Scoreflex® NC Scoring PTCA Catheter: The New Kid On The Block In Focused Force Angioplasty

Gautam Kumar MBBS, MRCP(UK), FASE, FACC, FSCAI, Associate Professor of Medicine
Rajesh Sachdeva MD, FACC, FSCAI, Professor of Medicine, Emory University / Atlanta VA Medical Center Division of Cardiology

INTRODUCTION

Following the initial description of balloon angioplasty for coronary artery stenosis by Dr Gruentzig, in the last 30 years, there has been an explosion in devices and techniques available to interventional cardiologists to treat coronary stenoses[1]. However, there is a subset of coronary stenosis which have remained resistant to plain old balloon angioplasty (POBA), leading to the development of complex plaque modification techniques involving specialty balloons and atherectomy (Table 1).

In its simplest form, focused force balloon angioplasty (FFA) can be accomplished with a "buddy wire" placed alongside a balloon which is inflated across a resistant lesion[2,3]. FFA has been shown to achieve increased longitudinal dilation force at a lower stenosis resolution pressure and thus minimize vessel dissection, recoil and subsequent restenosis.

With the increase in "complex PCI" procedures and newly approved devices such as the Scoreflex® NC catheter, there is a need to be familiar with these techniques[4].

Table 1

PLAQUE MODIFICATION	
Specialty Balloons	Atherectomy
Scoring	Rotational
Cutting	Laser
Chocolate	Orbital
Lithotripsy	

CASE PRESENTATION

A 68-year-old man presented with progressive exertional angina which is now Canadian Cardiovascular Society (CCS) Class 3 severity. He has multiple cardiovascular risk factors including diabetes mellitus, hypertension and hyperlipidemia and had coronary artery bypass surgery 4 years ago with LIMA-LAD, SVG-OM and SVG-RPDA. He had recurrent angina 2 years ago after bypass surgery and coronary angiography at that time revealed atretic LIMA. At the same time, distal LAD 80% stenosis had non-ischemic iFR (0.91) and FFR (0.81). Medical management was optimized. At that time, he was able to achieve 4.6 MET on the treadmill with right knee pain limiting exercise.

Scoreflex NC Scoring PTCA Catheter

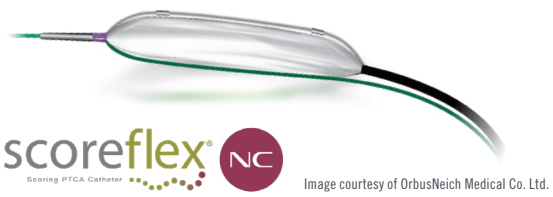


Image courtesy of OrbusNeich Medical Co. Ltd.

With this new presentation, the referring cardiologist elected to perform a pharmacological nuclear SPECT with Tc-99 revealing a 20% anterior and apical reversible defect. Patient was referred for coronary angiography and this revealed patent SVGs with 80% tandem lesions in the moderately calcified distal LAD (Figures 1 and 2). Functional assessment of the distal LAD revealed iFR of 0.71. Based on this, we elected to proceed with percutaneous coronary intervention of the distal LAD.

The proximal portion of the distal LAD was predilated with a 2.5 x 20 mm Scoreflex NC catheter at 12 atm x 20 s and then a 2.0 x 15 mm Scoreflex NC catheter was advanced into the more distal portion and inflated at 10 atm x 20 s (Figures 3 and 4). Although we had no difficulty in advancing the Scoreflex NC balloon into the distal vessel, we were unable to advance a stent and had to use an adjunctive 5 Fr GuideLiner® catheter. We then deployed a 2.25 x 38 mm drug-eluting stent in the distal sub-segment of the distal LAD and then overlapped this in the more proximal sub-segment with a 2.75 x 15 mm drug-eluting stent (Figures 5 and 6). These stents were then post-dilated with 2.5 x 35 mm and 2.75 x 12 mm balloons at 18 atm. Excellent final angiographic results were obtained (Figures 7 and 8).

During a clinical follow-up at two years, the patient did not have any anginal symptoms on exertion and has increased his ability to walk further following knee surgery.

DISCUSSION

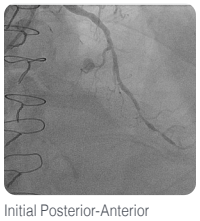
The Scoreflex NC scoring angioplasty catheter* is designed with a short rapid-exchange tip distal to a non-compliant, high-pressure balloon and an integral wire outside of the balloon, such that the guidewire and the integral wire act as scoring elements during balloon inflation. The Scoreflex NC Scoring PTCA Catheter Study (clinicaltrials.gov identifier NCT03763747) was a prospective, single-arm, multicenter trial which enrolled 200 patients undergoing initial angioplasty using the Scoreflex NC balloon catheter as part of clinically indicated percutaneous coronary intervention procedure. For an Investigation Device Exemption (IDE) trial, this study[4] enrolled a large percentage of complex lesions including true bifurcations (20%), moderate/severe calcification (36.6%) and Type B2/C ACC/AHA lesions (45.5%). The study primary endpoints[4] were (1) procedural success was achieved in 93.5% of patients, (2) the rate of successful device delivery was 95.5% with attainment of a final diameter stenosis ≤50% in 98.5% of cases, (3) no unanticipated device related events were observed and (4) in-hospital adverse events were infrequent and principally related to periprocedural MI without clinical sequelae.

