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A prospective study of external stenting of saphenous vein grafts to the right coronary artery: the VEST II study

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Abstract

OBJECTIVES: External stents significantly reduce intimal hyperplasia and improve lumen uniformity and flow pattern in saphenous vein grafts (SVG) 1 year after coronary artery bypass grafting. However, recent studies have shown that at 1 year there is a lower patency of externally stented SVG to the right coronary artery (RCA) (55–60%) when compared to the left sided coronary arteries (85–90%). In the current study, we investigated whether avoidance of both fixation of the external stent to the anastomoses and the use of metal clips to ligate SVG side branches would improve the early patency of externally stented SVG to the RCA.

METHODS: Thirty patients received a SVG to the right territory supported with an external stent. Graft patency was confirmed at the end of surgery in all patients. The primary endpoint was SVG patency assessed by computed tomography angiography (CTA) at 3–6 months. Graft failure was defined as > 50% stenosis.

RESULTS: Twenty-nine patients (96.6%) completed the follow up period and CT angiography data was available for a total of 43 SVGs, (29 supported and 14 unsupported SVGs) and 47 arterial grafts. Patency of stented SVGs was 86.2% (25/29 on CTA). All non-stented SVGs to the left territory were patent. Patency rates of the left internal mammary arteries and right internal mammary arteries grafts were 96.6% and 83.3%, respectively.

CONCLUSIONS: Avoidance of both metallic clips to ligate side branches and of fixation of venous external support trial (VEST) stents to the anastomoses mark a significant improvement in patency of stented SVG to the right coronary territory.

Keywords: Coronary artery bypass surgery • External stenting • Graft patency • CT angiography

INTRODUCTION

Coronary artery bypass grafting (CABG) remains the gold standard treatment for multivessel coronary artery disease [1]. Even though the benefits of multiple arterial grafts are well documented [2, 3], autologous saphenous vein grafts (SVGs) remain the most widely used bypass conduits in CABG [4]. Nevertheless, progressive SVG failure frequently occurs following CABG, limiting the long-term success of the operation [5]. Overall, 20–25% of SVGs occlude by the end of the first year after surgery, 35% by 5 years and over 50% by 10 years [5–7].

Arterial pressure coupled with abnormal flow patterns, generated mainly by luminal irregularities, are the main contributors to both focal and diffuse intimal hyperplasia in SVG that progresses over time. A dysfunctional endothelial layer leads to occlusive thrombosis and accelerates atheroma formation that leads to eventual SVG failure [5, 8].

Until recently, only persistent use of statin therapy and β blockers have been shown to reduce intimal hyperplasia in SVGs [9]. However, recent clinical studies have demonstrated that external stenting of SVG also significantly reduces diffuse intimal hyperplasia by improving lumen uniformity and haemodynamic flow patterns [10–12]. Conversely, a notable limitation was the lower patency rate of externally stented SVGs to the right compared to the left coronary vessels at 1 year (55–60% vs 85–90% respectively) [12, 13]. Due to the acute angulation of the SVG on its course to the inferior wall, it was hypothesized that fixation of the external stent to the anastomoses and ligation of SVG side branches with metallic clips may, respectively, have led to tension on the anastomoses site and deformation of the lumen resulting in early technical failure [12].

The venous external support trial (VEST) II clinical study is a direct continuation of the VEST I in which a novel cobalt

chromium external stent (VEST, Vascular Graft Solutions, Tel Aviv, Israel) was used to support SVGs [12]. Our goal in the VEST II trial was to evaluate patency data 3–6 months after surgery in stented SVGs to the right side of the heart with only suture ligation of side branches and avoidance of fixation of the proximal and/or distal anastomoses.

MATERIALS AND METHODS

Study design and population

The VEST II trial (NCT02332330) was a post market clinical investigation of the CE marked VEST device. Conducted from January 2015 to January 2016, the VEST II was a prospective, single centre study that was approved by a UK Research Ethics Committee and all enrolled subjects gave informed consent. The study recruited eligible patients with atherosclerotic coronary artery disease who were scheduled to undergo on-pump SVG, CABG on clinical grounds, with arterial grafting of the internal mammary artery (IMA) to the left anterior descending artery (LAD) and at least one SVG to bypass the right coronary artery or posterior descending artery. In each patient, the SVG going to the right territory was externally supported by a VEST stent, whereas all other venous grafts to the left side were not supported. The protocol mandated that the target right coronary arteries should have a minimum diameter of 1.5 mm with a satisfactory distal vascular bed, as assessed by preoperative coronary angiography. The degree of proximal stenosis in the coronary arteries was measured by an independent observer using quantitative coronary angiography (Horizon Cardiology version 12.2, McKesson, Israel). The primary safety endpoint at 4–6 weeks postoperatively, was the occurrence of the composite all-cause mortality, stroke, myocardial infarction and coronary revascularization, whereas the primary effectiveness end-points was the mid-early SVG failure (occlusion or >50% stenosis) at 3–6 months, assessed by CT angiography (CTA).

