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The role of enhanced stent visualization imaging in percutaneous coronary intervention: a systematic review of efficacy and clinical outcomes

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ROCEPTED MANUSCRIPT

ABSTRACT

Introduction

Coronary artery disease (CAD) is a major global cause of morbidity and mortality. Percutaneous

coronary intervention (PCI) is central to its management, and optimal stent deployment is

critical. This systematic review evaluates the efficacy and clinical outcomes associated with

enhanced stent visualization (ESV) systems-x-ray-based fluoroscopic tools such as

StentBoost and CLEARstent—in PCI.

Methods

A systematic literature search of PubMed, PubMed Central, and Cochrane Library was

conducted according to PRISMA guidelines. Inclusion criteria comprised all study types

evaluating ESV use in PCI, excluding case reports and non-English articles. Study quality was

assessed using Newcastle-Ottawa tool.

Results

Twelve studies involving ESV were included. ESV improved detection of stent expansion and

deployment versus standard angiography and showed strong agreement with OCT and IVUS.

ESV-guided PCI was associated with reduced rates of major adverse cardiac events (MACE),

particularly in long-term follow-up. Radiation exposure was modestly increased but deemed

acceptable.

Conclusions

ESV systems enhance stent deployment accuracy and clinical outcomes in PCI, offering a cost-

effective and accessible alternative to OCT and IVUS. Evidence supports routine integration of

ESV in PCI workflows, although further large-scale trials are warranted.

Registration: PROSPERO identifier is CRD420251020834.

KEYWORDS

CLEARstent, fluoroscopy, coronary angiography, coronary artery disease, StentBoost,

percutaneous coronary intervention, stent boost, clear stent

1. Introduction

Coronary Artery Disease (CAD) remains one of the leading causes of morbidity and mortality worldwide[1], with an estimated 2.3 million sufferers in the UK, including 1.4 million heart attack survivors[2]. Over the past decades, the management of CAD has evolved significantly, with percutaneous coronary intervention (PCI) becoming a cornerstone of treatment. The widespread use of coronary stents has revolutionized PCI, improving outcomes for patients with CAD[3]. However, optimal stent deployment is critical in achieving favourable long-term results and minimizing complications such as in-stent restenosis and stent thrombosis. Given the prevalence and impact of CAD, improving stent deployment strategies is essential. In this context, enhanced stent visualisation systems (ESV), an x-ray-based imaging technology, have emerged as a valuable tool for enhancing stent visualization and deployment assessment during PCI. The two major ESV tools are StentBoost (Phillips Healthcare, NL) and CLEARstent (SIEMENS, Germany).

ESV is a fluoroscopy-based imaging technique that improves the real-time visibility of stents during coronary procedures[4]. Using principles of digital subtraction angiography and motion compensation algorithms, it generates high-resolution images of deployed stents. ESV enhance the radiologic edge of the stent, allowing for better visualization of struts[5].

The advent of ESV addresses several limitations of conventional coronary angiography, which often fails to provide sufficient detail about stent expansion and integrity due to its limited resolution. ESV bridges the gap between conventional angiography and advanced intravascular imaging modalities by offering enhanced stent visualization without requiring additional invasive procedures. By providing detailed insights into stent expansion and positioning, ESV enables interventional cardiologists to optimize stent deployment and potentially improve procedural outcomes[6].

This systematic review aims to comprehensively examine the current evidence on ESV technology, its clinical applications, and its impact on PCI outcomes. By synthesizing the available research, we seek to provide a thorough understanding of ESV's role in modern interventional cardiology and its potential to improve patient care.

2. Methods

We conducted a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

2.1. Data collection and search strategy

An electronic search of published studies was conducted to identify relevant articles in the following databases: PubMed, Cochrane Library, and PubMed Central. The PubMed search MeSH terms (Medical Subject Headings) were:

- (StentBoost OR "Stent Boost" OR CLEARstent OR "Clear Stent") AND ("Coronary Artery Disease" OR CAD OR "Percutaneous Coronary Intervention" OR PCI OR "Percutaneous Transluminal Coronary Angioplasty" OR PTCA)
- (StentBoost OR "Stent Boost" OR CLEARstent OR "Clear Stent") AND ("Coronary Artery Disease" OR CAD) OR ("Percutaneous Coronary Intervention" OR PCI) OR ("Percutaneous Transluminal Coronary Angioplasty" OR PTCA) AND ("Major Adverse Cardiac Events" OR MACE) OR ("Myocardial Infarction" OR MI) OR "Revascularization" OR "Angiography"

2.2. Study selection and eligibility criteria

All articles were transferred to a worksheet in Microsoft Excel. Duplicate articles were excluded. Each article was screened by title and abstract to determine relevance and was either included or excluded accordingly. All included articles were further evaluated by reviewing the full text to exclude any irrelevant studies.

