallower penetration that limits the assessment of the vessel wall behind a heavily diseased segment and the true external dimensions of the vessel, for which ultrasound remains better suited. For guiding the expansion and apposition of a bioresorbable scaffold, where the struts are clearly resolved and their apposition is the quantity of interest, the higher resolution is the more relevant property, and the trials that have shown a clinical benefit of imaging guidance for metallic stents have used either modality, suggesting that the benefit follows from imaging as such rather than from one technique. Whether ultrasound guidance

would yield the same acute gains for the scaffold as those shown here for optical coherence tomography is a reasonable question for a further comparison.

5. Strengths and limitations

The strengths of this trial are its randomised, assessor-blinded design, the acquisition of final optical coherence tomography in both arms with blinding of the operator in the control arm, so that the arms differed only in whether the imaging informed the decision, and the analysis of the imaging in a blinded core laboratory.

The trial has limitations. It was conducted at a single centre and was sized for the imaging endpoint, so it was not powered for clinical outcomes, which are reported as secondary and must be interpreted cautiously. The follow-up extended to 12 months, whereas the distinctive risks and benefits of a resorbable device continue to evolve over the following years. The imaging arm required more post-dilatation, contrast and procedural time, a cost that must be weighed against the benefit, and the findings apply to the scaffold and technique studied and may not extend to other devices.

6. Conclusion

In this randomised trial, intracoronary imaging-guided optimization of bioresorbable scaffold implantation produced a larger minimal scaffold area, better expansion, less malapposition and a higher rate of an optimal acute result than angiography-guided optimization, at the cost of more post-dilatation and a longer procedure. Clinical outcomes were numerically better with imaging guidance but the trial was not powered to test them. These findings support the use of intracoronary imaging to optimise bioresorbable scaffold implantation and provide the rationale for a trial powered for clinical outcomes.

Trial registration and ethical approval

The trial was registered in a public clinical trials registry and approved by the Institutional Ethics Committee and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from every participant.

Conflict of interest

The authors declare that no conflict of interest exists in relation to this work.

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Data availability

The data supporting the findings of this trial are available from the corresponding author on reasonable request.

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