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Original article

New scoring balloon to treat moderate-to-severe calcified coronary lesions. The first-in-man Naviscore study

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ABSTRACT

Introduction and objectives: Calcified coronary lesions are becoming more prevalent and remain therapeutically challenging. Although a variety of devices can be used in this setting, cutting balloons (CB) and scoring balloons (SB) are powerful and simple tools to treat calcified plaques vs more complex devices. However, there are some drawbacks: these are stiff and bulky balloons that, as a first device, complicate lesion crossing and navigability in the presence of tortuosity, thus making it extremely difficult to recross once the balloon has been inflated. The objective of this study was to evaluate the safety and efficacy profile of the new Naviscore SB designed to overcome these drawbacks.
Methods: The first-in-man Naviscore Registry is a multicenter, prospective trial that included 85 patients with moderate (34%) or severe (66%) de novo calcified coronary lesions located in the native arteries, with stable angina and an indication for percutaneous coronary intervention.
Results: Mean age was 71 ± 11 years, with a high prevalence of comorbidities. Used as the first device, the Naviscore was able to cross 76% of the lesions and was used in 98% of the cases effectively modifying the calcified plaque. Procedural success was achieved in 94% of cases. Basal stenosis of 81 ± 12% decreased to 33 ± 8.5% after Naviscore and to 7.5 ± 2.6% after stent implantation. There were no major adverse cardiovascular events during admission. Perforation, device entrapment or flow-limiting dissections did not occur—only type A/B dissections in 13%—which were fixed with stent implantation. Device performance was deemed superior to the usual SB or CB used by the participant centers.
Conclusions: The Naviscore SB is very effective crossing severely calcified lesions as the first device, with effective plaque modification, stent expansion and an excellent safety profile. The Naviscore improves the behavior of current CB and SB. Due to its simplicity of use and performance, the Naviscore can be the first-choice SB to treat significant calcified lesions.

Keywords: Calcified coronary lesions. Scoring balloon. Plaque modification.

Nuevo balón *scoring* para el tratamiento de lesiones coronarias con calcificación de moderada a grave. Primer estudio en humanos Naviscore

RESUMEN

Introducción y objetivos: Las lesiones coronarias calcificadas son cada vez más prevalentes y suponen un reto terapéutico. Aunque se pueden tratar con distintos dispositivos, los balones de corte (BC) y de *scoring* (BS) son herramientas potentes y de más fácil uso que otros dispositivos de mayor complejidad. Sin embargo, tienen un alto perfil de cruce, son rígidos y cuesta cruzar la lesión como primer dispositivo; navegan mal y es difícil recruzar cuando ya se ha dilatado el balón. El objetivo del estudio fue evaluar la eficacia y la seguridad del nuevo BS Naviscore, diseñado para soslayar estos inconvenientes.

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Métodos: El Registro Naviscore es un estudio por primera vez en humanos, multicéntrico y prospectivo, en 85 pacientes con lesiones coronarias *de novo* con calcificación moderada (34%) o grave (66%), localizadas en arterias nativas, con angina estable e indicación de angioplastia.
Resultados: La edad media fue de 71 ± 11 años y hubo una alta prevalencia de comorbilidad. Naviscore cruzó como primer dispositivo en el 76% de los casos y se empleó hasta en el 98% para dilatar la lesión. Se logró el éxito del procedimiento en el 94%. La estenosis basal pasó del 81 ± 12 al 33 ± 8,5% después de Naviscore y al 7,5 ± 2,6% después del *stent*. No se registraron eventos coronarios adversos durante la hospitalización. Tampoco hubo casos de perforación, atrapamiento del dispositivo ni disección limitante del flujo; solo disecciones tipo A/B en el 13%, resueltas tras el *stent*. El comportamiento de Naviscore se evaluó como superior al de los BC o BS habituales en los centros participantes.
Conclusiones: Naviscore tiene una alta capacidad de cruce de las lesiones como primer dispositivo, una gran eficacia en la modificación de la placa y un excelente perfil de seguridad. Por su facilidad de uso y eficacia, Naviscore podría considerarse como el BS de primera elección en el tratamiento de lesiones calcificadas complejas.

Palabras clave: Lesiones coronarias calcificadas. Balón *scoring*. Modificación de placa.

Abbreviations

CB: cutting balloon. **PCI:** percutaneous coronary intervention. **SB:** scoring balloon.