The inclusion criteria encompassed all study types and designs from inception to the present day related to the topic of ESV, Percutaneous coronary intervention and Coronary Artery Disease. All population groups were included. Only full-text articles published in peer-reviewed journals were used. Grey literature or unpublished articles were excluded, as well as non-English articles and case reports.

2.3. Risk of bias assessment

The quality of included studies was assessed by the Newcastle-Ottawa checklist (Supplementary Table S1).

3. Results

3.1. Study identification and selection results

The initial search yielded 31 published articles. There were no duplicates or non-English articles. Of these, 16 were excluded because they were case reports, and 2 were excluded after title and abstract screening due to irrelevance. Additionally, 1 article was excluded because the full text was not accessible. Ultimately, after a thorough quality assessment, 12 articles were

selected. Of these, 10 relate to StentBoost and 2 relate to CLEARstent. Figure 1 illustrates the search process using a PRISMA flow diagram.

The articles were classified according to their design and finding, with Table 1 summarising studies comparing ESV with other imaging modalities including standard angiography, IVUS and OCT, with the majority suggesting superiority to angiography in detecting complications.

Table 2 summarised studies looking at ESV and its implication on radiation exposure compared to standard angiography, indicating modest increase in radiation exposure compared to angiography alone. Finally, Table 3 summarised studies which reported on clinical outcomes, including major adverse cardiac events (MACE: composite of death, periprocedural infarcts and stroke), in procedures employing ESV versus comparators, suggesting improve outcomes with samples sizing ranging from 138 to 2614 cases.

4. Discussion

ESV technology has gained recognition as a practical imaging tool for guiding percutaneous coronary intervention (PCI), bridging the gap between standard coronary angiography and advanced intravascular imaging modalities such as Optical Coherence Tomography (OCT) and Intravascular Ultrasound (IVUS). While OCT and IVUS remain the gold standards for assessing stent expansion and integrity, their widespread adoption is often limited by cost, availability, and procedural complexity. This review highlighted the growing body of evidence supporting ESV's utility, demonstrating its ability to provide improved stent visualization and diagnostic accuracy in a cost-effective and accessible manner, whilst also improving clinical outcomes such as MACE compared with standard angiography alone. The integration of ESV into PCI workflows has been explored in terms of comparative imaging capabilities, clinical outcomes, and radiation exposure, showcasing a balance between procedural utility and practicality.

4.1. ESV vs other imaging modalities

The accurate assessment of stent deployment is crucial for procedural success and optimal clinical outcomes in PCI While advanced intravascular imaging modalities such as OCT and IVUS are considered the gold standards for evaluating stent expansion and integrity, their routine use is often constrained by cost, limited availability globally, and procedural complexity. ESV bridges the gap between conventional coronary angiography and advanced intravascular imaging, by being superior to coronary angiography but comparable to intravascular imaging in terms of detecting stent sizing and complications (Table 1).

Coronary angiography, despite its widespread use, has significant limitations in accurately assessing stent deployment. Mansour et al. reported that angiography-guided PCI resulted in suboptimal outcomes in 38% of cases, underscoring the need for more precise imaging techniques. ESV imaging addresses this gap by enhancing the radiologic visualization of stent edges through digital manipulation of X-ray images, enabling improved detection of stent underdeployment[7]. Blicq et al. demonstrated that ESV identified stent underexpansion in 18% of cases that appeared satisfactory on angiography, highlighting its superior diagnostic capability compared to angiography alone[9].

When compared with OCT, ESV demonstrates strong diagnostic performance. In a study of 138 STEMI patients undergoing PCI with drug-eluting stents, ESV detected stent underexpansion in 24% of cases, closely approximating OCT's detection rate of 27.2%. The diagnostic accuracy of ESV was notable, with a sensitivity of 80%, specificity of 96%, and positive and negative predictive values of 88% and 93%, respectively[10]. These findings suggest that while ESV may lack the resolution and detailed vessel wall assessment provided by OCT, it offers a reliable, cost-effective alternative for routine stent evaluation.