Procedure and follow up

Routine on-pump CABG was performed in all patients by only two surgeons (DT and GK) in equal numbers. In all but one patient (97%) the study protocol was followed. SVGs were harvested either with an open (53%) or endoscopic technique (47%) and sutures rather than metal clips were used to ligate side branches. SVGs were preserved in heparinized blood buffered saline. After completing the distal anastomoses of the SVG to the right territory, an adequately sized VEST device was selected from twelve available models based on SVG diameter and length. The device was threaded on a non-pressurized SVG, the proximal anastomosis was performed and the device was expanded to cover the entire SVG. A gap of 5–10 mm was intentionally maintained from the device to both the distal and the proximal anastomoses as described in Fig. 1. No fixation of the device was required as it maintains its shape post deployment.

Transit Time Flow Measurement was used to assess Mean Graft Flow (MGF) and Pulsatility Index (PI) and revision was considered for MGF <20 ml/min and/or PI >5.

Following surgery, all patients were prescribed statins, b-blockers and antiplatelet medication and all pre, peri and postoperative routine patient management was carried out according to

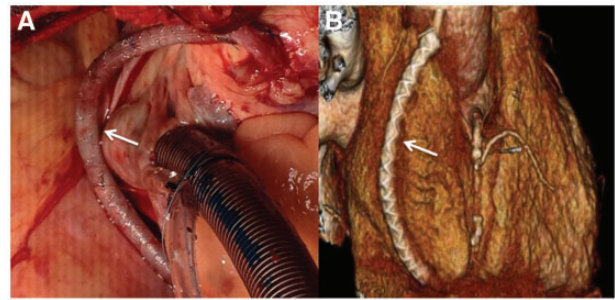


Figure 1: Example of optimally deployed VEST-stent. (A) A VEST (Vascular Graft Solutions Ltd, Tel Aviv, Israel) supported vein graft to the right coronary territory. (B) Computed tomography-based 3D reconstruction of the heart showing a VEST-supported vein graft to the right coronary artery.

protocol, including the administration of 300 mg of Aspirin per rectum within the first six postoperative hours.

The first scheduled follow-up visit was conducted at 4–6 weeks and the second scheduled follow-up was conducted at 3–6 months after the operation. At both follow-up appointments the patients underwent a full clinical examination with ECG, chest x-ray, medication review and detailed recording of all major adverse cardiac and cerebral (MACCE) and other serious adverse events. At the second follow-up the patients underwent a CTA to assess graft patency (Fig. 2).

Coronary computed tomography angiography

CTA was performed to assess graft patency (Aquilion one 320 slices, Toshiba Medical Systems Cooperation) Fig. 2. Oral nitroglycerin was given prior to the scan in order to achieve coronary vasodilatation. After defining the region of interest, 80 ml of an iodine based contrast agent (Niopam 370, Bracco, UK Ltd.) was injected at a flow rate of 4.5 ml/sec followed by a saline chaser bolus of 60 mL at 4.5 ml/sec, via a 20 gauge needle in the antecubital fossa. The gantry rotation time was 0.35 sec, peak tube voltage was 120kVp, and current (mA) was adjusted per patient's body weight. Additional Beta-blockers were administered in the event heart rate exceeded 60 bpm. Graft patency was classified using three grade scale; < 50% stenosis, ≥ 50% stenosis or occluded and graft failure was defined as ≥ 50% stenosis. Analysis was performed by an independent observer.

Statistical analysis

Continuous variables were presented as mean ± standard deviation along with the corresponding 95% confidence intervals of the mean, whereas categorical values were presented as number of cases (%). Mann-Whitney non-parametric or chi-square test was used to compare continuous or categorical variables between the two groups (patent versus occluded grafts), when appropriate. Results were analysed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp. Armonk, NY, USA) and significance was set at 5%.