INTRODUCTION

Currently, the number of percutaneous coronary interventions (PCI) involving moderate-to-severe calcified plaques is increasing due to a progressively aging population and extending procedural indications into more comorbid patients. The presence of such calcification is extremely relevant as it is strongly associated with worse outcomes, specially by means of stent underexpansion, a potent predictor of stent thrombosis or in-stent restenosis.[1-3] Moreover, calcified plaques can make advancing the devices difficult and trigger stent deformation and entrapment, coronary artery dissection, or perforation.[1,4-6]. Currently, there is a growing interest in the assessment of plaque morphology and its modification prior to stent implantation, which has led to the development of multiple tools such as rotational atherectomy, lithotripsy, orbitational atherectomy, cutting balloons (CB) and scoring balloons (SB).[7-11] The latter are easy to use and aim to create a controlled fracture of calcium deposits and plaque dilatation to facilitate stenting.[12-14] However, despite their theoretical simplicity, these devices are bulky and stiff, making it difficult to cross the lesion at the first attempt, navigate the vessel, and recross the lesion once inflated. Therefore, there is a need for a more trackable and better-profiled SB to improve the uptake of these devices to treat calcified coronary artery disease.

The newly designed Naviscore SB (iVascular, Spain) seeks to address these drawbacks. Its structure is based on 125-µm thick nitinol laser cut filaments arranged in an axial pattern placed over a semi-compliant high-pressure balloon with a nominal pressure of 8 atm, a rated burst pressure of 20 atm, and a mean burst pressure of 26 atm (figure 1). A nylon compensation tube in the shaft helps to re-wrap during balloon deflation. The mechanical properties of nitinol tend to regain its original shape once the balloon has been deflated. The nylon compensation tube elongates once the balloon has been inflated and due to its elastic properties, it regains its original length when deflated (video 1 of the supplementary data). The 2 mechanisms produce a powerful re-wrapping of the entire system when the balloon has been deflated, regaining its original crossing profile, which allows for easy lesion recross and further dilatations as many times as required. Axial distribution of scoring elements provides a high push against calcified lesions. Nitinol elastic properties provide a better navigability through tortuous calcific vessels compared with rigid scoring elements, such as stainless steel. The durable hydrophilic coating of the Hydrax Plus catheter (iVascular, Spain) significantly reduces its coefficient of friction to 0.04 by increasing slip and navigability. Also, its axial design enables a far larger contact area with the vessel wall compared with other devices with spiral configuration of nitinol filaments such as the AngioSculpt catheter (Philips Healthcare, The Netherlands) (figure 2). In vitro testing (iVascular, Spain) was conducted to measure the crossing profile of different SBs using a non-contact laser meter where the profile is calculated through the shadow that has been created. This allows us to measure the profile without exerting any pressure on the device.[15] The Naviscore crossing profile is 5% lower than Angiosculpt, and 31% lower than Wolverine (Boston Scientific, United States). This catheter is available in a wide range of measures from 1.5 mm up to 3.5 mm in diameter and from 6.0 mm up to 15 mm in length, all of them compatible with a 6-Fr guiding catheter.

The present study aims to demonstrate the safety and efficacy profile associated with crossing and treating calcified coronary lesions with the Naviscore SB.

METHODS

The Naviscore first-in-man study is a multicentric and prospective registry that evaluated the device safety and efficacy profile in the treatment of calcified lesions in 85 patients from 10 centers (9 in Spain and 1 in Portugal), all from the Euro 4C Group, founded in 2018 and focused on the cardiac care of calcified and complex patients. All operators involved in this study were experts in the treatment of calcified coronary lesions and familiar with most tools designed to treat such lesions.

Inclusion criteria were the presence of de novo moderate-to-severe calcified lesions by angiographic criteria in the native coronary tree of patients with chronic coronary syndrome scheduled for a PCI due to symptom persistence despite optimal medical therapy and/or evidence of inducible ischemia. The only exclusion criterion was the presence of the patient's hemodynamic compromise.