Similarly, ESV shows considerable utility when compared with IVUS, particularly in challenging anatomical settings such as ostial lesions. Zhang et al. evaluated ESV and IVUS in 58 ostial lesions and found that ESV had a specificity of 100% and sensitivity of 80% in detecting inadequate stent deployment. Furthermore, a strong correlation was observed between ESV-measured and IVUS-measured minimal stent area, with a regression coefficient of 0.95[11]. These results validate ESV as a practical alternative to IVUS for assessing stent expansion and integrity, especially in settings where IVUS is unavailable or cost-prohibitive.

The utility of ESV in complex interventions is further supported by its application in bifurcation lesions, which are technically demanding and often challenging to assess with conventional imaging. Fysal et al. demonstrated that ESV was invaluable in the deployment of the Tryton dedicated side branch stent. The enhanced visualization provided by ESV allowed for accurate assessment of stent expansion, coverage, and recrossing of the struts closest to the carina, all without adding significant cost or procedural complexity[14]. Similarly, Silva et al. evaluated ESV in 97 patients undergoing bifurcation PCI and found that it significantly improved stent visualization, rewiring of side branches, and assessment of stent expansion. In 79.6% of cases,

ESV provided optimal visualization of the stent and guidewire, while in 19.4% of cases, the visualization was suboptimal but still provided useful information. Notably, in three cases, ESV enabled the identification of guidewires and angioplasty balloons passing outside the stent borders during side branch rewiring, preventing potential complications[8]. These findings underline the role of ESV as a quick, simple, and effective imaging technique during bifurcation PCI. Additionally, ESV may provide the operator with better visualisation of wire position and stent integrity in complex bifurcations to prevent abluminal wire position, confirm wire position in relation to struts/cells overlying a side branch and detect unintended stent deformation. All of these were noted to be common, even in OCT-guided cases (up to 9.3% in the OCTOBER trial[19]), which could potentially be detected or even prevented by ESV.

While OCT and IVUS remain the gold standards for detailed imaging of stent deployment and vessel wall morphology, ESV offers several practical advantages. It is a quick, cost-effective, and widely accessible imaging modality that can be easily integrated into routine PCI workflows without significantly increasing procedural time. These attributes make ESV particularly valuable in settings where advanced intravascular imaging modalities are unavailable or impractical.

4.2. Major adverse cardiac events (MACE) and mortality outcomes

The impact of ESV-guided PCI on clinical outcomes has been evaluated in both short- and longterm studies, as summarised in Table 3. Oh et al. demonstrated no significant differences in short-term outcomes (1-month post-procedure) between ESV-guided and non-ESV-guided groups, with comparable rates of cardiac death (0.8% vs. 1.5%, p=0.503), total death (1.5% vs. 2.4%, p=0.523), Q-wave myocardial infarction (0% vs. 0.4%, p=1.000), and repeat PCI (1.5% vs. 2.0%, p=0.751)[16]. Similarly, the incidence of target lesion revascularization (TLR)-MACE was not significantly different (2.3% vs. 3.1%, p=0.542). However, long-term outcomes at 12 months revealed a significant reduction in adverse events in the ESV group, with lower rates of TLR (4.5% vs. 10.3%, p=0.009) and TLR-MACE (5.3% vs. 12.0%, p=0.008)[16]. This suggests that while ESV-quided PCI may not provide immediate clinical benefits, it potentially improves long-term outcomes by reducing the need for repeat revascularization and lowering overall MACE rates. Duan et al. corroborated these findings in a study focused on STEMI patients, reporting a significant reduction in MACE rates at 9 months in the ESV group compared to the conventional angiography group (2.94% vs. 13.4%, p=0.026)[10]. It is difficult to completely understand the mechanistic basis for this improved MACE result and why it is more pronounced in longer term follow ups, but it may relate to better stent expansion which may reduce future stent thrombosis/reinfarction, or better post-dilation balloon position which may prevent unintended injury to non-stented portions of the vessel.