RESULTS

Patients, procedure and follow-up

A total of 30 patients (mean age 66.3 ± 8.5 years, 83% males) were enrolled between January 2015 and October 2015 (demographic

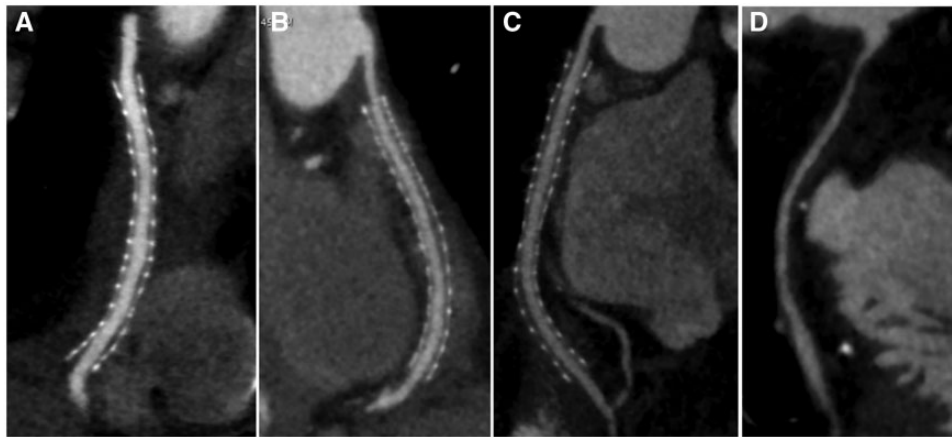


Figure 2: CT angiogram of VEST-supported (A–C) and non-supported (D) vein grafts. (A–C) Normal CT angiogram of three different patent VEST-supported vein grafts to the right coronary artery. (D) Normal CT angiogram of unsupported vein graft to the left territory.

characteristics for the study population are presented in Table 1). Thirty SVGs to the right coronary territory were each supported by the VEST device, whereas the 15 SVGs to the left territory were not. There were an additional 48 arterial grafts to the left territory [30 left internal mammary arteries (LIMAs), 18 right internal mammary arteries (RIMAs)]. Baseline grafting characteristics of SVG to the right territory are described in Table 2. Quantitative coronary angiography of the degree of proximal stenosis and lesion length in the native coronary arteries is presented in Table 3. No graft revisions were performed following MGF and PI measurements. Intraoperative MGF and PI measurements for all venous and arterial grafts are described in Table 4.

Major adverse cardiac and cerebral rate at 6 weeks was 7% (2/30). One patient died 10 days postoperation due to ischaemic colon and sepsis and one patient had a stroke. All adverse events were defined as non-device related. CTA data were available for 29 patients (in one patient CTA was performed 5 days postoperation for investigation of ischaemic bowel). One patient was lost to follow up due to diagnosis of cholangiocarcinoma and renal failure. Data were available for analysis for a total of 43 SVGs, (29 supported and 14 unsupported SVGs) and 47 arterial grafts. The average time interval from operation to CTA was 102.0 ± 23.1 days. Four stented SVGs (13.8%) were occluded on CTA. All 14 non-stented SVGs to the left territory were patent. Patency rates of the LIMA and RIMA grafts were 96.7% and 83.3% respectively as described in Table 5.

In an attempt to identify risk factors for VEST supported SVG failure the CT angiograms were carefully analysed in a qualitative way to determine whether factors such as kinking of the graft or stent oversizing might have affected graft patency. Similarly pre-operative coronary angiographs were quantitatively analysed to determine the likely prognostic effect of target lesion on vein graft success. All patients that received slightly oversized stents had no SVG failure on follow-up. In one patient with a failed VEST-supported SVG (Fig. 3A) kinking of the graft was observed at the proximal anastomosis (Fig. 3B). Further statistical analysis demonstrated no significant differences either in the patient demographics or SVG characteristics (Table 2) between the patent and occluded VEST groups.

For arterial grafts, a significantly lower intraoperative MGF was measured in the occluded grafts (23.0 ± 18.8 ml/min vs 46.3 ± 21.4 ml/min, P -value 0.039). This is most likely explained by the presence of competitive flow.