The study was designed to assess the safety and efficacy profile of Naviscore in terms of delivery success when used as the first device to dilate the lesion, plaque modification capabilities, and

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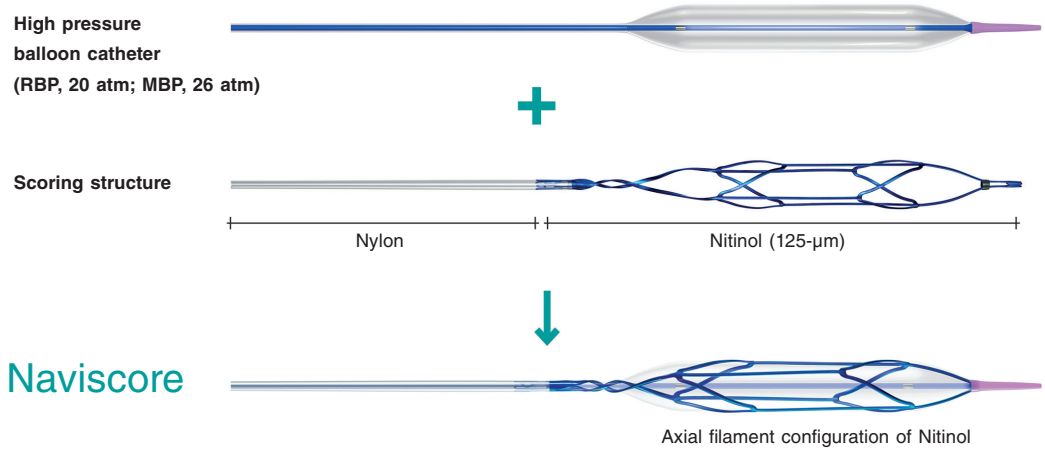

Figure 1. Structure of the Naviscore SB. MBP, mean burst pressure; RBP, rated burst pressure.

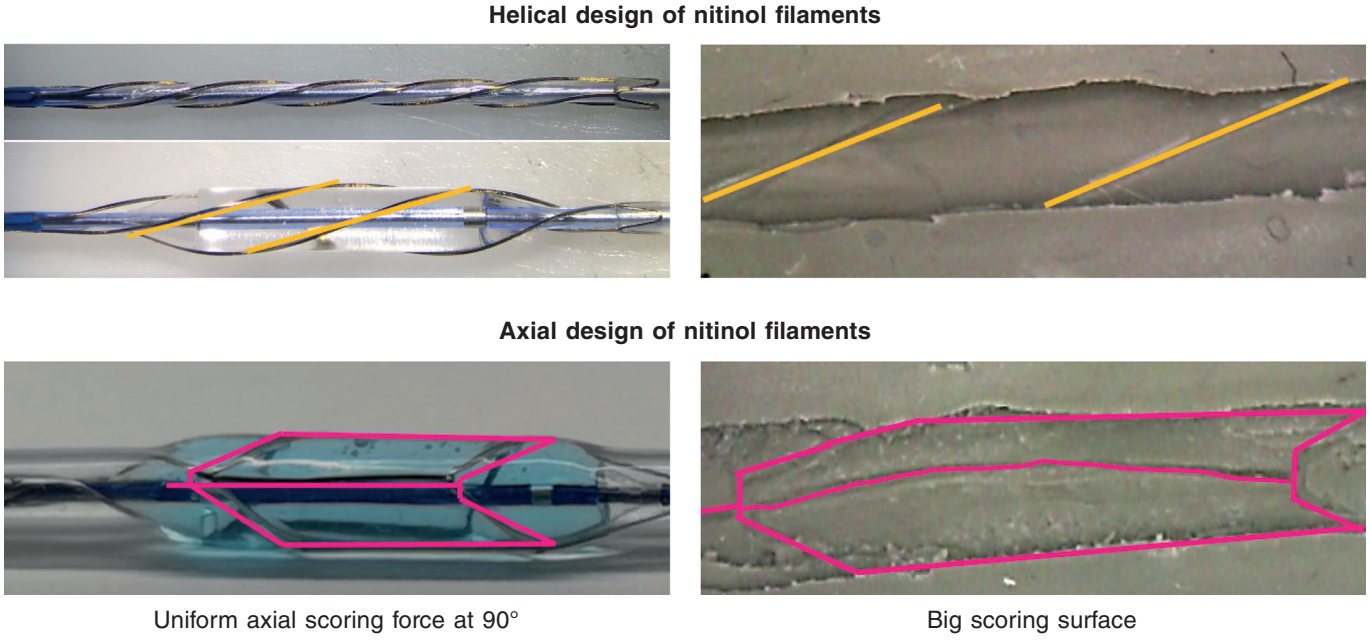

Figure 2. In vitro model assessment of the AngioSculpt scoring surface (upper image) vs the Naviscore (lower image). The Naviscore scoring surface is 6 times larger than that of the AngioSculpt.

complications. Consequently, operators were asked to use the Naviscore in all cases as the first device to cross and dilate the lesion. However, in cases of failed lesion crossing, dilatation with a small balloon was recommended with subsequent re-use of the same Naviscore catheter.

