

# Very high pressure dilatation for undilatable coronary lesions: indications and results with a new dedicated balloon

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## KEYWORDS

- calcific lesions
- coronary angioplasty
- drug-eluting stents
- non-compliant balloon
- percutaneous coronary intervention

## Abstract

**Aims:** Calcific coronary lesions impose a rigid obstacle to optimal balloon and stent expansion and the 20 to 30 atm limit that non-compliant (NC) balloons reach can be insufficient. The aim of our study was to evaluate the safety and efficacy of a new dedicated super high pressure NC balloon (OPN NC<sup>®</sup>; SIS Medical AG, Winterthur, Switzerland).

**Methods and results:** We retrospectively evaluated a consecutive series of 91 lesions in which conventional NC balloons at maximal pressure failed to achieve an adequate post-dilatation luminal gain and were therefore treated with an OPN NC balloon up to 40 atm. Angiographic success was defined as residual angiographic diameter stenosis <30%. MLD and %DS were measured at baseline, after NC balloon, OPN NC balloon and stent implantation. Angiographic success was achieved in 84 lesions (92.3%). All of the remaining lesions received rotational atherectomy with the exception of two cases in which rotational atherectomy was not attempted because of small vessel size and excessive tortuosity. MLD and acute gain were significantly greater and % DS was significantly lower post OPN NC balloon compared with conventional NC balloon inflation ( $p < 0.001$ ). No coronary perforations occurred. No acute or 30-day follow-up MACE was reported.

**Conclusions:** When conventional NC balloons fail, the new OPN NC dedicated high pressure balloon provides an effective and safe alternative strategy for the dilatation of resistant coronary lesions.

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## 54 Abbreviations

55	<b>ACT</b>	activating clotting time
56	<b>ATM</b>	atmosphere
57	<b>CABG</b>	coronary artery bypass graft
58	<b>CB</b>	cutting balloon
59	<b>DES</b>	drug-eluting stent
60	<b>DS</b>	diameter stenosis
61	<b>ISR</b>	in-stent restenosis
62	<b>IVUS</b>	intravascular ultrasound
63	<b>LVEF</b>	left ventricular ejection fraction
64	<b>MACE</b>	major adverse cardiovascular events
65	<b>MLD</b>	minimum lumen diameter
66	<b>MVD</b>	multivessel disease
67	<b>NC</b>	non-compliant
68	<b>OCT</b>	optical coherence tomography
69	<b>PCI</b>	percutaneous coronary intervention
70	<b>PTCA</b>	percutaneous transluminal coronary angioplasty
71	<b>QCA</b>	quantitative coronary angiography
72	<b>TIMI</b>	thrombolysis in myocardial infarction
73	<b>TVR</b>	target vessel revascularisation
74	<b>ZES</b>	zotarolimus-eluting stent

## 76 Background

77 Heavily resistant coronary lesions remain a challenge in interven-  
78 tional cardiology. Calcification or dense fibrosis of the vessel wall  
79 or thick neointimal hyperplasia can create a rigid obstacle to uni-  
80 form balloon expansion and optimal stent deployment that might  
81 result in an increased risk of in-stent restenosis (ISR) and stent  
82 thrombosis<sup>1</sup>.

83 Increasing the pressure beyond the recommended limits during  
84 dilatation of resistant lesions often accentuates non-uniform bal-  
85 loon expansion with the consequent overdilatation of the more  
86 compliant segments at the lesion edges (so-called “dog-boning”  
87 effect) leading to an increased risk of vessel damage<sup>2-4</sup>.

88 Conventional non-compliant (NC) balloons have more predicta-  
89 ble responses and more uniform dilatation than semi-compliant bal-  
90 loons, but even at pressures of 24-30 atm dog-boning also occurs.

