Novel Use of a Peripheral, Self-Expanding Nitinol Stent in Adjunct to Excimer Laser Coronary Atherectomy in the Treatment of Degenerated Vein Graft Disease

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Decades of successful surgical revascularization of coronary artery disease have led to a growing population with saphenous vein graft disease. However, the treatment of degenerated saphenous vein graft still remains controversial. We report a novel but successful use of a peripheral, self-expanding nitinol stent in adjunct to excimer laser coronary atherectomy (ELCA) in the treatment of symptomatic, degenerated saphenous vein graft disease. The procedure was tolerated well without any short- or long-term complications. The case report is followed by a review of the literature on the treatment of vein graft disease.

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Key words: Saphenous vein graft disease • Peripheral, self-expanding nitinol stent • Excimer laser coronary atherectomy (ELCA)

Decades of successful surgical revascularization of coronary artery disease have led to an ever-growing population of patients with saphenous vein graft disease. Limitations of coronary artery bypass graft (CABG) surgery are recurrent ischemia, venous graft failure, and a need for repeat revascularization. Occlusive vein graft disease occurs in 20% of CABG patients at 1 year and in 87% of patients at 10 years; however, survival remains quite good with

less than 20% mortality at 10 years.[1,2] Among the survivors who present with ischemic symptoms, more than 85% will be found to have a vein graft as the culprit vessel, with percutaneous coronary intervention or repeat CABG required in a fair proportion of these patients.[3]

The optimal treatment strategy for degenerated saphenous vein grafts still remains unknown. Therapy of symptomatic patients after bypass surgery is problematic because repeat CABG not only is technically more challenging and carries increased morbidity and mortality, but also is less likely to provide symptomatic relief. Transcatheter management of patients with saphenous vein graft disease has its own inherent tribulations, including perforation, distal embolization, no-reflow phenomenon, abrupt closure, and restenosis. Above all, a small number of patients may not be candidates for any standard intervention due to either the size of the vein graft or the location of the disease.

Among survivors who present with ischemic symptoms, more than 85% will be found to have a vein graft as the culprit vessel.

We report a case of symptomatic saphenous vein graft (SVG) disease successfully treated with a peripheral, self-expanding nitinol stent in adjunct to excimer laser coronary atherectomy (ELCA) without any short- or long-term complications. The case report is followed by a review of the literature on the treatment of saphenous vein graft disease.

Case Report

A 75-year-old male with a history of coronary artery bypass graft surgery presented with an acute coronary syndrome. The patient had undergone two coronary artery bypass graft surgeries previously, the latest one 9 years earlier. The patient's other past medical history was significant for diet-controlled diabetes mellitus, hypertension, and dyslipidemia. The patient underwent cardiac catheterization after informed consent was obtained. Cardiac catheterization revealed a 70% disease in the left main artery. Left anterior descending artery (LAD) demonstrated a 100% stenosis after giving off a small septal perforator and diagonal branches. The left circumflex artery was diffusely diseased with 100% proximal and 100% mid lesions. The dominant right coronary artery (RCA) had 90% proximal and 90% distal lesions at the bifurcation to the posterior descending artery. The SVG to the RCA and to the first obtuse marginal branch of the left circumflex artery were found patent. However, the proximal SVG to the LAD had a focal, eccentric 75% diameter stenosis by quantitative coronary analysis (QCA) with clot, and was deemed to be the culprit vessel (Figure 1). Left ventriculography revealed a small apical aneurysm but normal left ventricular systolic function. Due to lack of adequate distal targets the patient was not considered a good surgical candidate. Therefore, it was decided to proceed with the percutaneous coronary intervention. Contrast within the graft was flushed with copious amounts of heparinized saline. ELCA was performed on the proximal SVG to the LAD followed by a deployment of 5 mm × 20 mm Cordis Precise™, a peripheral, self-expanding nitinol stent. Poststent deployment angiography revealed a 0% residual stenosis by QCA with a transient ischemic myocardial infarction (TIMI) grade III flow distally. The patient tolerated the procedure well without any complications. Cardiac enzymes were not elevated and renal function remained unchanged 3 days after the intervention at the time of discharge. Five months later, an adenosine nuclear test performed for the patient's atypical symptoms demonstrated no perfusion defects.