Operators involved in the study had little prior experience with the Naviscore in, at least, 3 cases and were asked to include, at least, 5 patients in the study. The operators assessed the performance of the catheter in each procedure in terms of pushability, navigability, crossing, deflation time, re-wrap, recrossing capabilities and ease of retrieval, and made a subjective comparison with their routinely used SB or CB.

The baseline clinical characteristics were recorded prior to the procedure and angiographical and optical coherence tomography (OCT) images were analyzed separately by 2 different operators. Coronary angiography was performed using, at least, 2 orthogonal projections to show stenosis as it is commonly used in the routine clinical practice. The view with the most severe stenosis was selected for the quantitative analysis of the lesion before and after the PCI. Lesion calcification was angiographically categorized as none/mild, moderate (radiopacities were only noted during the cardiac cycle movement prior to contrast injection) or severe (radiopacities noted without cardiac movement prior to contrast injection involving both sides of the arterial lumen).[16] Lesions were categorized as A, B1, B2 and C based on the modified ACC/AHA Task Force classification, which is in turn, based on the morphology and potential complexity of the PCI.[17] Procedural success was defined as an angiographically residual percent diameter stenosis < 30% after stent implantation, absence of major complications and final Thrombolysis in Myocardial Infarction (TIMI) grade-3 flow.[18] OCT analysis was performed as recommended in the routine clinical practice: lesion and proximal and distal references within 5 mm were used to estimate diameters and areas. Calcium cracks were defined as fissures involving a calcified region.[19,20]

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Table 1. Baseline clinical and angiographic characteristics

Clinical and angiographic characteristics (n = 85)	n (%)
Age, years	71 ± 11
Male	68 (80%)
Diabetes	37 (44%)
Dyslipidemia	59 (70%)
Hypertension	67 (75%)
Chronic kidney disease	15 (18%)
Current/former smokers	53 (62%)
Prior PCI/CABG	37 (43%)
Type B2/C lesions	74 (87%)
Severe calcification	56 (66%)
Moderate calcification	29 (34%)
Basal percent diameter stenosis	81 ± 12%
Chronic total occlusion	8 (10%)
Lesion location: Left main coronary artery	13 (15%)
LAD	35 (41%)
RCA	24 (28%)
LCx	13 (16%)

CABG, coronary artery bypass graft; LAD, left anterior descending coronary artery; LCx, left circumflex artery; PCI, percutaneous coronary intervention; RCA, right coronary artery.

Statistical analysis

Data are expressed as mean ± standard deviation for continuous variables with a normal distribution, median and interquartile range [IQR] for continuous variables with a non-Gaussian distribution, and counts and percentages for categorical data.

Statistical analyses were performed using the Stata software version 16.1 (College Station, TX, United States).

Ethical considerations

Informed consent was obtained from all the patients and the study was approved by the Research Ethics Committee. The authors declare that procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and the Declaration of Helsinki of the World Medical Association.

RESULTS

From November 2021 through February 2022, a total of 85 patients—80% males—with a mean age of 71 ± 11 years were included in the present study. One center included a total of 21 patients and the remaining 9, between 5 and 10 patients each. Baseline patient and lesion characteristics are shown in table 1. Regarding comorbidities, the prevalence of diabetes mellitus, dyslipidemia, hypertension, and chronic kidney disease was 44%, 70%, 75%, and 18% respectively. Prior revascularization was present in 43% of the patients (PCI in 38% and coronary artery bypass graft in 16%). The left anterior descending coronary artery was the most common location of target lesions (41%), followed by the right coronary artery (28%), left circumflex artery (16%) and left main coronary artery (15%). Most lesions (87%) were categorized as type B2/C, 66% were severely calcified and 34% had moderate calcification by angiographic assessment. Chronic total occlusion was reported in 10% of treated lesions. Reference vessel diameter was 3.0 ± 0.5 mm; mean lesion length, 20.3 ± 9.4 mm; and diameter stenosis, 81.4 ± 12%.