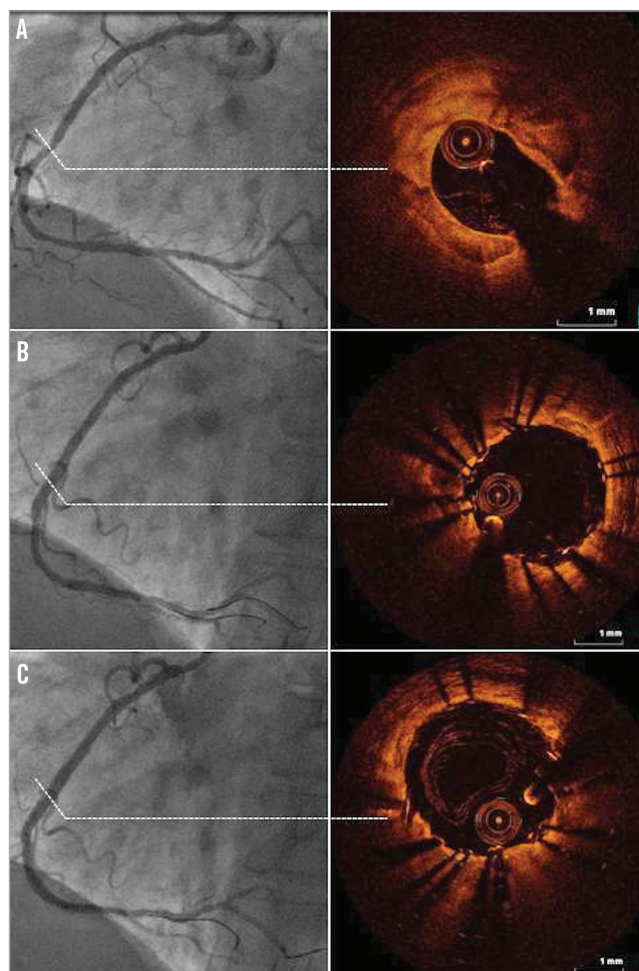
91 A variety of devices and technologies have been developed to  
92 overcome these limitations. Cutting balloons (CB), designed to  
93 concentrate the dilatation force along three or four blades, are often  
94 too bulky to cross truly undilatable lesions and they also may fail to  
95 expand at their maximal pressures. Above 16 atm the risk of rupture  
96 is quite high, and a ruptured CB might become difficult to reinsert  
97 into the guiding catheter. Scoring balloons have a lower profile and  
98 accept higher pressure but their efficacy is limited<sup>5-9</sup>. Modification  
99 of the vessel wall compliance using rotational atherectomy is cer-  
100 tainly the best option, but this technique requires specific exper-  
101 tise in handling a poorly steerable, uncoated 0.010 inch wire and  
102 advancing the burr. Excimer laser therapy has been described as an  
103 effective last resource in anecdotal cases but a laser is rarely avail-  
104 able and perforations are possible. The complexity and the cost of  
105 these devices, together with the increased risk of coronary perfora-  
106 tion, have hindered their widespread use<sup>10</sup>.

This registry tested the safety and efficacy of a dedicated, super high pressure non-compliant balloon (OPN NC<sup>®</sup>; SIS Medical AG, Winterthur, Switzerland) in a consecutive series of highly resistant coronary lesions.

## Methods

### LESION SELECTION

We evaluated 91 consecutive highly resistant coronary lesions in which conventional NC balloons failed to achieve an adequate post-dilatation luminal gain. After the failed attempt with the conventional NC balloon, the OPN NC balloon was inflated up to 40 atm (**Figure 1**). Other coronary lesions could be treated, when necessary. No exclusion criteria were applied. The OPN balloon is a CE

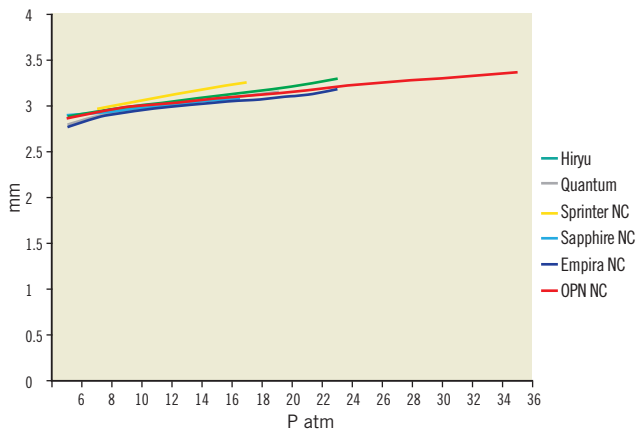


**Figure 1.** Angiographic and OCT images of a heavily calcified lesion pre-stenting (A), post 3.0×18 mm ZES implantation followed by an NC balloon inflated at 22 atm (B), and post-dilatation with a 3.0×15 mm OPN NC balloon inflated at 38 atm (C). Please note that the MLD increased to 2.92 mm (after the NC balloon dilatation) and to 3.18 mm (after the OPN NC dilatation). In the IVUS/OCT-guided PCI of the calcified lesion, we found calcium around the vessel contour accounting for at least >65% of the plaque, while OCT/IVUS imaging post-OPN NC dilatation shows diffuse vascular injuries following high pressure inflation but without a significant difference from the conventional NC balloon-treated lesions.

mark device. Patients signed informed consent for data treatment for scientific purposes, and the study was conducted according to the Declaration of Helsinki.