Table 1: Patient demographics

Characteristic (n=30)	Mean \pm SD or n (%)	Median (range)
Age (yrs.)	66.3 \pm 8.5	
Gender (male)	25 (83)	
Height (cm)	174.6 \pm 7.5	
Weight (kg)	83.0 \pm 14.1	
Smoking status		
Current smoker	2 (7)	
Ex-smoker (>6m)	17 (57)	
never smoked	11 (36)	
Diabetes		
No history	21 (70)	
Insulin dependent - treated	3 (10)	
Insulin dependent - not treated	1 (3)	
Non-insulin dependent - treated	4 (13)	
Non-insulin dependent - not treated	1 (3)	
Hypertension		
Normotensive	4 (13)	
Yes, controlled by medication"	26 (87)	
Yes, untreated	-	
Hyper lipid		
None	4 (13)	
Yes, controlled by medication"	25 (84)	
Yes, untreated	1 (3)	
COPD		
No history	26 (87)	
Mild	4 (13)	
Severe	-	
NYHA class		
I	11 (37)	
II	12 (40)	
III	5 (16)	
IV	2 (7)	
LVEF (%)	56.2 \pm 7.4	57.5 (35–66)
Creatinine (umol/L)	85.7 \pm 14.9	85 (46–114)
EuroScore (%)	3.1 \pm 3.5	2.1 (0.51–18.1)

OVH: open vein harvesting; NYHA class: New York Heart Association (heart functional classification); EuroScore: European system for cardiac operative risk evaluation.

DISCUSSION

This is the first study to attempt to improve the early-midterm patency rates for VEST-supported grafts to the right territory of

Table 2: Baseline characteristic of saphenous vein graft to the right coronary artery or the posterior descending artery

N	Mean [95% CI of mean] \pm SD or n (%)			P-value
	Total 30	Patent 25	Occluded 4	
Right territory artery diameter (mm)	1.75 [1.64–1.86] \pm 0.3	1.75 [1.62–1.88] \pm 0.3	1.75 \pm 0.2	NS
SVG length (cm)	15.9 [15.2–16.5] \pm 1.7	15.8 [15.1–16.5] \pm 1.7	15.7 \pm 1.9	NS
Systolic pressure at TTFM (mmHg)	111.0 [105.6–116.4] \pm 14.5	110.8 [104.4–117.1] \pm 15.3	115.30 \pm 9.0	NS
TTFM Mean graft flow (ml/min)	56.3 [46.0–66.7] \pm 27.7	53.5 [44.7–68.5] \pm 27.5	50.3 \pm 29.0	NS
TTFM Pulsatility index	2.1 [1.9–2.4] \pm 0.7	2.3 [1.9–2.5] \pm 1.0	1.8 \pm 0.7	NS
VEST type 1	22 (73)	19 (76)	2 (50)	NS
VEST Model				
B (13.1–15 cm)	8 (27)	7 (28)	1 (25)	NS
C (15.1–17 cm)	15 (50)	13 (52)	2 (50)	NS
D (17.1–19 cm)	7 (23)	5 (20)	1 (25)	NS
Open harvesting technique	16 (53)	13 (52)	2 (50)	NS

CI: confidence interval; SD: standard deviation; SVG: saphenous vein graft; TTFM: transit time flow-metry; NS: non-significant.

the heart, after earlier studies had raised concerns of lower patency rates of externally stented SVGs to the right side [12, 13]. Adherence to recommended instructions for VEST use, which exclude both the use of metal clips to ligate side branches and VEST fixation to either the proximal and/or distal anastomoses, resulted in a significant improvement in patency rates compared with VEST I [12]. Indeed the current patency rates in VEST II are comparable to those generally described in literature of early patency rates of SVGs to the right coronary territory in the range of 71–86% at 6–12 months [6, 14–16]. The VEST II study therefore confirms that when specific recommendations for use are followed the VEST external stent for SVGs to the right territory is safe.

Different types of mechanical external stents for SVGs have shown considerable promise in pre-clinical testing with a reduction of proliferative intimal hyperplasia by reducing wall tension, improving lumen uniformity and creating a protective 'neo-adventitia' layer rich with micro vasculature [17–19].

VEST has already shown promising results both in pre-clinical and clinical studies. In a large animal CABG setting, VEST use was associated with a decrease in thrombotic occlusion events, lumen irregularities and intimal hyperplasia [20]. Early clinical studies confirmed the preclinical findings and demonstrated significant reduction of intimal hyperplasia, thrombus formation and SVG lumen irregularities and ectasia one year after CABG [10–12]. By targeting the root causes of vein graft disease, VEST may offer the potential to improve long-term patency rates, and further studies (VEST III and VEST IV) are ongoing to address this question.