Review of the Literature

The peri-operative risks of repeat CABG are nearly 5-fold greater than initial CABG, with 10-year survival being about 72%.[1] However, a 5-year major adverse cardiac event (MACE)-free survival and angina-free survival is reported to be 64% and 50%, respectively.[4] Numerous non-randomized studies have shown a lesser in-hospital death and myocardial infarction (MI) rate following percutaneous transluminal coronary angioplasty (PTCA) compared to repeat CABG. The success rate of PTCA of SVG is 78%–97% with a low in-hospital complication rate of 0%–12%.[5,6] The major limitation of PTCA of SVG is restenosis occurring in 23%–73% of patients within 6 months. Distal embolization occurs in 2%–15% of the vein grafts more than 3 years old, whereas no-reflow phenomenon following SVG intervention is seen in about 5%–15% of the cases.[7,8] The incidence of abrupt closure, usually caused by severe dissection, is lower in the SVG intervention (1%–2%) than in the native vessel PTCA (2%–12%).[4] Although rare, the rate of coronary artery and vein graft perforation is higher following atherectomy or laser angioplasty than following balloon angioplasty.

Approximately 75% of vein grafts are treated by devices other than PTCA.[4] Thrombectomy devices and

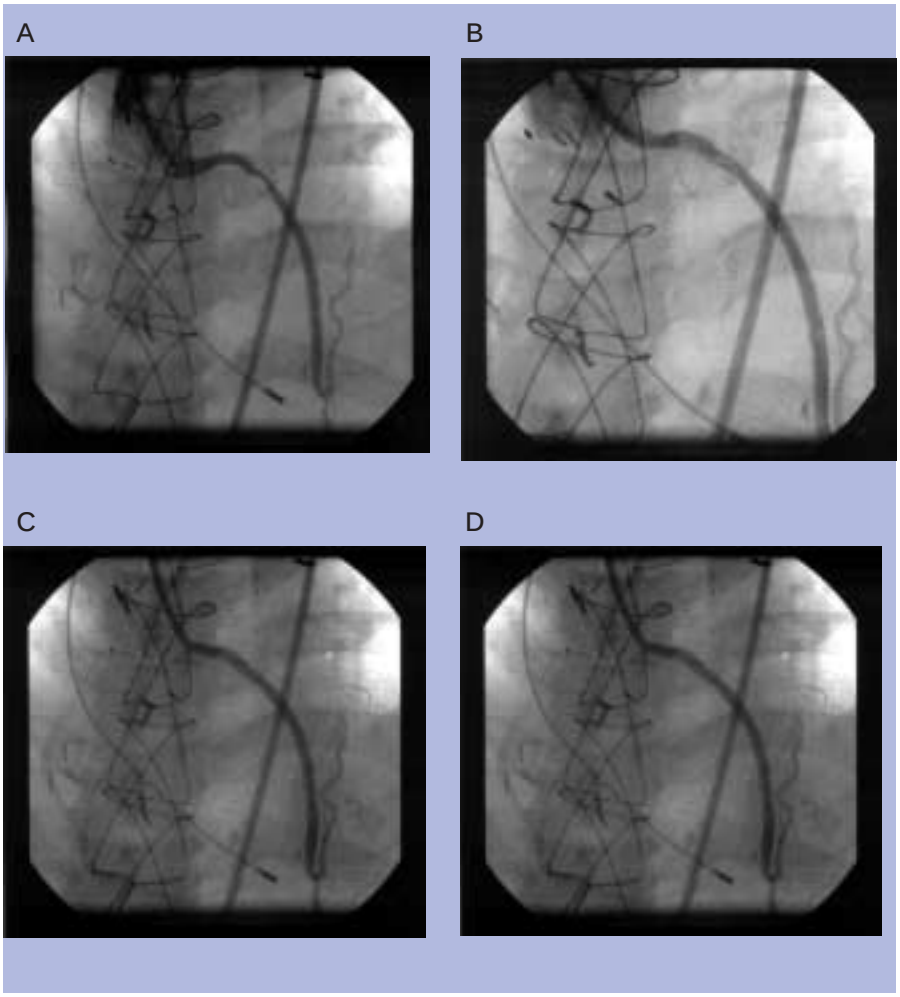

Figure 1. *Cardiac catheterization showing the diagnostic focal, eccentric lesion (75% by QCA) with a clot in the proximal saphenous vein graft to the LAD* **(A)**. *Grade I dissection noted after the ELCA* **(B)**; *stent placement across the lesion* **(C)**; *post percutaneous coronary intervention angiography with a residual stenosis (0% by QCA)* **(D)**.

