Cardiovascular Revascularization Medicine 35 (2022) 85–90

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Procedural Effectiveness With a Focused Force Scoring Angioplasty Catheter: Procedural and Clinical Outcomes From the Scoreflex NC Trial☆

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ARTICLE INFO

Article history:
Received 29 January 2021
Received in revised form 12 March 2021
Accepted 15 March 2021

Keywords:
Angioplasty
Percutaneous coronary intervention
Dilation
Scoring balloon

ABSTRACT

Background: 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 external scoring elements enable a focal stress pattern facilitating expansion of resistant lesions at lower pressures using a focused force angioplasty effect.

Methods: Patients undergoing elective percutaneous coronary intervention (PCI) were enrolled in a prospective, single-arm study conducted at 12 centers in the United States. The primary endpoint was device procedural success, defined as the composite of successful device delivery to the target lesion with balloon inflation and deflation; absence of vessel perforation, flow-limiting dissection or reduction in TIMI flow from baseline; and achievement of final TIMI 3 flow.

Results: Among 200 patients (234 lesions), lesion complexities included: bifurcation disease (37.6%), moderate/severe calcification (36.6%), and total occlusions (5.0%). Successful delivery to the target lesion, inflation and removal of the balloon catheter was achieved in 95.5% of patients (191/200). Procedural success was achieved in 93.5% (187/200) of patients, and final TIMI 3 flow was observed in 99.0% of cases (198/200). No unanticipated device-related events occurred. In-hospital major adverse events were reported in 4.5% of patients (9/200), related to periprocedural myocardial infarction (8/200, 4.0%) and target lesion revascularization (1/200, 0.5%).

Conclusions: Among patients undergoing elective PCI and with varied lesion complexity, these results support the safety and effectiveness of a dilation strategy using the Scoreflex NC scoring catheter.

1. Introduction

Despite significant advancements in interventional devices and techniques, the subset of dilatation-resistant lesions, such as *de novo* fibro-calcific and in-stent restenotic lesions, remains a common procedural challenge with clinical consequences. A fundamental approach to dilatation-resistant lesions involves plaque modification to permit stent delivery and optimal stent expansion and apposition. Non-compliant balloons are routinely used for lesion preparation because of their predictable and uniform dilatation diameters at higher inflation

☆ Clinicaltrials.gov identifier: NCT03763747.Study support: OrbusNeich Medical Trading, Inc., Fort Lauderdale, FL.

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https://doi.org/10.1016/j.carrev.2021.03.013
1553-8389/

pressure, maintaining a uniform radial force along the vessel wall irrespective of the inflation pressure [1–3]. Nevertheless, approximately 20% to 30% of stents are identified by intravascular imaging to be under-expanded or malapposed following deployment [4–6], a finding associated with higher rates of peri-procedural complications, restenosis and stent thrombosis [7–12].

To address the challenges specific to this complex lesion anatomy, the Scoreflex NC scoring angioplasty catheter (OrbusNeich Medical Trading, Inc., Fort Lauderdale, FL) 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 (Fig. 1). The external scoring elements enable a focal stress pattern facilitating expansion of resistant lesions at lower pressures using a focused force angioplasty effect. As a new catheter design representing technology different from existing approved catheters, we performed a registration trial to evaluate the procedural effectiveness of this device as part of a dilation strategy in percutaneous coronary revascularization.

2. Methods

2.1. Study overview

The Scoreflex NC Scoring PTCA Catheter Study (clinicaltrials.gov identifier NCT03763747) is a prospective, single-arm, multicenter trial designed to enroll a minimum of 200 patients undergoing initial dilation angioplasty using the Scoreflex NC balloon catheter as part of a clinically indicated percutaneous coronary intervention (PCI) procedure. Each patient was treated for a maximum of 2 lesions (with at least 1 target lesion) involving a *de novo* or restenotic narrowing with angiographic stenosis ≥70% (including chronic total occlusions) in a native coronary artery. Treatment of a non-target lesion, if any, must have fulfilled protocol-specified angiographic and clinical success criteria prior to target lesion treatment.