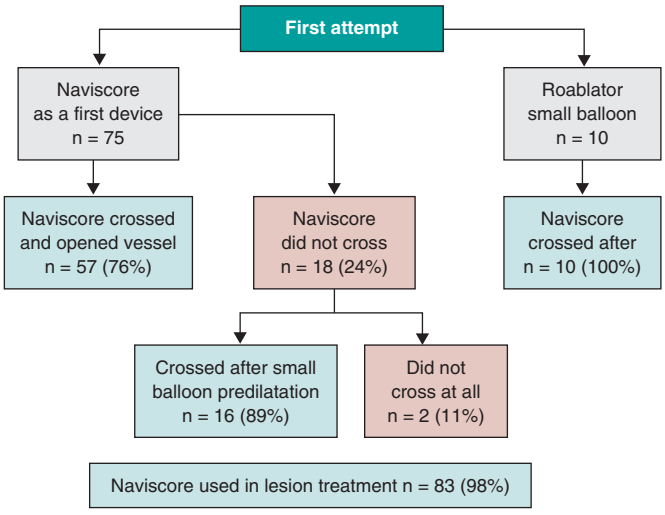

Figure 3. Crossing performance of the Naviscore.

The Naviscore catheter diameters used to dilate the lesions were 2.0 mm (21%), 2.5 mm (38%), 3.0 mm (31%), and 3.5 mm (10%). Mean number of device inflations was 2.7 ± 1.5 times.

The Naviscore crossing performance of is shown in figure 3. Despite the strong recommendation to use Naviscore as the first device, some operators decided to use Rotablator or small balloons first in 10 patients due to severely narrowed and/or calcified vessels. In all those cases, the Naviscore successfully crossed and dilated the lesion after the first attempt. In the 75 patients in whom the Naviscore was used as the first device, the lesions were crossed and treated successfully in 57 (76%) of them. In the remaining 18 (24%) patients, the Naviscore crossed the lesion after pre-dilatation with a small balloon in 16 (89%) patients. Only 2 patients had non-crossable lesions.

PCI results and in-hospital outcomes are shown in table 2. Procedural success was achieved in 94% of cases. The mean lesion percent diameter stenosis decreased from 81.4 ± 12% at baseline to 33.3 ± 8.5% after Naviscore dilatation, with a residual percent diameter stenosis of 7.5 ± 2.6% after stent implantation. There were no in-hospital major adverse cardiovascular events or any cases of perioperative perforation or device entrapment. Coronary dissections occurred in 13% of the cases (all of them type A or B) and resolved after stent implantation.

Ten procedures were OCT-guided. Pre-dilatation analysis could only be performed in 5 lesions; the OCT catheter could not cross the remaining lesions. Four of those had Fujino's scores[8] of 4 and in 2 of them the nodules protruded into the lumen. After dilatation, all lesions exhibited dissections that covered the intima and the media. Fractures were seen in all calcified plaques, which were deeper and wider in non-nodular calcified regions. Enlargement of lumen area after treatment with the Naviscore and correct stent apposition and expansion was observed in all imaging-guided cases (figure 4).

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Table 2. Angiographic and in-hospital results

Angiographic and in-hospital clinical results (n = 85)	n (%)
Procedural success: residual percent diameter stenosis < 30% after stenting, absence of major complications and TIMI grade-3 flow	80 (94%)
Percent diameter stenosis pre-Naviscore	81 ± 12%
Percent diameter stenosis post-Naviscore	33 ± 8.5%
Percent diameter stenosis post-stenting	7.5 ± 2.6%
MACE (in-hospital)	0%
Death, MI, emergency CABG	0%
Perforation	0%
Limiting flow dissection	0%
Type A or B dissection	11 (13%)
Device entrapment	0%

CABG, coronary artery bypass graft; MACE, major adverse cardiovascular events; MI, myocardial infarction; TIMI, Thrombolysis in Myocardial Infarction.

Table 3 shows the subjective performance of the Naviscore as evaluated by the operators of the present study. The Naviscore performance including push, navigability, crossing, deflation time, re-wrap, recrossing capabilities and ease of retrieval was deemed superior to the Wolverine, NSE Alpha (Nipro Co. Ltd., Japan), AngioSculpt, and Scoreflex (OrbusNeich, China).