Nevertheless, careful analysis of the individual cases where VEST-supported SVGs failed may improve the understanding of the pathophysiology of vein graft failure. For instance, competitive flow from the native coronary arteries has been long established as a risk factor for graft failure, and arterial grafts are more susceptible to this phenomenon than saphenous venous grafts [21]. Grafts used to bypass high-grade stenosis demonstrate better patency rates than those to vessels with low-grade stenosis, where there is much greater residual flow through the native coronary artery. In occluded SVGs that had good intraoperative flows it is possible that storage of the graft in heparinized saline led to endothelial damage and graft failure as reported recently in a sub-analysis of the PREVENT IV [22]

The early failure observed in the IMA grafts is most probably due to competitive flow from the native coronary arteries [23–25]. The measured intraoperative flows in the occluded LIMA and RIMA grafts were significantly lower than in the patent internal mammary artery grafts (approximately 30% lower than in the patent RIMA grafts), although this failed to reach statistical significance, most likely because of the small number of grafts involved.

Several recent publications have shed light on the magnitude of the effect of competitive flow on early and intermediate patency of arterial grafts [25–26]. Recently, Harskamp *et al.* [26] published an angiographic study of 1539 LIMA to LAD grafts 12–18 months after CABG. Study findings showed that moderate LAD lesions (50–75%) and/or an additional bypass graft to the diagonal branch (which increases the competitive flow in the LAD) are both significant risk factors for LIMA-LAD graft failure.

Our study did not raise any concerns over the effect of VEST size on patency rates. An important issue that arises when trying to select the appropriate VEST size for a saphenous vein graft is whether to use a slightly oversized stent that can be loosely attached to the graft wall or rather a more firmly attached stent. Previous pre-clinical studies on external venous support systems for SVGs in pigs, have shown that oversized stents are equally or more effective at reducing intimal hyperplasia compared with more restrictive ones [18].

The present study has several limitations. Firstly, one important limitation of the VEST II trial is that the lack of a control group does not allow comparison of the primary safety and effectiveness end-points in VEST-supported versus non-supported SVGs to the right coronary artery. Furthermore, only right territory arteries with a minimum diameter of 1.5 mm with a satisfactory distal vascular bed were included, which could potentially result in selection bias. In addition, the study follow-up was limited to 3–6 months and therefore no conclusions can be drawn on the mid-late and long-term patency rates of VEST-supported SVGs to the right territory.

In conclusion, the current trial demonstrates that by avoiding both metallic clips to ligate side branches and avoidance of fixation of VEST to the anastomoses, there was a marked improvement in patency of stented SVG to the right coronary territory. If the proven beneficial effects of VEST on intimal and medial

Table 3: % Diameter stenosis and lesion length in native coronary arteries assessed by quantitative coronary angiography

Mean [95% CI of mean] ± SD									
Averaged overall			Patent graft			Failed Graft			
n	%DS	LL (mm)	n	%DS	LL (mm)	n	%DS	%LL (mm)	P-value %LL
Right territory									
VEST supported SVG	30	82.4 [76.2–88.7] ± 16.6	25	80.7 [73.7–87.7] ± 17.0	10.3 [7.9–12.8] ± 4.8 (n = 17)	4	88.8 ± 13.7	11.1 ± 6.4 (n = 2)	NS
Left territory									
Arterial grafts	48	74.1 [69.8–78.5] ± 15.0	43	74.9 [70.4–79.3] ± 14.5	12.2 [10.5–13.9] ± 5.5 (n = 42)	4	66.6 ± 22.6	8.7 ± 3.3 (n = 4)	NS
LIMA	30	74.3 [68.7–79.9] ± 15.0	28	75.3 [69.6–81.0] ± 14.7	12.3 [10.6–14.0] ± 4.3 (n = 27)	1	48.8	13.3 (n = 1)	–
RIMA	18	73.9 [66.2–81.6] ± 15.5	15	74.2 [66.1–82.2] ± 14.6	12.0 [8.0–16.1] ± 7.3 (n = 15)	3	72.5 ± 23.6	7.2 ± 1.4 (n = 3)	NS
SVG	15	73.5 [65.2–81.7] ± 14.3 (n = 14)	13	73.0 [64.1–81.9] ± 14.8	11.8 [9.2–14.4] ± 4.3 (n = 13)	0	–	–	–

CI: confidence interval; DS: diameter stenosis (native vessel); LL: lesion length (native vessel); SVG: saphenous vein graft; LIMA: left internal mammary; RIMA: right internal mammary; SD: standard deviation; NS: non-significant.