### THE OPN NC BALLOON DEVICE

The OPN NC super high pressure balloon (SIS Medical AG) is a rapid-exchange percutaneous transluminal coronary angioplasty (PTCA) catheter compatible with 0.014" coronary wires. The most distinctive feature of the OPN NC balloon is the presence of proprietary twin-layer balloon technology, which permits the use of very high pressure inflations and ensures uniform expansion over a wide range of pressures (**Figure 2**). The balloon is highly non-compliant with a nominal pressure of 10 atm and a rated burst pressure of 35 atm (**Table 1**). Each balloon is factory tested at 45 atm. The balloon diameters currently available cover a range from 1.5 mm up to 4.0 mm with ½ mm intervals. Lengths are 10, 15 and 20 mm. The commercial name OPN comes from an abbreviation of op(e)n.



**Figure 2.** Comparison between different NC balloons compliance 3.0 mm diameter: Hiryu™ (Terumo Medical, Tokyo, Japan), NC Quantum Apex™ (Boston Scientific, Marlborough, MA, USA), NC Sprinter® RX (Medtronic, Minneapolis, MN, USA), Sapphire NC™ (OrbusNeich, Wanchai, Hong Kong, China), Empira™ NC (Cordis, Johnson & Johnson, Warren, NJ, USA), OPN NC® (SIS Medical AG, Winterthur, Switzerland). Please note that the OPN NC balloon is the only commercially available NC PTCA balloon catheter with a satisfactory compliance up to 35 ATM.

**Table 1. OPN balloon compliance chart.**

PRESSURE (ATM)	OPN NC 2.0	OPN NC 2.5	OPN NC 3.0	OPN NC 3.5	OPN NC 4.0
10	2.0	2.5	3.0	3.5	4.0
20	2.1	2.6	3.14	3.67	4.19
30	2.18	2.7	3.29	3.85	4.37
35	2.2	2.77	3.36	3.91	4.41

### INTERVENTIONAL PROCEDURE

PCI was routinely performed with standard techniques via the femoral or radial approach using 6 or 7 Fr guiding catheters. Patients

not preloaded with oral aspirin and/or clopidogrel received a loading dose of intravenous aspirin (500 mg) and clopidogrel (600 mg) or prasugrel (60 mg) as standard practice in our catheterisation laboratory. Intravenous heparin (70 UI/Kg body weight) was administered before the procedure with subsequent boluses aimed at achieving an activated clotting time (ACT) of between 250 and 300 sec. The use of GP IIb/IIIa inhibitors was minimised and left to the discretion of the operator. In all cases, lesion predilatation was performed with a low-profile normal balloon slightly undersized according to conventional angiographic criteria. In case of incomplete balloon expansion with visible indentation at inflation pressures close to the rated burst pressure the lesion was approached using a conventional NC balloon inflated at least at the rated burst pressure and often higher. If this step also failed to provide an adequate luminal gain because of residual underexpansion of the balloon, the OPN NC balloon (with the same diameter as the NC balloon) was inflated up to 40 atm. Finally, all lesions were treated with DES optimised by NC balloon inflation when needed. In case of stent underexpansion with residual stenosis >40% assessed by angiography, the OPN NC balloon (with the same diameter as the NC balloon used) was inflated up to 40 atm for stent optimisation.

### ANGIOGRAPHIC ANALYSIS

As is routine in our centre, standard image acquisition of the treated stenosis was performed using two or more angiographic projections after intracoronary nitroglycerine 100-200 mcg or isosorbide dinitrate 2-3 mg to provide maximum coronary dilation. We identified the projection where the lesion was best visualised and appeared more severe with no overlapping and minimal foreshortening. We filmed the lesion in this view during all balloon inflations and for final angiography. Quantitative coronary angiography (QCA) was performed using a computer-based QCA system (MEDIS, Leiden, The Netherlands) with the dye-filled guiding catheter used for calibration. MLD and %DS were measured at baseline, after conventional NC balloon dilatation, and after OPN NC balloon dilatation. The interpolated reference diameter was considered as reference segment diameter. Lesion length was defined as the distance from the proximal to the distal shoulder of the lesion. Acute gain after conventional NC balloon was defined as MLD (mm) post NC conventional balloon – baseline MLD (mm). Acute gain after OPN NC balloon was defined as MLD post OPN NC balloon (mm) – baseline MLD (mm). Incremental gain after OPN NC balloon was defined as MLD post NC OPN balloon (mm) – MLD post conventional NC balloon (mm).

### FOLLOW-UP

Clinical events were evaluated post-procedure, during hospitalisation and at 30-day follow-up.

### DEFINITIONS

Angiographic success was defined as the achievement of residual angiographic stenosis <30% assessed by visual estimation with TIMI 3 flow. Procedural success was defined as the achievement

160 of angiographic success without any MACE, defined as death,  
161 myocardial infarction and repeat revascularisation (coronary artery  
162 bypass graft [CABG] or percutaneous transluminal coronary angi-  
163 oplasty [PTCA]). Twelve-lead electrocardiograms were recorded  
164 before, immediately after the procedure and at hospital discharge.  
165 In-hospital MACE was defined as any MACE occurring during  
166 hospitalisation for the index procedure. Follow-up MACE was  
167 defined as myocardial infarction, death or target lesion revasculari-  
168 sation (any repeat PCI or CABG at the lesion site) occurring dur-  
169 ing the follow-up period. Postprocedural access site “bleeding” was  
170 defined according to TIMI criteria<sup>11</sup> and haematoma was defined as  
171 an arterial puncture site swelling >5 cm.