DISCUSSION

Findings of this first-in-man registry with the new SB Naviscore in moderately to severely calcified coronary lesions performed in CHIP (complex and high-risk intervention in indicated patients) by highly experienced operators on this field can be summarized as follows: *a)* the Naviscore was able to cross the lesions as the first device in 3 out of 4 patients in such difficult scenario; *b)* this device proved to be effective to treat complex coronary lesions, with procedural success rates of 94%; *c)* the Naviscore was safe as no major dissection, perforation, or device entrapment were observed and *d)* the performance of the Naviscore SB was better compared with other commercially available SB and CB as subjectively assessed by the experienced operators in this study.

Calcified coronary lesions account for up to 30% of lesions scheduled for PCI and are associated with worse clinical outcomes.[1] Furthermore, these lesions are probably the most challenging ones for PCI operators. Thus, it is of paramount importance to develop specific devices for this scenario.[21-23] Although several plaque-modification techniques have appeared in recent years, there are not very many head-to-head comparisons, thus complicating the choice between them. In contrast, several treatment combinations and algorithms have been published.[24-27] Ablation techniques, such as rotational or orbital atherectomy, are especially indicated in uncrossable or undilatable lesions with balloon catheters. However, since there are more potential complications and a steeper learning curve associated with these therapies, developing new tools with a better crossing profile would be very positive in this scenario. The good crossability of the Naviscore SB showed in the present study is probably related to its unique nitinol structure in an axial configuration. CB such as the