The case discussed here is an example of a complex lesion that was treated during the course of this clinical trial with at least moderately calcified severe diffuse disease in a relatively small caliber distal LAD. There was no difficulty in crossing the lesion with the Scoreflex NC catheter, which is extremely deliverable in complex anatomy even via radial access. In addition, it is noteworthy that we were able to perform relatively low-pressure inflations to minimize barotrauma and yet successfully deliver and expand the drug-eluting stent.

CONCLUSION

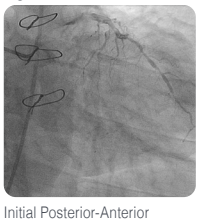
The Scoreflex NC coronary PTCA scoring catheter is an essential addition to the complex PCI armamentarium.

Figure 1



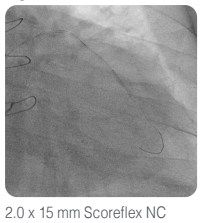
Initial Posterior-Anterior Cranial view of the distal LAD.

Figure 2



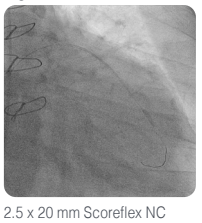
Initial Posterior-Anterior Caudal view of the distal LAD.

Figure 3



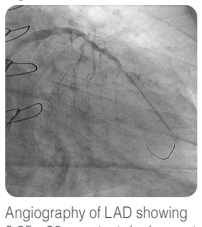
2.0 x 15 mm Scoreflex NC catheter inflated in distal sub-segment of distal LAD.

Figure 4



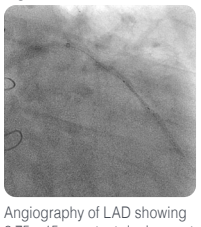
2.5 x 20 mm Scoreflex NC catheter inflated in proximal sub-segment of distal LAD.

Figure 5



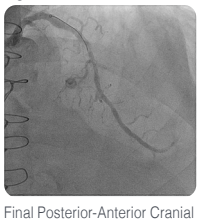
Angiography of LAD showing 2.25 x 38 mm stent deployment in distal sub-segment of distal LAD.

Figure 6



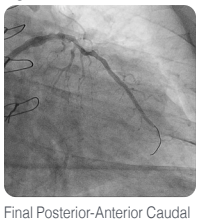
Angiography of LAD showing 2.75 x 15 mm stent deployment in proximal sub-segment of distal LAD.

Figure 7



Final Posterior-Anterior Cranial view of the distal LAD.

Figure 8



Final Posterior-Anterior Caudal view of the distal LAD.

REFERENCES:

1. Gruntzig AR, Senning A, Siegenthaler W. Nonoperative dilatation of coronary artery stenosis. Percutaneous transluminal coronary angioplasty. *N Engl J Med* 1979; 301: 61-8.
2. Yazdanfar S, Ledley GS, Alfieri A, Strauss C, Kotler MN. Parallel angioplasty dilatation catheter and guide wire: a new technique for the dilatation of calcified coronary arteries. *Catheter Cardiovasc Diagn* 1993; 28:72-5.
3. Stillabower ME. Longitudinal force focused coronary angioplasty: a technique for resistant lesions. *Catheter Cardiovasc Diagn* 1994; 32: 196-8.
4. Kandzari D, Hearne S, Kumar G, Sachdeva R, Adams G, Blossom B, Dahle T, Sanghvi K, Cohen MG, Imperi G, Riley R, Almonacid AP. Procedural effectiveness with a focused force scoring angioplasty catheter: Procedural and clinical outcomes from the Scoreflex NC trial. *Cardiovasc Revasc Med* 2021 Mar 20: S1553-8389(21)00147-0..

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*Scoreflex NC Scoring PTCA balloon is distributed by CSI and Manufactured by OrbusNeich Medical Company Limited.

INDICATIONS: The Scoreflex® NC Scoring PTCA Catheter is indicated for: Balloon dilatation of a de novo stenotic portion of a coronary artery and in-stent restenosis in coronary arteries in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS: The use of the Scoreflex NC Scoring PTCA Catheter is contraindicated in the following patient types: Patients with an unprotected left main coronary artery; Patients with coronary artery spasm in the absence of a significant stenosis.

WARNINGS: When using this type of device, the following warnings should be observed: This device is intended for single use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of cross-contamination. This balloon is not intended for the expansion or delivery of a stent. PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip or catheter breakage, catheter kink, or balloon separation. Do not twist the catheter shaft in excess of 180 degrees when the tip is constrained. Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Do not re-straighten a kinked hypotube; straightening a kinked metal shaft may result in breakage of the shaft. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication .

PRECAUTIONS: Use the catheter prior to the "Use By" date specified on the package. Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used. The catheter system should be used only by physicians trained in percutaneous transluminal coronary angioplasty. During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. After the procedure, anticoagulant therapy should be continued for a period of time as determined by the physician. Never advance the Scoreflex NC Scoring PTCA Catheter without the guidewire extending from the tip. Do not use oil-based contrast medium, organic solvents, or alcohols; there is a possibility of catheter leak, damage, or lubrication loss. The balloon deflation time has been established as 15 seconds based on in vitro bench testing results. Do not reinsert the PTCA catheter into the coil dispenser after procedural use. Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

CAUTION: Federal law (USA) restricts this device to the sale by or on the order of a physician.

See the instructions for use before performing Scoreflex NC Scoring PTCA Catheter procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events.