distal embolic protection systems have largely replaced the transluminal extraction catheter (TEC) atherectomy. Distal embolization during TEC procedure was reported to occur in 7.4% of lesions resulting in a 6-fold increase in hospital mortality and a 5-fold increase in MI in the multicenter New Approaches to Coronary Interventions (NACI) registry.[9] The Coronary Angioplasty versus Excisional Atherectomy Trial (CAVEAT-II) demonstrated higher success rates and better luminal enlargement with directional coronary atherectomy (DCA) compared to PTCA. However, DCA had a higher incidence of complications and showed no differences in acute and long-term outcomes; it also showed restenosis at 6 months. Major procedural complications including dissection and perforation were significantly higher.[10] Rotablator atherectomy is contraindicated in degenerated SVGs as well as lesions containing thrombus due to a high incidence of complications. However, the successful use of rotablator atherectomy has been reported in some aorto-ostial, mid-body, and distal anastomotic vein graft lesions.[11,12] The Food and Drug Administration has approved AngioJet® (Possis Medical) to treat the thrombotic lesions including the vein grafts, based on the multicenter, randomized VEGAS-II Trial (Vein Graft AngioJet® Study) comparing AngioJet® to the intracoronary urokinase infusion. However, in-hospital MACE has been reported in about 14% of the patients.[13] Urokinase therapy has not proven as successful in SVG as it is in peripheral vascular occlusions and it is also associated with increased bleeding complications. The EPIC Trial demonstrated that pretreatment with abciximab (glycoprotein IIb/IIIa receptor antagonist) reduced the incidence of distal embolization more than placebo, but the 30-day and 6-month MACE rates were similar.[14] Distal embolic protection systems rely on the use of a balloon, catheter occlusion, or filter devices to trap and remove debris during intervention. The recent SAFER (Saphenous vein Free of Emboli Randomized) trial, comparing PercuSurge GuardWire™ (Medtronic) versus no distal protection, was interrupted prematurely because of marked benefit shown in 551 patients, with a 50%–60% reduction in the in-hospital as well as 30-day MACE, irrespective of the use of glycoprotein IIb/IIIa receptor antagonists.[15]

There is relatively little published data about the short- and long-term results of ELCA. The first use of laser atherectomy was described in the late 1980s for vein grafts refractory to angioplasty.[16] Success rates greater than 90% were plagued by high procedural complication rates leading to a waned interest in laser angioplasty. Despite the development of pulsed excimer systems, multifiber catheters, and improved techniques, procedural success often required adjunct balloon angioplasty or stent and long-term outcomes did not

Table 1
Review of the Literature on the Various Treatment Modalities Used in SVG Disease

Year	Author	No of Pts	Graft Age (y)	F/U (mo)	Graft Anatomy			Treatment Modality			Success Rates	Early Complication Rates	Late Complication	Restenosis Rates
					AO	GB	Anast	PTCA	Stent	Debulking				
1989	Platko et al[25]	107	~3	16.8	—	—	—	100%	—	—	91.8%	2%–7.1%	33.1%–64.1%	61.2%
1990	Linnemeier et al[26]	29	—	—	—	—	—	16 adj	—	17 PLCA	94%	3%	—	62%
1992	Power et al[27]	43	—	6	—	—	—	37 adj	—	51 ELCA	98%	1.7%	30%	50%
1993	Bittl et al[28]	200	—	4.5	—	—	—	88% adj	—	100% ELCA	93%	—	—	—
1994	Bittl et al[18]	545	8	6	12%	—	—	91% adj	—	100% ELCA	92%	0.6%–6.1%	—	55%
1995	Strauss et al[29]	106	8	12	20%	67%	13%	83% adj	—	100% ELCA	91%	0.9%–4.5%	8.6%–51.8%	52%
1996	Berger et al[30]	77	7.7	24	—	—	—	100%	—	—	71%	1.3%–13%	23%–49%	44%
1996	Natarajan et al[31]	41/39	8.4/8.2	12	11.4%	63.6%	25%	50% alone	—	50% ELCA+PTCA	100%	—	2.3%–19.6% vs 2.6%–18%	58% vs 74%
1999	Gruberg et al[32]	259	—	17	0	0	100%	70%	30%	—	96% vs 99%	0.6%–2.4% vs 0%	1%–38% 0%–36%	—
2000	Ahmed et al[20]	320	97.8% vs 94.2%	12	100%	0	0	0	201 prim 139 adj	139 adj vs 97.8%	97.4% vs 97.8% 0%–3.4%	0%–2.2% vs 1.5%–19.4	0.5%–18.2%	—