Decisions regarding balloon length, number of catheters and number of inflations were performed according to the investigators' discretion. Similarly, there were no protocol requirements regarding

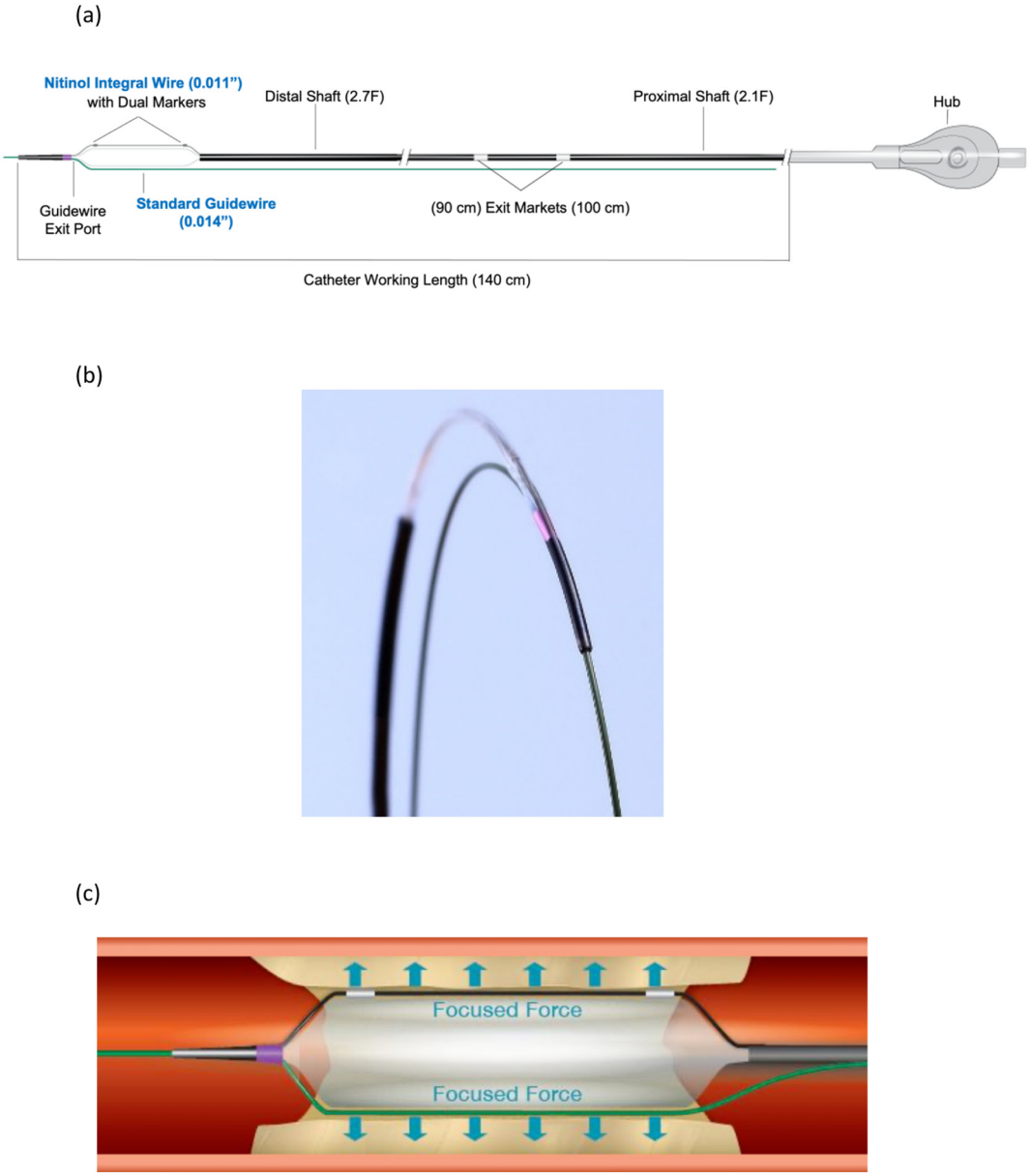

Fig. 1. The Scoreflex NC Scoring PTCA Catheter is a coronary dilatation catheter designed with a short rapid-exchange tip distal to the dilation balloon and an external integral wire on the outside of the balloon, such that the guidewire and the integral wire act as scoring elements external to the balloon when the balloon is inflated. (a) Schematic of catheter design, (b) image of the distal rapid-exchange catheter tip, and (c) illustration of focused force angioplasty effect with the scoring design.