## 173 STATISTICAL ANALYSIS

174 Continuous variables were expressed as mean±standard devia-  
175 tion, while categorical variables were presented as numbers with  
176 percentage. Continuous variables were compared using the paired  
177 Student’s t-test. Categorical variables were compared using the chi-  
178 square test. A p-value <0.05 was considered statistically significant.

## 180 Results

181 Patients and lesion characteristics are shown in **Table 2** and  
182 **Table 3**, respectively. The average age was 69.4±9.5 years with  
183 a prevalence of male sex (80.2%) and standard distribution of risk  
184 factors (hypertension 82.4%, hypercholesterolaemia 69.2%, dia-  
185 betes 46.1%, previous or current smoking 65.9%). Out of the 91  
186 lesions, 54 were heavily calcified or fibrotic lesions (59.3%) in  
187 previously untreated vessels, and seven were ISR (7.7%) in which  
188 conventional NC balloons did not expand during predilatation. In  
189 the remaining 30 cases the OPN NC balloons were used after stent  
190 deployment for stent optimisation (33%). Procedural characteristics  
191 are shown in **Table 3**. Predilatation using a semi-compliant balloon  
192 was performed in all cases and was then followed by a successive

194 **Table 2. Baseline patient characteristics.**

Number of patients	91
Sex (male/female)	73/18 (80.2% 19.8%)
Age	69.4±9.5
<b>Risk factors</b>	
Hypertension	75 (82.4%)
Hypercholesterolaemia	63 (69.2%)
Smoking	60 (65.9%)
Family history	52 (57.1%)
Diabetes	42 (46.1%)
Prior MI	35 (38.4%)
Prior CABG	21 (23%)
Renal failure	19 (28.9%)
LVEF (%)	52.6±12.9
<b>Clinical presentation</b>	
Stable angina	76 (83.6%)
Unstable angina	11 (12%)
NSTEMI	4 (4.4%)
CABG: coronary artery bypass graft; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NSTEMI: non-ST elevation myocardial infarction	

**Table 3. Lesion and procedural characteristics.**

Number of treated lesions	91
<b>Vessel</b>	
Left main	2 (2.2%)
LAD	45 (49.4%)
LCX	15 (16.5%)
RCA	26 (28.6%)
SVG	3 (3.3%)
Multivessel disease	43 (47.2%)
<b>Lesion characteristics</b>	
Length (mm)	21±12
True bifurcation	38 (41.7%)
Ostium involved	12 (13.2%)
Calcific lesion	37 (40.6%)
CTO	17 (18.7%)
Optimisation after stenting	30 (33%)
ISR	7 (7.7%)
<b>Balloon</b>	
Number of NC balloon/lesion	128/91 (1.4)
Final NC balloon inflation (atm)	21.4±2.8
NC balloon mean diameter	2.6±0.6
Number of OPN NC balloon/lesion	91/91 (1.0)
Final OPN NC balloon inflation (atm)	37.2±2.7
OPN NC balloon mean diameter	2.8±0.4
Number of stent/lesion	124 (1.35)
IVUS guided	21 (23.1%)
OCT guided	10 (11%)
CTO: chronic total occlusion; ISR: in-stent restenosis; IVUS: intravascular ultrasound; LAD: left anterior descending artery; LCX: left circumflex artery; NC: non-compliant; OCT: optical coherence tomography. RCA: right coronary artery; SVG: saphenous vein graft	

dilatation using a conventional NC balloon, sized according to con-  
ventional angiographic criteria and inflated up to the rated burst  
pressure or slightly higher. A total of 128 NC balloons were used  
(1.4 per lesion). In all cases, the dilatation performed with the con-  
ventional NC balloon failed to achieve an adequate balloon expan-  
sion and luminal gain. After the failed attempt the OPN NC balloon  
with the same diameter as the conventional NC balloon was inflated  
up to 40 atm. A total of 91 OPN NC balloons were used (one per  
lesion). Angiographic success was achieved in 84 lesions (92.3%).  
In three severely calcified subocclusive stenoses (3.3%) the OPN  
NC balloon failed to cross, while in two cases, despite successful  
crossing, the OPN NC failed to achieve an adequate luminal gain  
(2.2%). All five lesions were finally successfully treated with rota-  
tional atherectomy (5.5%). The remaining two cases were undilat-  
able lesions in small and tortuous vessels for which both rotational  
atherectomy and excimer laser therapy were deemed unsafe (2.2%).  
GpIIb/IIIa inhibitors were used in six patients (6.6%).