Similarly, Chen et al.[17] demonstrated that ESV-optimized PCI improved procedural results in diabetic and non-diabetic patients, with significant increases in stent dimensions' post-dilatation (P<0.001). Importantly, the five-year follow-up data revealed similar mortality rates between the diabetic and non-diabetic groups (4.92% vs. 2.86%; P=0.67) and comparable rates of MACE (11.48% vs. 11.43%; P=1.0). However, the recurrence of angina pectoris was significantly higher in the diabetic group (47.54% vs. 29.52%; P=0.02), suggesting that while ESV optimizes stent expansion, diabetes remains a significant factor influencing symptom recurrence.

Finally, of the studies assessed, two described the use of CLEARstent[13,18], echoing the findings of StentBoost in the remaining studies, with improved minimum lumen diameter (p<0.01) and a reduction in MACE with a median follow up of 2.4 years (HR 0.86, 95% CI: 0.73-0.98). Overall, given the variation in reported outcomes and differences noted in the short and long term outcomes of ESV-guided procedures, more comprehensive data with standardized and longer follow-up periods are necessary to confirm sustained clinical advantages.

4.3. Radiation exposure with ESV imaging

Radiation exposure is a key concern during PCI, as prolonged fluoroscopy increases the risk of radiation-induced complications for both patients and operators. The use of ESV imaging, while enhancing stent visualization, has been shown to have a minimal impact on radiation dose (Table 2), albeit with an overall small sample size illustrating this finding. Fysal et al. reported that the incorporation of ESV during the deployment of the Tryton SideBranch Stent resulted in only a modest 3.7% increase in radiation exposure. This additional exposure was deemed acceptable given the significant procedural benefits, including improved visualization of stent expansion, coverage, and recrossing of struts, particularly in complex bifurcation stenting [11,14].

Jin et al.[15] further evaluated the impact of ESV imaging on radiation exposure in a cohort of 414 patients. Although the group utilizing ESV showed slight increases in dose-area product, fluoroscopy time, and cine frames, these increases were attributed to procedural complexity rather than the imaging technique itself. Importantly, the study found no significant difference in overall radiation dose between the ESV and non-ESV groups (P > 0.05). Adequate operator

experience in radiation protection and ESV imaging was highlighted as a key factor in minimizing radiation exposure.

4.4. Evidence base and limitations

The current evidence base for ESV, as summarised above, is mainly composed of observational and retrospective studies, with only limited randomized data available and an overall small number of published studies. This highlights the need for further prospective randomised trials to improv the power of the findings and address both clinical outcomes and impact on radiation exposure. The studies also varied in design, patient populations (e.g., STEMI, stable CAD, diabetes), lesion complexity, and outcome measures with particular variation noted in the duration of outcomes reported. These differences make direct comparisons challenging and limit the strength of pooled estimates. Another limitation is that lesion-level details such as morphology, stent length, and the proportion of bifurcation lesions were not consistently reported. This restricts the ability to define the role of ESV in specific anatomical settings. In addition, variability related to operator experience and institutional protocols may influence reproducibility.

4.5 Clinical implications

Despite the limitations in the published literature, the accumulated evidence suggests that ESV is a valuable adjunct to conventional angiography. It provides improved stent visibility, supports more accurate procedural decision-making, and in several studies has been associated with improved long-term outcomes. Its ease of integration into existing workflows, low cost, and minimal impact on radiation exposure make it especially attractive in centres where IVUS or OCT are not readily available. While ESV should not be considered a replacement for intravascular imaging in centres where OCT or IVUS are accessible, it represents a practical middle ground that enhances precision and safety in everyday PCI practice.

5. Conclusions

ESV imaging enhances stent visualization during PCI, addressing limitations of conventional angiography while offering a cost-effective and accessible alternative to advanced imaging modalities like OCT and IVUS. Its ability to optimize stent deployment has been associated with improved procedural outcomes and long-term clinical benefits, including reduced rates of revascularization and MACE. As a reliable and efficient imaging tool, ESV holds great potential to further advance the quality of care in interventional cardiology and should be employed routinely in standard PCI work flows.

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Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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Author contributions

M Protty conceived and designed the study. V Sant Bakshsingh analysed and interpreted the data. M Protty, V Sant Bakshsingh, and S Bundhoo contributed to drafting. All authors approve the final version and agree to be accountable for the work.