Adj, adjunct; Anast, anastomotic site; AO, aorto-ostial; ELCA, excimer laser coronary angioplasty; F/U, follow-up; GB, graft body; Prim, primary; Pts, patients; PTCA, percutaneous transluminal coronary angioplasty.

improve significantly, with reported restenosis rates greater than 50%. First-generation laser catheters used an argon laser and bare fibers that produced enormous vascular trauma. Subsequent development of metal-tipped multifiber catheters and pulsed excimer laser systems has not only improved acute outcomes, but has also contributed significantly to its safety and success. The ELCA investigators found that in over 3000 interventions (16% vein graft), vessel perforation occurred in 1.6% of earlier cases but only in 0.6% during the later experience.[17] The percutaneous excimer laser coronary angioplasty (PELCA) registry (Spectranetics) demonstrated a 1.6% rate of minor perforation in approximately 550 vein grafts treated successfully with balloon occlusion without any serious consequences.[18] In both series, significant CK elevation occurred in 4%–5% of patients, which is comparable to stand-alone angioplasty.

Understanding the explosive interaction of laser energy with local vessel media, responsible for acute complications, has led to innovations with potential to reduce acute procedural risk. Displacement of blood and contrast by use of saline flush not only limits undesirable acoustic trauma to vascular tissue but also preserves the ability to deliver ablative energy to obstructive vascular tissue.[19] In addition, reduction of the diffuse intimal trauma may influence subsequent neointimal response to intervention. ELCA has been found to be safe and highly successful in treatment of complex lesions (eg, aorto-ostial lesions, diffuse disease, and chronic total occlusions).[18,20] The Spectranetics Laser Registry showed comparable procedural success and complication rates for complex lesions.[18] Favorable graft characteristics are ostial lesions and small vein grafts, whereas aorto-ostial and graft body lesions, diffusely diseased grafts, and chronic total occlusions are more prone to restenosis. Numerous studies have demonstrated failure to improve restenosis rates despite successful ELCA. A meta-analysis of more than 1500 vein graft interventions revealed restenosis rates of 51%–58%. Also, MACE remained consistent for target lesion revascularization (18%–29.2%), MI (1.5%–2.6%), and death (7.4%–8.6%). When comparing case matched studies of stand-alone balloon angioplasty no significant differences in MACE were observed.[15,20–22]

Stent placement is now the treatment of choice for non-degenerated vein graft lesions. Subsequent application of stents for vein graft disease (the SAVED trial) demonstrated high procedural success rates (92% vs 69%, $P < .001$), enhanced acute decrease in final diameter stenosis (12% vs 32%, $P < .001$), significant reduction in 6-month MACE (26% vs 39%), but restenosis rates remained unchanged.[23] However, subsequent observational studies suggest improved restenosis rates of about

Table 2
Review of the Literature on Self-Expanding Stents

Year	Author	No of Patients	Stents	F/U (mo)	Graft Anatomy			Graft Disease		Success Rates	Early Complication Rates	Late Complication Rates	Restenosis Rates
					AO	GB	Anast	T/O	SS				
1989	Urban et al[37]	13	14	7	1	13	0	0	14	95%	7%–14%	11.5%	29%
1992	De Scheerder et al[34]	69	136	6	7	127	4	5	64	100%	3%–33%	4%–49%	47%
1992	Strauss et al[38]	145	—	20	—	—	—	—	—	—	7%–9%	30%–37%	39%
1994	Nordrehaug et al[39]	19	—	7	19	—	—	—	19	100%	10%–16%	7%–43%	16%
1994	Dorros et al[40]	96	101	7 days	49%	36%	15%	—	—	98%	3%–23%	—	1%
1994	Eeckhout et al[41]	40	56	42	1	38	1	—	—	—	2%–14%	7%–21%	33%
1997	Kelly et al[42]	26	—	18.8	0	26	0	7	19	100%	3.8%–7.7%	5%–31%	—
2002	Konig et al[36]	34 (11 SVG)	52	6.5	—	—	—	—	—	100%	—	—	No difference vs.age-matched PS stents

Anast, anastomotic site; AO, aorto-ostial; F/U, follow-up; GB, graft body; PS, polystyrene; SS, severe stenosis; T/O, total occlusion.