subsequent dilation with larger diameter balloon catheters or stent selection. Treatment with additional device therapies (*e.g.*, atherectomy) was not permitted. Selection of antiplatelet and anticoagulation therapies was allowed according to operator preference.

Clinical and angiographic inclusion and exclusion criteria are detailed in the accompanying Supplement (Section A). Principal exclusion criteria were recent (<72 h) myocardial infarction (MI); left ventricular ejection fraction <30%; treatment of unprotected left main coronary disease; arterial or venous bypass graft disease; bifurcation disease requiring treatment with more than one stent or involving dilation of a side branch ≥2.0 mm diameter; or any general contraindication to the revascularization procedure and routine pharmacologic therapies. Target lesion(s) were required to have a reference vessel diameter between 1.75 and 4.0 mm by visual estimate. There were no restrictions regarding target lesion length. The study protocol was approved by the institutional review board at each enrolling center, and the study was conducted in accordance with the Declaration of Helsinki. All eligible patients signed written informed consent prior to the interventional procedure.

2.2. Device description

The Scoreflex NC Scoring PTCA Catheter is a coronary dilatation catheter designed with a short rapid-exchange tip distal to the dilation balloon and an external integral nitinol wire on the outside of the balloon, such that the guidewire and the integral wire act as scoring elements external to the balloon when the balloon is inflated (Fig. 1). Two radiopaque platinum/iridium marker bands are located on the scoring wire and aligned with the balloon shoulders to ensure accurate positioning of the balloon. The tip lumen is compatible with a standard 0.014 in. (0.36 mm) guidewire. The guidewire enters the catheter tip and advances coaxially out the rapid exchange port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guidewire. Scoreflex NC is available with balloon diameters 1.75 to 4.0 mm, balloon lengths of 10 to 20 mm and a catheter working length of 140 cm. The nominal and rated burst pressures are 12 and 20 atm upon inflation, respectively.

2.3. Study endpoints and definitions

Clinical events and procedural success were assessed per patient, and other device-specific outcomes were evaluated per lesion. The primary endpoint of this study was procedural success, defined as fulfilling all of the following with use of the study device: (1) successful device delivery to the target lesion; (2) successful inflation and deflation of the balloon; (3) absence of perforation, flow-limiting dissection (grade C or higher) or reduction in baseline Thrombolysis in Myocardial Infarction (TIMI) grade; and (4) final achievement of TIMI 3 flow. Secondary procedural-related endpoints included all individual components of the primary endpoint, achievement of final diameter stenosis ≤50% following completion of the interventional procedure and angiographic demonstration of improvement in minimal luminal diameter (MLD) after dilation with the scoring balloon catheter. The improvement in MLD was defined any measurable increase following treatment with the Scoreflex balloon compared with baseline, as determined by the independent angiographic core laboratory. Angiographic results were submitted to an independent core laboratory for review (Harvard Clinical Research Institute, Beth Israel Deaconess Medical Center, Boston, Massachusetts).

In-hospital clinical safety and efficacy endpoints included major adverse cardiac events (MACE; composite of all cause death, MI, and clinically-indicated target lesion revascularization by PCI or bypass surgery). Other secondary clinical endpoints include the individual components of the composite endpoint, stent thrombosis and clinically significant arrhythmias requiring intervention. Both MI and stent thrombosis were determined per Academic Research Consortium (ARC) definition criteria [13]. All clinical endpoints were adjudicated by an independent clinical events committee.