## ANGIOGRAPHIC RESULTS

QCA analysis is shown in **Table 4**. Both MLD and acute gain  
were significantly greater and %DS was significantly lower post  
OPN NC balloon inflation compared with post plain NC balloon  
inflation (1.7±0.8 mm vs. 2.4±0.9 mm, p<0.001; 41.1±15.8%



**Table 4. QCA analysis.**

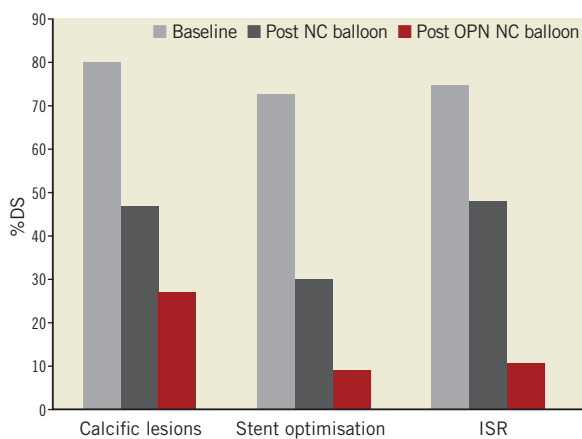
	Baseline	Post NC balloon	Post OPN NC balloon	p-value
RD (mm)	2.6±0.8	–	–	<0.001
MLD	0.7±0.3	1.7±0.8	2.4±0.9	
% DS	73.6±9.9	41.1±15.8	20.2±14.9	<0.001
Lesion length	11.9±6.4	–	–	<0.001
Acute gain (mm)	–	1.1±0.7	1.9±0.8	
Incremental gain (mm)	–	–	0.8±0.4	

DS: diameter stenosis; MLD: minimum lumen diameter; RD: reference diameter

vs. 20.2±14.9%,  $p<0.001$ ). These results were achieved with no increase in balloon size but with a higher inflation pressure (37.2±2.7 atm vs. 21.4±2.8 atm,  $p<0.001$ ) (**Figure 3**).

### PROCEDURAL AND CLINICAL OUTCOME

Angiographic and technical success with OPN NC balloons was achieved in 84 lesions (92.3%). In the remaining seven cases (7.7%), five lesions were successfully treated with rotational atherectomy (5.5%), while the remaining two cases were undilatable lesions for which both rotational atherectomy and excimer laser therapy were not attempted because of small vessel size and excessive tortuosity (2.2%). No coronary perforation or balloon rupture and ST change were reported after the procedure. No in-hospital or 30-day MACE was reported. No major postprocedural bleeding was reported. Haematoma of the access site occurred in five patients treated by the transfemoral approach (5.5%).



**Figure 3.** Decrease in % of diameter stenosis (DS) in calcific lesions (Group A), stent optimisation (Group B) and in-stent restenosis (ISR) (Group C). The incremental gain offered by the OPN NC balloon was sufficient to achieve angiographic success in all the three subgroups (0.81±0.47 mm in Group A; 0.77±0.41 mm in Group B; 1.34±0.31 mm in Group C).

### Discussion

In our registry we tested the safety and efficacy of the OPN NC super high pressure balloon in a consecutive series of truly heavily resistant coronary stenosis nonresponsive to plain NC balloon

dilatation. With the OPN NC balloon we were able to achieve a more than acceptable post-dilatation luminal gain in 92% of the cases without the need of additional expensive devices.

The mechanical properties of the arterial wall are critically dependent on the thickness, distribution and characteristics of the intimal plaque<sup>12</sup>. Thick neointimal hyperplasia and severe coronary calcification contribute to increase the hoop stress to the point that even high pressure non-compliant balloons might be insufficient to overcome the hoop stress and induct a satisfactory dilatation.

During dilatation of resistant coronary lesions, the non-uniform balloon expansion with the consequent overexpansion of the more compliant segment (the so-called “dog-boning” effect) may lead to an increased risk of vessel wall damage, including edge dissections and coronary perforation. A variety of devices and strategies have been developed to overcome this limitation. Cutting balloons have been designed to relieve the vessel hoop stress by creating controlled small incisions in the vessel wall and they present the practical advantage that they do not move during inflation due to the stabilising effect of the blades. Cutting balloons present several advantages for the treatment of severe calcified lesions, allowing a larger luminal gain at lower pressure compared to balloon angioplasty alone and preventing late recoil due to the incisions created by the blades<sup>7,13</sup>. The lack of clinical benefit observed in early studies of cutting balloon vs. conventional balloon angioplasty in *de novo* lesions has created scepticism on the potential mechanical usefulness offered by a focal concentration of force on the intimal plaque.