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Figure legends

Figure 1: PRISMA flow diagram outlining the systematic review process.

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses



Table legends

Table 1: ESV compared to other imaging modalities including standard angiography.

Table 2: ESV and radiation exposure.

 Table 3: ESV and major adverse cardiac events (MACE)/clinical outcomes.



Supplementary material legends

Supplementary Table S1. The Newcastle-Ottawa checklist for studies included in this systematic review article.



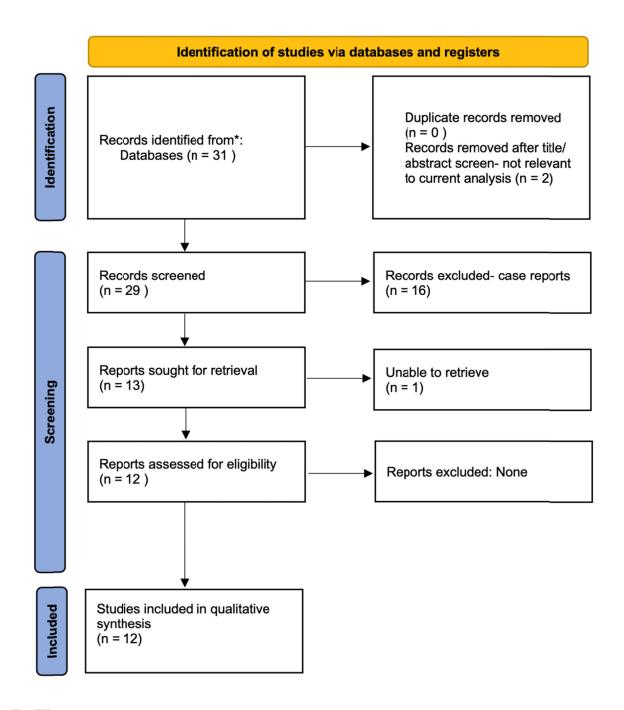


Figure 1: PRISMA flow diagram outlining the systematic review process PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

TABLE 1
ESV compared to other imaging modalities including standard angiography

Title	Authors	Year	Study design	Population	Outcome
Value of stent boost imaging in decision making after coronary stenting	Mansour et al.[7]	2020	Cross sectional	120 patients	Improved detection of suboptimal results in 38% of PCI cases leading to changes in the final decision for further optimization.
The utility of stent enhancement to guide percutaneous coronary intervention for bifurcation lesions	Silva et al.[8]	2013	Prospective study	97 patients	Improved detection of stent distortion and malexpansion which was present in 19.4% of cases. In 3 cases, ESV prevented complications by identifying guidewires/ balloons outside stent borders.
Detection of Stent Underdeployment by StentBoost Imaging	Blicq et al.[9]	2013	Retrospectiv e study	261 patients	Improved detection of underexpansion in 18% of cases

					that appeared
					satisfactory on
					angiography.
					Good
					agreement with
					comparator and
					improved
					outcomes:
				0	ESV identified
					underexpansion
					in 24.4% while
Optical coherence tomography:			_ (OCT identified
evaluating the effects of stent	Duan et		Prospective		in 27.2%. ESV
boost subtract imaging on	al.[10]	2022	study	138 patients	and OCT
stent underexpansion in STEMI	ai.[10]		Study		showed good
patients					agreement
					(kappa value =
	,	11			0.789, p <
					0.001). ESV
)			demonstrated:
					sensitivity 80%,
					specificity 96%,
					PPV 88%, NPV
					93%.
					Good
					agreement with
Stent boost subtract imaging					comparator:
for the assessment of optimal					ESV and IVUS
stent deployment in coronary	_	2014	Prospective	55 patients	showed
ostial lesion intervention:	al.[11]		study	- 1	significant
comparison with intravascular					positive
ultrasound					correlation
					(regression
					coefficient 0.95).