22%.[22,24] Various treatment modalities used for vein grafts are tabulated in Table 1.

Stents have improved long-term outcomes associated with vein graft disease. However, the problem of acute procedural complications (ie, distal embolization) has not been solved. Other stent platforms have been employed to address this problem, including covered and self-expanding stents. Poly-tetrafluoro ethylene (PTFE)-covered stents have the potential of trapping debris that might otherwise dislodge and embolize; however, results of one trial reveal no distinct advantage in reduction of distal embolization or restenosis.[33] In addition, self-expanding wall stents failed to show any reduction in distal embolization (7%–8%) when high pressure predilatation was performed.[15] When predilatation was limited there was a trend toward decreased incidence of distal embolization (3%), but acute thrombosis was problematic (10%) and restenosis (47%) was high; however, there was a large proportion of complex lesions in relatively small grafts.[35] In larger grafts, thrombosis and restenosis appears to be less problematic (0% and 20%, respectively).[17] Subsequently, attempts to oversize and postdilate wall stents in native coronaries and vein grafts were examined but did not influence late lumen losses due to enhanced neointima formation from postdilatation barotrauma despite continued stent expansion.[36] When compared to age-matched patients with Palmaz-Schatz stents, self-expanding wall stents showed no difference in luminal net gains (1.63 ± 1.11 mm vs 1.44 ± 0.63 mm) or loss index (0.38 ± 0.42 vs 0.36 ± 0.23). Table 2 reviews various studies using self-expanding stents.

Nitinol provides a unique self-expanding platform with protracted radial expansion that has beneficial effects on neointimal composition and restenosis. Histologic comparison of balloon-expandable and nitinol stents in porcine models revealed similar rates of neointimal smooth muscle proliferation at 7, 14, and 28 days, but due to continued radial expansion, nitinol stent cross-sectional area enlarged by 18% despite an increase in neointimal proliferation.[43] The enhanced neointimal volume is thought to be due to an increase in extracellular matrix protein that may regress over time.[44] Recent studies have shown similar angiographic success with the nitinol stent compared to balloon-expandable stents. Six-month intravascular ultrasound follow-up demonstrated as much as 21.4% gains in stent cross-sectional area, whereas balloon-expandable stents suffered losses of up to 8.1%. However, the improvement in lumen cross-sectional area in the nitinol groups was slightly limited due to excessive neointimal formation. However, these losses occurred early and remained stable over time. Restenosis rates were low (17%–23.5%) and comparable to balloon-expandable stents.[45,46] The potential advantages include lower pressure or no postdeployment balloon inflations, prolonged radial expansion, better contouring, and modified

neointimal composition. Clinical experience in native coronary arteries has established these stents as safe and effective with comparable long-term outcomes.

Conclusion

In this case, we have demonstrated a successful, safe, and effective application of ELCA followed by self-expanding nitinol stent deployment as a potential treatment for symptomatic, degenerated vein graft disease. Laser angioplasty enjoys high rates of procedural success and, more importantly, angiographic success when combined with adjunctive balloon and/or stent. Early experience was discouraged by frequent coronary vascular complications but advances in catheter design, laser pulse energy, and technique have largely overcome this problem, although the high incidence of restenosis has been unchanged. When obstructive atheroma and clot are ablated it is expected that stents will track better, deploy more successfully, and improve acute outcomes. Therefore, employing laser angioplasty to debulk prior to self-expanding stent deployment in saphenous vein grafts may have significant advantages with improved long-term angiographic and clinical outcomes. Larger-scale trials are warranted to evaluate the use, safety, and efficacy of the self-expandable nitinol stents with or without adjunctive therapy in the saphenous vein graft disease. ■

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Main Points

- Among survivors who present with ischemic symptoms, more than 85% will be found to have a vein graft as the culprit vessel.
- Therapy of symptomatic patients after bypass surgery is problematic because repeat CABG not only is technically more challenging and carries increased morbidity and mortality, but also is less likely to provide symptomatic relief.
- Nitinol provides a unique self-expanding platform with protracted radial expansion that has beneficial effects on neointimal composition and restenosis.
- Employing laser angioplasty to debulk prior to self-expanding stent deployment in saphenous vein grafts may have significant advantages with improved long-term angiographic and clinical outcomes.

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