Mehran et al<sup>14</sup> showed that when treating in-stent restenosis with balloon angioplasty, luminal gain is achieved by a combination of additional stent expansion and neointimal tissue compression through the stent, resulting in a displacement through the stent struts and compression of neointimal tissue. Although satisfactory initial clinical and angiographic results were obtained with balloon angioplasty, a significant early lumen loss was also observed shortly after in-stent restenosis treatment due to recoil and re-intrusion of neointimal tissue in the lumen<sup>15</sup>. This early phenomenon possibly influences the long-term outcome after balloon angioplasty for in-stent restenosis, affected by a high re-restenosis rate<sup>16,17</sup>. Despite these findings, several randomised studies showed no real advantage of CB over PTCA with a conventional balloon and both the rigidity and the risk of balloon entrapment can limit their routine use during treatment of heavily calcified coronary lesions.

266 Modification of the vessel wall using rotational atherectomy and  
 267 excimer laser therapy improves vessel wall compliance, thus faci-  
 268 lilitating uniform stent expansion.

269 Excimer laser therapy is based on the principle of photoablation,  
 270 converting occlusive material into microbubbles which are imme-  
 271 diately dissolved in the blood<sup>18</sup>. Its successful use during treatment  
 272 of resistant coronary lesions has been described previously<sup>19</sup>.

273 Rotational atherectomy is a technique in which a small  
 274 grinder is inserted into the coronary arteries to ablate the plaque.  
 275 Specifically, it is effective in the treatment of calcified lesions  
 276 because of its differential cutting mechanism, a phenomenon by  
 277 which soft tissues (such as the normal arterial wall) are deflected  
 278 so that the grinder will not contact them during high-speed rota-  
 279 tion, while hard calcified plaques are not deflected and can be  
 280 ablated by the grinder<sup>20</sup>. Up-sizing the burr might enable bet-  
 281 ter lesion modification, resulting in greater stent expansion and  
 282 strut apposition. It is, however, unknown whether routine usage  
 283 of aggressive rotational atherectomy is superior to conventional  
 284 balloon dilatation as a means of lesion modification, followed  
 285 by DES implantation, because of the lack of systemic long-term  
 286 results of such a strategy<sup>21,22</sup>.

287 Despite the fact that the majority of resistant coronary lesions can  
 288 be treated with balloon dilatation and stent implantation alone<sup>23</sup>,  
 289 the rigid obstacle imposed by calcium or thick neointimal hyper-  
 290 plasia might prevent an optimal balloon expansion and symmet-  
 291 ric stent deployment, thus resulting in a gross malapposition of the  
 292 stent struts. The importance of this is indirectly confirmed by find-  
 293 ings from the e-Cypher registry correlating calcific lesions with  
 294 the future occurrence of stent thrombosis<sup>24</sup>. The real clinical con-  
 295 sequence of strut malapposition is still matter of debate but surely  
 296 it may impinge on the elution properties of DES, increase the acti-  
 297 vation of fibrin and platelets, and thus result in accelerated intimal  
 298 hyperplasia or stent thrombosis. Although the use of dedicated  
 299 techniques such as rotational atherectomy might certainly improve  
 300 procedural success in the treatment of resistant coronary lesions,  
 301 the complexity, the cost and the need of dedicated operators have  
 302 hindered their widespread application.

303 Conversely, the OPN NC super high pressure balloon is a plain  
 304 rapid exchange PTCA catheter which can be attempted easily in case  
 305 of the failure of conventional balloons<sup>25</sup>. Thanks to its twin-layer  
 306 technology, it allows the use of very high pressure inflations, ensur-  
 307 ing uniform expansion over a wide range of pressures and reducing  
 308 the risk of vessel damage<sup>26</sup>. In our registry we found a significant  
 309 increase of MLD and acute luminal gain after OPN NC balloon  
 310 dilatation compared with plain NC balloon inflation. Moreover, as  
 311 a consequence of the OPN NC's uniform expansion we had no ves-  
 312 sel rupture despite the use of very high pressure inflations.

313

### 314 Limitations

315 The main limitation of the OPN NC balloon is its high profile  
 316 which, together with the stiffness of the twin-layer technology, in  
 317 the vast majority of cases undermines any attempt to recross when  
 318 inflated. The balloon does not refold well, and after inflation it is

very difficult to use it again (for instance for both pre- and post-dil-  
 atation). An independent core lab and multiple observer QCA anal-  
 ysis would have improved reliability of data. Moreover, our results  
 come from a small sample, retrospective and non-randomised com-  
 parison which is certainly susceptible to selection bias.

## Conclusions

When conventional NC balloons fail, OPN NC super high pres-  
 sure balloons can provide an effective strategy for treatment of  
 severely calcified coronary lesions. Moreover, our data suggest that  
 the unique twin-layer technology offered by the OPN NC balloon  
 achieves uniform balloon expansion, reducing balloon rupture, ves-  
 sel damage and coronary perforation.