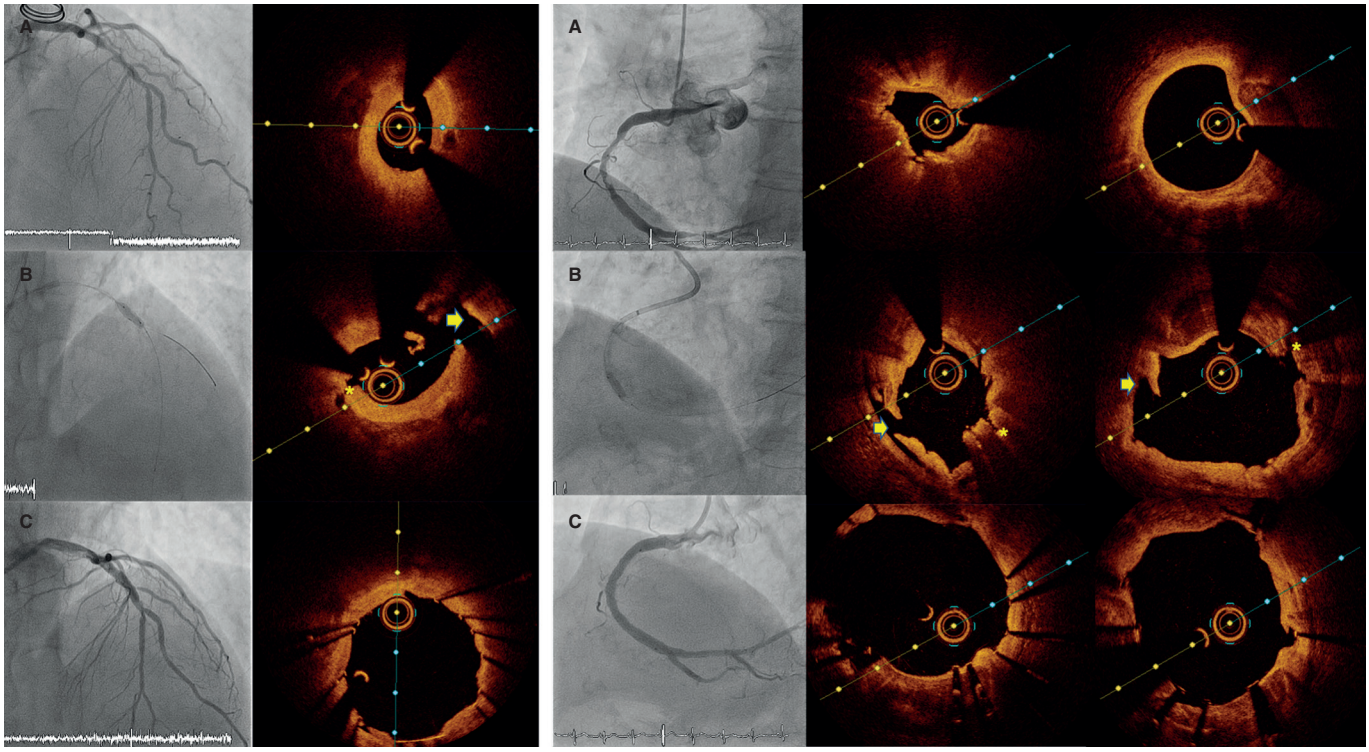

Figure 4. Clinical examples of 2 different lesions treated with the Naviscore. Angiography and baseline OCT (A) after dilatation with the Naviscore catheter (B) and post-stent implantation (C). On the left side, panel A shows a severely stenotic fibrocalcific plaque on the left anterior descending coronary artery that Naviscore (B) modifies creating calcium fractures (*) and dissection (arrow) resulting in stent implantation with good apposition and expansion (C). The right side shows a severely calcified plaque on the right coronary artery (A) with an arc of calcium of 180º at its proximal edge (lateral OCT picture) and 360º at its distal edge (central OCT picture) that the Naviscore modifies (B) creating calcium fractures (*) and dissection (arrow) resulting in stent implantation with good apposition and expansion (C). OCT, optical coherence tomography.

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Table 3. Subjective performance of the Naviscore compared with traditional and scoring or cutting balloons of participant centers. Push, capacity to cross the lesion, deflation time, rewrap and recrossing capabilities were the most valued characteristics of the Naviscore

Parameter	Push	Navigability	Crossing	Friction	Device visibility	Deflation time	Rewrap	Recrossing capability	Ease of retrieving	Global evaluation
Better	60%	54%	63%	52%	34%	65%	65%	69%	53%	78%
Equal	38%	46%	35%	46%	65%	34%	34%	29%	46%	21%
Worse	2%	0%	2%	2%	1%	1%	1%	2%	1%	1%

Wolverine or the NSE Alpha have a similar axial configuration of their cutting elements. However, the crossing profile of the Naviscore is 31% smaller than the CB. Although a comparative study on the crossing capabilities of those devices is not available, such a different profile favors the superior crossing capabilities of the Naviscore device. In fact, the operators of the present registry highlighted the ability to cross and recross lesions as one of the best features of the device compared with their usual CB or SB. Compared with the AngioSculpt—a SB that shares a nitinol structure with the Naviscore—the helical configuration of nitinol filaments in front of the axial alignment of the Naviscore nitinol filaments can make a difference. Axial alignment adds push to the device through the lesion, while the helical nitinol configuration can deform the structure under friction, thus reducing its navigability and, in some cases, cause device entrapment.[28] Furthermore, as shown in figure 2, helical distribution of nitinol significantly reduces the nitinol scoring surface in front of an axial distribution.

The efficacy of the Naviscore balloon has proven to be good in the present study, with a procedural success rate of 94%. Furthermore, quantitative angiographic analysis showed a reduction of basal stenosis from 81% to 31% after Naviscore dilatation and to 7.5 ± 2.6% after stent implantation. Finally, the OCT evaluation confirmed the presence of extensive calcium fractures caused by the scoring filaments (figure 4). As the balloon gradually inflates, the radial forces concentrate along the surface of the nitinol scoring elements, resulting in a more controlled balloon expansion, increasing the force of the nitinol frame filaments to break down the calcified plaques.[29] In vitro experiments comparing a simple SB (Scoreflex) with a conventional balloon catheter to dilate concentric tubes of calcium revealed that the inflation pressure required to break down the calcium tubes was consistently lower with SB. Finite element analysis revealed that the first main stress applied to the calcified plaque was, at least, 3-fold higher when inflating the balloon catheter with scoring elements.[30] Naviscore has the largest scoring surface in the SB current market, being 6 times more extensive than the AngioSculpt (figure 2). Pressure concentration of the scoring elements is the mechanism of the increased ability of SB to dilate calcified lesions and facilitate stent expansion. Residual stenosis after stent placement was 7.5 ± 2.6% in our study.