2.4. Statistical methods

The primary endpoint was assessed using descriptive statistics on the intention to treat (ITT) patient population with no hypothesis testing performed. Continuous variables are reported as means ± standard deviation (SD) and categorical variables as frequencies, percentages and two-sided exact 95% confidence interval (CI). The secondary endpoints were also evaluated in the ITT patient population using descriptive statistics. For binary clinical endpoints, frequencies, percentages and two-sided exact 95% CI were reported as appropriate. All analyses were performed with SAS version 9.42 and SAS Enterprise version 8.1 (SAS Institute, Cary, NC).

The authors had full access and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript as written.

3. Results

3.1. Angiographic and clinical characteristics

Between February 2019 and December 2019, 200 subjects undergoing PCI of 234 lesions with the Scoreflex NC catheter were enrolled at 12 centers in the United States (Supplement, Section B). The mean (±standard deviation) age was 67.3 ± 8.98 years, 23.0% were female, 44% had diabetes, 53% underwent previous coronary intervention and 30.5% had prior MI (Table 1). The majority (83.0%) of patients underwent attempted treatment of a single target lesion, and the left anterior descending artery was the most commonly treated vessel (43.9% of lesions). The average lesion length was 18.37 ± 12.93 mm, and nearly one-third of lesions exceeded 20 mm in length. The mean vessel diameter was 2.6 ± 0.45 mm. More than one-third of lesions involved bifurcation disease (37.6%), including 20% of lesions representing true bifurcations (Supplement, Section C), moderate/severe calcification (36.6%), and total occlusions and in-stent restenosis represented 5.0% and 9.5% of procedures, respectively.

3.2. Procedural and clinical outcomes

A total of 239 Scoreflex NC angioplasty catheters were used to treat 234 lesions. Successful use of the study balloon was demonstrated in 93.5% (187/200) of patients, with 2 (2/239, 0.8%) episodes of balloon rupture and no occurrence of catheter entrapment (Table 2). Among 7 cases of unsuccessful delivery of the study balloon, 5 cases involved inability to deliver to the target lesion, 1 case involved a chronic total occlusion that could not be crossed with any catheter, and 1 case was successfully crossed with a lower profile Scoreflex NC catheter but not the initial catheter used.

The primary endpoint of device procedural success—a composite of successful use of the study balloon, freedom from device-related injury and final post-procedural TIMI 3 flow—was achieved in 93.5% (187/200; 95% CI: 90.1 to 96.9) of subjects (Table 2). One coronary perforation event occurred related to guidewire manipulation (distal sidebranch guidewire perforation unrelated to balloon catheter or target lesion), and 3 cases of reduced TIMI flow from baseline following treatment with the study device were identified. No unanticipated device related events were reported. Final achievement of TIMI 3 flow was observed in 99.0% of cases (198/200).

Dilation with the study device was associated with a measurable improvement in the mean minimal luminal diameter (0.8 mm to 1.5 mm) and an approximate 40% reduction in diameter stenosis, from a mean 67.9% to 40.7% after scoring balloon use. Average inflation pressure was 12.9 ± 4.0 (239) atmospheres (Table 2). Altogether, an increase in the MLD was observed in 91.2% of lesions, and attainment of a final

Table 1
Baseline clinical and angiographic characteristics.