### Impact on daily practice

Heavy calcified coronary artery lesions impose a rigid obstacle  
 to optimal balloon expansion and symmetric stent deployment  
 resulting in an increased risk of in stent restenosis and thrombo-  
 sis. Surely, rotational atherectomy is the gold standard treatment  
 for calcific lesions but its use in daily practice is limited by the  
 cost and the need for dedicated operators. Conversely, the OPN  
 NC high pressure balloon is a plain rapid exchange PTCA cath-  
 eter which can be easily used in case of the failure of conventional  
 balloons, providing a safe and easy alternative strategy in case of  
 failure of conventional NC balloon dilatation.

## Conflict of interest statement

The authors have no conflicts of interest to declare.

## References

1. Fujii K, Carlier SG, Mintz GS, Yang YM, Moussa I, Weisz G, Dangas G, Mehran R, Lansky AJ, Kreps EM, Collins M, Stone GW, Moses JW, Leon MB. Stent underexpansion and residual reference segment stenosis are related to stent thrombosis after sirolimus-eluting stent implantation: an intravascular ultrasound study. *J Am Coll Cardiol.* 2005;45:995-8.
2. Hoffmann R, Mintz GS, Popma JJ, Satler LF, Kent KM, Pichard AD, Leon MB. Treatment of calcified coronary lesions with Palmaz-Schatz stents. An intravascular ultrasound study. *Eur Heart J.* 1998;19:1224-31.
3. Hoffmann R, Mintz GS, Kent KM, Pichard AD, Satler LF, Popma JJ, Hong MK, Laird JR, Leon MB. Comparative early and nine-month results of rotational atherectomy, stents, and the combination of both for calcified lesions in large coronary arteries. *Am J Cardiol.* 1998;81:552-7.
4. Raja Y, Routledge HC, Doshi SN. A noncompliant, high pressure balloon to manage undilatable coronary lesions. *Catheter Cardiovasc Interv.* 2010;75:1067-73.
5. Karvouni E, Stankovic G, Albiero R, Takagi T, Corvaja N, Vaghetti M, Di Mario C, Colombo A. Cutting balloon angioplasty for treatment of calcified coronary lesions. *Catheter Cardiovasc Interv.* 2001;54:473-81.