				1	FOV
					ESV predicted
					inadequate
					stent expansion
					with sensitivity
					80%, specificity
					100%, PPV
					100%, NPV
					96%.
					Good
Assessment of coronary stent					agreement with
deployment using computer					comparator:
enhanced x-ray images-	Davies et	0040	Prospective	22	High agreement
validation against intravascular	al.[12]	2012	study	33 patients	between ESV
ultrasound and best practice					and IVUS for
recommendations					stent expansion
					(r=0.74)
					Improved
	•	11			minimal lumen
					diameter:
Enhanced Stent Imaging)			(βeta
System Guided Percutaneous	Avci et	0004	Cross	404	coefficient:2.88
Coronary Intervention Is Linked	al.[13]	2024	sectional	164 patients	(95% CI:2.58-
to Optimize Stent Placement					2.99) vs βeta
					coefficient 2.55
					(95% CI 2.34-
() ^V					2.63), P < .001)

TABLE 2	
ESV and radia	ation exposure

Title	Authors	Year	Study design	Populatio n	Exposure
Evaluating stent optimisation technique (StentBoost®) in a dedicated bifurcation stent (the Tryton™)	Fysal et al.[14]	2014	Prospective study	8 patients	Modest increase in radiation exposure of 3.7%.
Impact of StentBoost subtract imaging on patient radiation exposure during percutaneous coronary intervention	Jin et al[15]	2013	Prospective study	414 patients	No significant difference in dose-area product, fluoroscopy time or cine frames between ESV and non-ESV

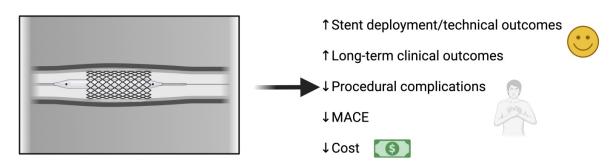
TABLE 3
ESV and major adverse cardiac events (MACE)/clinical outcomes

Title	Authors	Year	Study design	Population	Outcomes
Effect of StentBoost imaging guided percutaneous coronary intervention on mid-term angiographic and clinical outcomes	Oh et al.[16]	2013	Retrospective cohort study	870 patients	Improved incidence of TLR-MACE with ESV at 12 months (6% vs. 13.2%; p = 0.037).
Optical coherence tomography: evaluating the effects of stent boost subtract imaging on stent underexpansion in STEMI patients	Duan et al.[10]	2022	Prospective study	138 patients	Improved rates of MACE with ESV (2.94% vs 13.4%, p=0.026)
Five-year Clinical Outcomes of CAD Patients Complicated with Diabetes after StentBoost-optimized Percutaneous Coronary Intervention	Chen et al.[17]	2019	Retrospective cohort study	184 patients	Similar clinical outcomes at 5 years Mortality: 4.92% in DM vs 2.86% non-DM (p=0.67) MACE: 11.48% in DM, vs 11.43% non-DM (p=1.0)
Use of enhanced stent visualisation compared to angiography alone to guide percutaneous coronary intervention	McBeath et al.[18]	2020	Cohort study	2614 patients	Improved rates of MACE with ESV: 9.5% vs 14.4% (p=0.018)

Supplementary Table S1. The Newcastle-Ottawa checklist f

	Study details		Sele	cti
Study ID	Paper Title	1) Representativeness of the exposed cohort	2) Selection of the non exposed cohort	
Mansour et al	Value of stent boost imaging in decision making after coronary stenting	*	0	
Zhang et al	Stent boost subtract imaging for the assessment of optimal stent deployment in coronary ostial lesion intervention: comparison with intravascular ultrasound	*	0	
Davies et al	Assessment of coronary stent deployment using computer enhanced x-ray images-validation against intravascular ultrasound and best practice recommendations	*	0	
Fysal et al	Evaluating stent optimisation technique (StentBoost®) in a dedicated bifurcation stent (the Tryton™)	*	0	
Chen et al	Five-year Clinical Outcomes of CAD Patients Complicated with Diabetes after StentBoost-optimized Percutaneous Coronary Intervention	*	*	
Oh et al	Effect of StentBoost imaging guided percutaneous coronary intervention on mid-term angiographic and clinical outcomes	*	*	
Blicq et al	Detection of Stent Underdeployment by StentBoost Imaging	*	0	
Jin et al	Impact of StentBoost subtract imaging on patient radiation exposure during percutaneous coronary intervention (unable to access whole text)	*	*	
Silva et al	The utility of stent enhancement to guide percutaneous coronary intervention for bifurcation lesions	*	0	

al
McBeath et al
Avci et al



Enhanced Stent Visualisation (ESV) Technology in Percutaneous Coronary Interventions

ESV Central Illustration