Clinical characteristics, site reported	***N*** = 200 patients
Age (years)	67.3 ± 8.98 (200)
Male	77.0% (154/200)
Cigarette smoking (within 30 days)	18.5% (37/200)
Prior coronary interventions	66.0% (132/200)
Prior PCI	53.0% (106/200)
Prior CABG	13.0% (26/200)
Prior MI	30.5% (61/200)
Hypercholesterolemia (requiring treatment)	90.5% (181/200)
Diabetes mellitus	44.0% (88/200)
Insulin requiring	10.0% (20/200)
Hypertension requiring treatment	91.0% (182/200)
Number of coronary artery vessels requiring treatment during index procedure	
1	87.0% (174/200)
2	12.5% (25/200)
3	0.5% (1/200)
Current cardiac status	
Unstable angina	28.5% (57/200)
Stable angina	58.0% (116/200)
Silent ischemia	4.0% (8/200)
Other (asymptomatic, STEMI)	9.5% (19/200)
Lesion type	
De novo	90.5% (181/200)
Restenotic	9.5% (19/200)
Lesion classification B2/C[a]	45.5% (91/200)
Angiographic characteristics, core lab assessed	***N*** = 221 lesions
Reference vessel diameter (mean ± STD, mm)	2.6 ± 0.45 (221)
Diameter stenosis (%)	67.9% (221)
Minimal luminal diameter (mean ± STD, mm)	0.8 ± 0.40 (221)
Lesion length (mm)	18.37 ± 12.93 (221)
Vessel location	
LAD	43.9% (97/221)
LCX	24.9% (55/221)
RCA	30.8% (68/221)
Not identified	0.5% (1/221)
Lesion length (categorized)	
Discrete (<10 mm)	25.3% (56/221)
Tubular (10–20 mm)	43.0% (95/221)
Diffuse (>20 mm)	29.9% (66/221)
Not identified	1.8% (4/221)
Lesion location	
Ostial lesion	3.2% (7/221)
Proximal	44.3% (98/221)
Middle	42.1% (93/221)
Distal	10.4% (23/221)
Moderate/severe calcification	36.6% (81/221)
Moderate/severe tortuosity	3.2% (7/221)
Bifurcations, Medina type	
0,0,0	0.9% (2/221)
0,0,1	1.4% (3/221)
0,1,0	17.2% (38/221)
1,0,0	7.2% (16/221)
0,1,1	3.6% (8/221)
1,0,1	1.4% (3/221)
1,1,0	3.6% (8/221)
1,1,1	2.7% (6/221)
NA,NA,NA	62.0% (137/221)
Total occlusion	5.0% (11/221)
Baseline TIMI grade	
0/1	5.0% (11/221)
2	2.7% (6/221)
3	92.3% (204/221)

Data represented as percent (n/N) or mean ± standard deviation.
[a] For subjects with two lesions, the most severe ACC/AHA classification per lesion type is recorded by subject.

diameter stenosis ≤50% in at least one study device-treated lesion was achieved in 98.5% (197/200; 95% CI: 96.8 to 100.0) of subjects.

In-hospital events were uncommon with a MACE rate of 4.5% (9/200), related to periprocedural MI (8/200, 4.0%) and target lesion revascularization (1/200, 0.5%) (Table 3). No MACE events occurred in cases of procedural failure. There were no deaths, and no occurrence of stent thrombosis or arrhythmic events.

Table 2
Procedural characteristics and outcomes.

Procedure characteristics		N = 200 patients
Number of lesions treated		
1 lesion		83.0% (166/200)
2 lesions		17.0% (34/200)
Inflation pressure, (atm)[a]		12.9 ± 4.0 (239)
Number of inflations per lesion[a]		1.67 (239)
Balloon rupture[a]		0.8% (2/239)
Perforation[b]		0.4% (1/239)
Lesions treated with stent(s)[c]		93.6% (219/234)
Procedure duration (min)		47.6 ± 29.5 (200)
Procedural outcomes	**N = 221 lesions**	**N = 200 patients**
Device procedural success	N/A	93.5% (187/200)
Successful use of study balloon	95.4% (228/239[a])	95.5% (191/200)
Absence of vessel perforation, flow limiting dissection (grade C or higher), or reduction in TIMI flow from baseline as related to the study balloon.	98.5% (197/200)	98.0% (196/200)
Final TIMI flow grade of 3 at the conclusion of the PCI procedure.	99.1% (219/221)	99.0% (198/200)
Post-Scoreflex balloon minimal luminal diameter (mm)[d]	1.5 (221)	N/A
Post-Scoreflex balloon improvement in minimal luminal diameter[d]	91.2% (176/193)	91.0% (161/177)
Post-Scoreflex balloon diameter stenosis (%)[d]	40.7 (221)	N/A
Post-Scoreflex balloon TIMI 3 flow[d]	86.9% (192/221)	N/A
Lesion success	95.4% (228/239[a])	N/A

Data represented as percent (n/N) or mean ± standard deviation.
[a] Site reported data represented on the use of 239 devices.
[b] Related to guidewire manipulation (distal side branch guidewire perforation unrelated to balloon catheter or target lesion).
[c] Data represented on site reported treatment of 234 lesions.
[d] Reported acutely as per lesion analysis.