Finally, the Naviscore proved to be safe in the present study, which could be justified by the mechanism of action of the device that uses nitinol filaments as the anchor to avoid balloon slippage, and allows balloon controlled expansion, minimizing the risk of barotrauma, coronary dissection, and perforation. Using OCT imaging, SB broke down the calcified lesion without the undesirable dissection of noncalcified segments, thus allowing successful stent implantation with adequate expansion.[29,30]

Limitations

One limitation of the study is its own design as a registry and therefore, the absence of a randomized comparator. Instead, expert operators in the treatment of calcified coronary lesions were asked to subjectively compare the device at test with their commonly used SB or CB in terms of push, cross/recross, rewrap, navigability and time of deflation. The subjective nature of this assessment, while providing valuable information, could be a limitation.

Another limitation is the sample size of the study, especially the size of the population involved in the OCT imaging analysis. Unfortunately, in our setting, the use of this technique to analyze calcified lesions, although on the rise, is still far from what would be recommended. However, and despite the limitations in terms of number, the cases analyzed with intracoronary imaging homogeneously show us the effect of the device under study—calcium fractures, dissection and increase in luminal area—as well as the optimal stent expansion.

The small sample of patients in this study does not allow for a disaggregated analysis by sex to draw any valid results.

CONCLUSIONS

The Naviscore SB is a step ahead in this field with an innovative design using a nitinol frame with axial distribution of filaments placed over a high-pressure balloon to improve current SB or CB designs. This provides a strong pushing capability and flexibility to cross the most difficult calcified lesions in 3 out of 4 patients and easily navigate through tortuous anatomy. Superior scoring surface provides strong plaque modification capabilities by facilitating calcium fractures and controlled dissections, and ultimately, optimal stent expansion. Uniform and controlled balloon expansion and the anchor effect provided by the nitinol frame minimizes the risk of uncontrolled dissections and distal embolization, thus providing an outstanding safety profile, confirmed in this study by the absence of major adverse cardiovascular events, device entrapment or flow-limiting dissections. Therefore, the Naviscore can be considered as the front-line SB, either alone or in combination with atheroablative techniques in the treatment of moderate-to-severe calcified lesions.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M24000484.

FUNDING

This study was partly funded by iVascular, Barcelona, Spain, who provided the devices to perform the study.

ETHICAL CONSIDERATIONS

Informed consent was obtained from all patients and the study was approved by the Research Ethics Committee. The authors declare

that the procedures were followed in full compliance with the regulations set forth by the Clinical Research and Ethics Committee and Declaration of Helsinki of the World Medical Association. In accordance with the regulations of the SAGER guidelines, the small sample of patients in this study does not allow for a disaggregated analysis by sex to draw any valid results.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence has been used in the development of this paper.

AUTHORS' CONTRIBUTIONS

A. Serra Peñaranda designed the protocol, database and study outline, participated in data collection, coordinated data analysis and interpretation, and drafted the article. E. Fernández Peregrina participated in data collection, data analysis and interpretation and drafted the article. M. Jiménez Kockar participated in data collection, data analysis and interpretation, and performed the statistical analysis. B. García del Blanco, S. Romani, J. Martín-Moreiras, E. Pinar Bermúdez, A. Rodrigues, S. Ojeda, N. Gonzalo López, A. Regueiro and A. Serrador Frutos participated in data collection and critically revised the manuscript. All authors gave their final approval to the last version for publication.

CONFLICTS OF INTEREST

S. Ojeda is an associate editor of *REC: Interventional Cardiology*. The journal's editorial procedure to ensure impartial handling of the manuscript has been followed. A. Serra Peñaranda and Ander Regueiro received consulting fees from iVascular, Barcelona, Spain. The remaining authors declared no conflicts of interest whatsoever.

WHAT IS KNOWN ABOUT THE TOPIC?

- Calcified coronary lesions are becoming more prevalent in the routine clinical practice and remain therapeutically challenging for interventional cardiologists.
- Careful plaque modification is mandatory prior to stent implantation to achieve optimal results after the PCI.
- Several techniques and devices have been developed in this regard such as rotational and orbital atherectomy, lithotripsy and modified balloons.
- CB and SB are simple devices that do not require a learning curve. However, their design is that of a bulky and stiff device, which complicates lesion crossing, regarding navigation through vessels with some tortuosity and lesion recrossing once dilated.

WHAT DOES THIS STUDY ADD?

- The new Naviscore SB design is highly effective in crossing severely narrowed and calcified coronary lesions at the first attempt and has powerful plaque modification capabilities, while keeping an excellent safety profile.
- This device is a significant improvement over other CB and SB devices currently available in the market and could be selected as the first-choice SB tool to treat moderate-to-severe calcified lesions.

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