- 319 6. Fonseca A, Costa Jde R Jr, Abizaid A, Feres F, Abizaid AS,  
320 Costa R, Staico R, Mattos LA, Sousa AG, Grube E, Sousa JE.  
321 Intravascular ultrasound assessment of the novel AngioSculpt scor-  
322 ing balloon catheter for the treatment of complex coronary lesions.  
323 *J Invasive Cardiol.* 2008;20:21-7.
- 324 7. Secco GG, Foin N, Viceconte N, Borgia F, De Luca G, Di  
325 Mario C. Optical coherence tomography for guidance of treatment  
326 of in-stent restenosis with cutting balloons. *EuroIntervention.*  
327 2011;7:828-34.
- 328 8. Giugliano GR, Cox N, Popma J. Cutting balloon entrapment  
329 during treatment of in-stent restenosis: an unusual complication and  
330 its management. *J Invasive Cardiol.* 2005;17:168-70.
- 331 9. Sánchez-Recalde A, Galeote G, Martín-Reyes R, Moreno R.  
332 AngioSculpt PTCA balloon entrapment during dilatation of a heav-  
333 ily calcified lesion. *Rev Esp Cardiol.* 2008;61:1361-3.
- 334 10. Cohen BM, Weber VJ, Relsman M, Casale A, Dorros G.  
335 Coronary perforation complicating rotational ablation: the U.S.  
336 multicenter experience. *Cathet Cardiovasc Diagn.* 1996; suppl  
337 3:55-9.
- 338 11. Cannon CP, Battler A, Brindis RG, Cox JL, Ellis SG, Every NR,  
339 Flaherty JT, Harrington RA, Krumholz HM, Simoons ML, Van De  
340 Werf FJ, Weintraub WS, Mitchell KR, Morrison SL, Brindis RG,  
341 Anderson HV, Cannom DS, Chitwood WR, Cigarroa JE, Collins-  
342 Nakai RL, Ellis SG, Gibbons RJ, Grover FL, Heidenreich PA,  
343 Khandheria BK, Knoebel SB, Krumholz HL, Malenka DJ, Mark DB,  
344 McKay CR, Passamani ER, Radford MJ, Riner RN, Schwartz JB,  
345 Shaw RE, Shemin RJ, Van Fossen DB, Verrier ED, Watkins MW,  
346 Phoubandith DR, Furnelli T. American College of Cardiology key  
347 data elements and definitions for measuring the clinical management  
348 and outcomes of patients with acute coronary syndromes. A report of  
349 the American College of Cardiology Task Force on Clinical Data  
350 Standards (Acute Coronary Syndromes Writing Committee). *J Am  
351 Coll Cardiol.* 2001;38:2114-30.
- 352 12. Vito RP, Dixon SA. Blood vessel constitutive mod-  
353 els-1995-2002. *Annu Rev Biomed Eng.* 2003;5:413-39.
- 354 13. Lee MS, Singh V, Nero TJ, Wilentz JR. Cutting balloon angi-  
355 oplasty. *J Invasive Cardiol.* 2002;14:552-6.
- 356 14. Mehran R, Mintz GS, Popma JJ, Pichard AD, Satler LF,  
357 Kent KM, Griffin J, Leon MB. Mechanisms and results of balloon  
358 angioplasty for the treatment of in-stent restenosis. *Am J Cardiol.*  
359 1996;78:618-22.
- 360 15. Shiran A, Mintz GS, Waksman R, Mehran R, Abizaid A,  
361 Kent KM, Pichard AD, Satler LF, Popma JJ, Leon MB. Early lumen  
362 loss after treatment of in-stent restenosis: an intravascular ultra-  
363 sound study. *Circulation.* 1998;98:200-3.
- 364 16. Mehran R, Dangas G, Abizaid AS, Mintz GS, Lansky AJ,  
365 Satler LF, Pichard AD, Kent KM, Stone GW, Leon MB.  
366  
367  
368  
369  
370  
371
- Angiographic patterns of in-stent restenosis: classification and  
implications for long-term outcome. *Circulation.* 1999;100:  
1872-8.
17. Alfonso F, Cequier A, Angel J, Martí V, Zueco J,  
Bethencourt A, Mantilla R, López-Mínguez JR, Gómez-Recio M,  
Moris C, Perez-Vizcayno MJ, Fernández C, Macaya C, Seabra-  
Gomes R; Restenosis Intra-stent Balloon angioplasty versus elec-  
tive Stenting (RIBS) Investigators. Value of the American College  
of Cardiology/American Heart Association angiographic classifica-  
tion of coronary lesion morphology in patients with in-stent resten-  
osis. Insights from the Restenosis Intra-stent Balloon angioplasty  
versus elective Stenting (RIBS) randomized trial. *Am Heart J.*  
2006;151:681.e1-681.e9.
18. Schwarzwald U, Zeller T. Debulking procedures: potential  
device specific indications. *Tech Vasc Interv Radiol.* 2010;13:  
43-53.
19. Ben-Dor I, Maluenda G, Pichard AD, Satler LF, Gallino R,  
Lindsay J, Waksma R. The use of excimer laser for complex coro-  
nary artery lesions. *Cardiovasc Revasc Med.* 2011;12: 69. e1-8.
20. Kim MH, Kim HJ, Kim NN, Yoon HS, Ahn SH. A rotational  
ablation tool for calcified atherosclerotic plaque removal. *Biomed  
Microdevices.* 2011;13:963-71.
21. Tanigawa J, Barlis P, Di Mario C. Heavily calcified coronary  
lesions preclude strut apposition despite high pressure balloon dila-  
tation and rotational atherectomy: in-vivo demonstration with opti-  
cal coherence tomography. *Circ J.* 2008;72:157-60.
22. Moussa I, Di Mario C, Moses J, Reimers B, Di Francesco L,  
Martini G, Tobis J, Colombo A. Coronary stenting after rotational  
atherectomy in calcified and complex lesions. Angiographic and  
clinical follow-up results. *Circulation.* 1997;96:128-36.
23. Clavijo LC, Steinberg DH, Torguson R, Kuchulakanti PK,  
Chu WW, Fournadjiev J, Satler LF, Kent KM, Suddath WO,  
Waksman R, Pichard AD. Sirolimus-eluting stents and calcified  
coronary lesions: clinical outcomes of patients treated with and  
without rotational atherectomy. *Catheter Cardiovasc Interv.*  
2006;68:873-8.
24. Urban P, Gershlick AH, Guagliumi G, Guyon P, Lotan C,  
Schofer J, Seth A, Sousa JE, Wijns W, Berge C, Deme M, Stoll HP;  
e-Cypher Investigators. Safety of coronary sirolimus-eluting stents  
in daily clinical practice: one-year follow-up of the e-Cypher regis-  
try. *Circulation.* 2006;113:1434-41.
25. Raja Y, Routledge HC, Doshi SN. A noncompliant, high pres-  
sure balloon to manage undilatable coronary lesions. *Catheter  
Cardiovasc Interv.* 2010;75:1067-73.
26. Díaz JF, Gómez-Menchero A, Cardenal R, Sánchez-  
González C, Sanghvi A. Extremely high-pressure dilation with  
a new noncompliant balloon. *Tex Heart Inst J.* 2012;39:635-8.