4. Discussion

The present study was designed to evaluate the acute safety and procedural success of the Scoreflex NC scoring angioplasty catheter as part of a dilation strategy in patients undergoing PCI. The salient findings are: (1) the primary endpoint of 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 peri-procedural MI without clinical sequelae. For an IDE trial, this study included a relatively high percentage of complex lesions (20% true bifurcations, 36.6% moderate/severe calcification and 45.5% modified ACC/AHA Type B2/C), and altogether, these results support the safety and effectiveness of a dilation strategy using the Scoreflex NC scoring catheter.

Table 3
In-hospital clinical events.

Event	N = 200 patients
Major adverse cardiac event	4.5% (9/200)
Death	0.0% (0/200)
Myocardial infarction	4.0% (8/200)
Non-Q-wave MI	4.0% (8/200)
Q-wave MI	0.0% (0/200)
Target lesion revascularization (clinically indicated TLR)	0.5% (1/200)
Stent thrombosis (ARC definite/probable) In-hospital stent thrombosis (ST) within the target vessel	0.0% (0/200)
Clinically significant arrhythmias (requiring intervention)	0.5% (1/200)

Data represented as percent (n/N).

Almost 30 years ago, early experience in the development of interventional practice noted that performance of balloon angioplasty adjacent to a guidewire advanced across calcified and resistant lesions was effective in facilitating vessel expansion [14–16]. This technique, recognized as a 'buddy wire' method [14], was formalized with the concept of focused force angioplasty using a dedicated balloon angioplasty system designed specifically with the guidewire and an external wire on the outside of the balloon to introduce high focal stresses along the luminal surface of the balloon [17]. The intent was to deliver a uniform pressure along the luminal surface of the balloon to expand the longitudinal planes along the lesion length and increase the overall lumen size, but at lower inflation pressure to mitigate vessel trauma [18]. In contemporary PCI, aside from lesion expansion alone, lesion preparation prior to stenting or drug-eluting balloon angioplasty may also be essential to maximize surface contact between the drug-delivery device and neointimal plaque and facilitate effective drug transfer to the vessel wall [19]. Indeed, effective lesion preparation is essential to drug-coated balloon efficacy [20], and preclinical studies confirm that moderate localized injury enhances antiproliferative drug delivery and tissue retention [18,19].

Results from the present study not only support the safety and effectiveness of the Scoreflex NC balloon catheter but are also consistent with prior reports with scoring balloon catheter designs. Among 181 patients undergoing dilation with a scoring balloon (FX MiniRail, X Technologies, Tustin, CA) and with varied lesion complexity, in-hospital MACE was 5.0%, related exclusively to periprocedural MI, and a residual stenosis <50% after the scoring balloon was achieved in 88.0% of cases [21]. Similarly, in a matched analysis comparing procedural, angiographic and clinical outcomes among patients with in-stent restenosis ($N = 116$) treated with scoring *versus* non-compliant balloon angioplasty, rates of in-hospital MACE were also similar to the current study [22]. In addition, both procedural acute gain and follow-up angiographic restenosis and target lesion revascularization significantly favored treatment with a scoring balloon.

Although not fully represented in this trial, utilization of a non-compliant, low-profile scoring angioplasty catheter may permit successful delivery, lesion crossing and dilation in challenging anatomy that includes chronic total occlusions, severely calcified stenoses and in-stent restenosis. Previous studies comparing scoring balloon *versus* conventional angioplasty have demonstrated the superiority of the former method in achieving greater stent and scaffold expansion [23–25]. In restenotic lesions, for example, cutting and scoring balloons may also limit balloon slippage [26], or alternatively mitigate plaque shift following dilation of bifurcation disease. Even in lower risk anatomy, initial dilation with scoring balloon angioplasty may permit more controlled arterial injury, thereby potentially limiting stent length and reducing complications. Although not compared in this study, lesion expansion at lower pressures may offer an equally effective alternative to very high pressure inflations with standard non-compliant balloons [27,28] or to atherectomy [29].