Table 4: Intraoperative transient time flow and pulsatility index measurements

Mean [95% CI of the mean] ± SD									
Averaged overall			Patent graft			Failed Graft			
n	TTFM flow (ml/min)	Pulsatility index	n	TTFM flow (ml/min)	Pulsatility index	n	TTFM flow (ml/min)	Pulsatility index	P-value (PI)
Right territory									
VEST supported SVG	30	52.3 [42.2–62.4] ± 27.1	25	53.5 [42.2–64.9] ± 27.5	2.3 [1.9–2.7] ± 1.0	4	50.3 ± 29	1.8 ± 0.7	NS
Left territory									
Arterial grafts	48	44.4 [38.1–50.7] ± 21.7	43	46.3 [39.8–52.9] ± 21.4	2.3 [2.1–2.6] ± 0.8	4	23.0 ± 18.8	2.3 ± 0.6	NS
LIMA	30	47.8 [39.7–55.9] ± 21.8	28	49.0 [40.6–57.4] ± 21.8	2.3 [2.1–2.6] ± 0.7	1	17.0	1.6	–
RIMA	18	38.7 [28.2–49.1] ± 21.0	15	41.4 [30.1–52.6] ± 20.3	2.4 [1.9–2.9] ± 0.9	3	25.0 ± 22.5	2.5 ± 0.5	NS
SVG	15	52.8 [40.5–65.1] ± 22.2	14	50.4 [38.3–62.6] ± 21.0	2.1 [1.6–2.6] ± 0.8	0	–	–	–

CI: confidence interval; LIMA: left internal mammary; PI: pulsatility index; RIMA: right internal mammary; SD: standard deviation; SVG: saphenous vein graft; TTFM: transit time flow-metry; NS: non-significant.

Table 5: Grafts patency rates assessed by CT angiography

Variable	Rate %	(n/N)
Right Territory		
VEST supported SVG to RCA	86.2	(25/29)
Left territory		
LIMA graft	96.6	(28/29)
LIMA to LAD	94.4	(17/18)
LIMA to OM	100	(9/9)
LIMA to CRX	100	(1/1)
LIMA to Diagonal	100	(1/1)
RIMA graft	83.3	(15/18)
RIMA to LAD	88.9	(8/9)
RIMA to OM	83.3	(5/6)
RIMA to Diagonal	0	(0/1)
RIMA to IR	100	(2/2)
SVG	100	(14/14)
SV to OM	100	(7/7)
SV to CRX	100	(2/2)
SV to Diagonal	100	(3/3)
SV to LAD	100	(1/1)
SV to IR	100	(1/1)

VEST: venous external support technology; SVG: saphenous vein graft; RCA: right coronary artery; LAD: left anterior descending; OM: obtuse marginal; CRX: circumflex; IR: intermediate ramous.

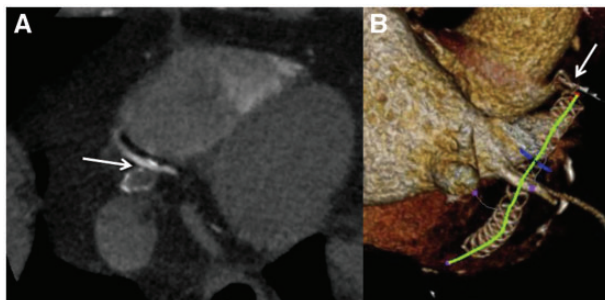


Figure 3: Possible technical reasons for failure of VEST supported vein grafts. **(A)** An axial computerized tomography angiogram demonstrating the anastomosis site of an occluded VEST-supported graft to the right coronary artery (white arrow). The graft is occluded proximally due to kinking. **(B)** An external three-dimensional reconstruction of an occluded VEST supported vein graft which shows kinking of the proximal end of the vein graft that might have resulted in early occlusion (white arrow). VEST should be shaped to the optimal configuration with relation to the proximal anastomosis to avoid kinking at the unsupported proximal segment of the vein graft, mainly in grafts which are slightly too long.

hyperplasia, ectasia and lumen deformity are maintained over the long-term this may lead to an improvement in long-term patency of vein grafts and, consequently, clinical outcomes.

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Conflict of interest: D.P. Taggart declares a conflict of interest as a shareholder at VGS and lecturing honoraria as an advisor and speaker for VGS.

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