4.1. Limitations

As a single-arm trial, the study design does not permit comparison with alternative pre-dilation strategies that include use of cutting balloon angioplasty catheters, conventional non-compliant balloons or atherectomy techniques. Despite this limitation, use of a non-compliant yet flexible, low-profile scoring angioplasty catheter may permit successful delivery, lesion crossing and dilation in challenging anatomy when not feasible with other bulkier, rigid technologies. In addition, an important limitation of this study is that inclusion criteria were not limited to only highly complex coronary anatomy; therefore, the results do not fully describe the clinical utility of the device in a broader patient population or high-risk lesion subsets not represented in this trial. Similarly, considering the practical limitations of performing a trial limited to infrequent and often unexpected challenges of complex percutaneous revascularization, the study intentionally did not include lesions determined non-dilatable with more conventional methods. Although calcified lesions, chronic total occlusions and other lesion complexities were included in this study, most were of moderate severity and may have been amenable to conventional angioplasty. The study period was also limited to procedural and in-hospital outcomes, precluding any conclusions regarding later term safety and efficacy. Finally, as a pre-approval trial intended to demonstrate reasonable assurance of safety and effectiveness, the sample size limits any definitive conclusions regarding estimates for clinical endpoints (*e.g.*, death, MI, repeat revascularization).

5. Conclusion

To our knowledge, this study represents the largest systematic evaluation of procedural and early clinical outcomes among scoring balloon technologies. For patients undergoing percutaneous revascularization of coronary anatomy represented by characteristics that challenge deliverability and lesion crossing, initial dilation using a non-compliant scoring angioplasty catheter was associated with favorable procedural safety and efficacy. Specifically, the effectiveness of a strategy using this catheter was demonstrated by favorable deliverability and lesion crossing, achievement of luminal gain following dilation, and an absence of acute device-related complications with a high rate of procedural success.

CRediT authorship contribution statement

David Kandzari – Principal Investigator; Conceptualization, Methodology, Investigation, Formal Analysis, Writing – Original Draft, Supervision

Steven Hearne – Investigation, Writing – Review & Editing

Gautam Kumar - Investigation, Formal Analysis, Writing – Original Draft

Rajesh Sachdeva - Investigation, Writing – Review & Editing

George Adams - Investigation, Writing – Review & Editing

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Thom Dahle - Investigation, Writing – Review & Editing

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Mauricio G. Cohen - Investigation, Writing – Review & Editing

Gregory Imperi – Investigation

Robert Riley - Investigation, Writing – Review & Editing

Alexandra Popma Almonacid - Methodology, Data Curation, Formal Analysis, Supervision, Writing – Review & Editing

Declaration of competing interest

The following authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Kandzari reports institutional research/grant support from Abbott Vascular, Biotronik, Boston Scientific, Cardiovascular Systems, Inc., OrbusNeich, Medtronic and Ablative Solutions; and personal consulting honoraria from Cardiovascular Systems, Inc., Magenta Medical and Medtronic. Dr. Sanghvi reports institutional research/graft support from Boston Scientific, Cardiovascular system Inc., Recor Medical, Ablative solutions and personal consulting honoraria and royalty payments from Cordis Cardinal Health. Dr. Cohen reports personal consulting honoraria from Medtronic, Merit Medical, Terumo Medical, Astra Zeneca, Zoll, and Abiomed and ownership in Accumed Radial Systems. Dr. Almonacid reports institutional grants from Boston Scientific, Medtronic, Abbott Vascular, COOK, and Terumo. Drs. Hearne, Kumar, Sachdeva, Adams, Blossom, Dahle, Imperi and Riley declare no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgment

We thank Danielle Libersan, PhD, for editorial support. Study support provided by Orbus Neich Medical Trading Inc.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.carrev.2021.03.013.

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