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Long-term outcomes of rotational atherectomy of underexpanded stents. A single center experience

Marco Hernández-Enríquez MD[1,2] (ID) | Francisco Campelo-Parada MD[2] (ID) |
Thibault Lhermusier MD, PhD[2] | Frédéric Bouisset MD[2] |
Jérôme Roncalli MD, PhD[2] | Meyer Elbaz MD, PhD[2] |
Didier Carrié MD, PhD[2] | Nicolas Boudou MD[2]

[1] Department of Cardiology, Cardiovascular Institute, Hospital Clinic de Barcelona, Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), University of Barcelona, Barcelona, Spain

[2] Department of Cardiology, Rangueil University Hospital, Toulouse, France

Correspondence
Nicolas Boudou, MD, Department of Cardiology, Rangueil University Hospital, 1, Avenue Jean Poulhés, TSA 50032, 31059 Toulouse Cedex 9, France.
Email: boudou.n@chu-toulouse.fr

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Objectives: To analyze the procedural and long-term outcomes of the use of rotational atherectomy (RA) in underexpanded stents in our cohort and to provide an overview of currently available data on this technique.

Background: Stent underexpansion (SU) has been related to stent thrombosis and restenosis. RA has been used to treat undilatable SU as a bail-out strategy with encouraging results.

Methods: This is an observational, single-center study. We included patients who underwent stentablation between 2013 and 2017. Baseline demographics, procedural results, in-hospital major adverse cardiac events (MACE), and long-term follow-up MACE were retrospectively collected.

Results: A total of 11 patients (90.9% males, mean age 65.4 ± 18.6) were included in this study. Median left ventricle ejection fraction was 53.5% [46.2-55]. Median calculated Syntax score was 16 [9-31] and 45.5% of patients were admitted for acute coronary syndrome. Radial approach was used in 63.6% of cases. Most patients only required one burr (45% used a 1.5 mm diameter burr) during the intervention. Procedural success was achieved in 90.9% of the cases. Acute lumen gain was 42.7% [30.7-61.49]. There were no in-hospital deaths or MACE. At a median follow-up of 26 months, only one patient (9.1%) suffered MACE in the context of acute coronary syndrome, and two patients (18.2%) required non-target lesion revascularization. No deaths were reported.

Conclusions: RA of under expanded stents is a feasible option with a high rate of procedural success. At long-term follow-up, all of them were alive and 90.9% of patients remained free from MACE.

KEYWORDS
outcomes, rotational atherectomy, stentablation, underexpanded stents

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1 | INTRODUCTION

Calcified coronary lesions are very common in contemporary interventional practice. The real prevalence is unknown, but a study showed its occurrence in 38% of all lesions evaluated by angiography and in 74% of cases when intravascular ultrasound was used.[1] Additionally, considering the aging of the population and the expansion of percutaneous coronary intervention indications, an increase in calcified lesions incidence is expected.[2]

Severely calcified lesions are challenging to deal with, and non-compliant or cutting-balloons may not be sufficient to prepare the plaque correctly prior stent implantation. Rotational atherectomy (RA) has been used as an alternative to manage undilatable calcified lesions, usually before stent deployment with good long-term results.[3] Overlooking a calcified lesion or the need of a rapid stent implantation in case of clinical instability can lead to a sub-optimal plaque preparation and subsequent stent underexpansion (SU).[4] Reports have shown that SU was related to stent thrombosis and restenosis.[5,6]

Stentablation, meaning the use of RA to treat SU, has been used as a bail-out strategy with encouraging results.[4,7–16] Nevertheless, data about the long-term clinical outcomes of this approach are limited to a few case reports and two recently published series.[17,18] Our purpose was to analyze the procedural and long-term impact of RA as an alternative strategy to ablate underexpanded stents in our population, and to provide a summary of the related data currently available

2 | MATERIALS AND METHODS

2.1 | Study population

Between January 2013 and July 2017, a total of 1078 patients were treated with RA at the Rangueil University Hospital, Toulouse, France. Patients with in-stent restenosis were excluded, and 11 patients (1.02%) requiring stent ablation were selected. Revascularization was indicated in acute coronary syndromes (ACS) and was either clinically driven, or ischemia driven in case of effort angina. All patients signed an informed consent form for the procedures and usage of their anonymized data for research purposes. The Institution Ethics Committee from our center approved the study.

2.2 | Procedure and follow-up

The procedures were performed by experienced operators in RA. Stentablation was performed when a "dogbone effect" was observed following a failure to expand the stent correctly, despite several dilatations with non-compliant balloons. RotaLink™ Plus system (Boston Scientific, Marlborough, MA) and a standard, 0.009 inch guidewire (RotaWire™; Boston Scientific) were used to perform RA, as reported.[2] Rotational speed was set between 150 000 and 180 000 rpm and all ablation times were inferior to 15 s to prevent a risk of thrombosis due to excessive thermal injury. Patients were pre-treated with dual-antiplatelet therapy before the procedure and the treatment was pursued for at least 6 months after the procedure. The

decision to further maintain antiplatelet therapy was at discretion of their treating physicians. Optimal medical treatment was achieved during hospitalization.

Baseline characteristics, procedural data, and clinical outcomes at follow-up were collected retrospectively and compiled in a database. In case of missing information in the electronic medical records, we contacted the patients primary care physicians, or contacted the patients directly in order to obtain complete sets of clinical data.

2.3 | Definitions and endpoints

Procedural success was defined as the correct RA of the under-expanded stent and the successful delivery of an adequately apposed stent with a residual stenosis <30%.

Major adverse cardiac events (MACE) were defined as the composite of death, myocardial infarction, and target vessel revascularization (TVR) events. Myocardial infarction was defined as recurrent symptoms of ischemia with new re-elevation of cardiac markers to at least twice the upper limit of normal. TVR was defined as the repeated revascularization of the target vessel. The Academic Research Consortium definition of stent thrombosis was used.[19] Quantitative angiography analysis was performed with Q-Angio XA 7.3 (Medis Medical Imaging systems, Leiden, the Netherlands).

2.4 | Statistical analysis

Statistical analysis was performed using SPSS 15.0. Continuous variables are presented as mean ± SD or median [interquartile range] when needed. Categorical variables are presented as frequencies and percentages. To evaluate the differences between residual diameter stenosis before and after stentablation, a paired t test was performed.

3 | RESULTS

Table 1 shows the main baseline demographics of the population. A total of 11 patients underwent stentablation over the whole period considered. The mean age was 65.4 ± 18.6 years old and 10 patients (90.9%) were males. An important prevalence of cardiovascular risk factors was found among them. Median left ventricle ejection fraction was 53.5% [46.2-55%] and median glomerular filtration rate was 66 mL/min [46-80]. The calculated median Syntax score was 16 [9-31] and nearly half of patients were admitted in the context of an ACS (45.5%).

The procedural characteristics are presented in Table 2 and an example of patient treated with stentablation is displayed on Figure 1. A radial vascular approach was used in 63.6% of the procedures. The left anterior descending artery and the right coronary artery were the most frequently treated arteries: 36.4% of cases, respectively. Nine of the patients (80.8%) had a previously implanted drug eluting stent, one had a bare metal stent and one had a polymeric bioresorbable vascular scaffold. Stentablation in an underexpanded scaffold was performed without any complication and a drug eluting stent was implanted with good angiographic

TABLE 1 Main baseline demographics

	Total (n = 11)
Age (years)	65.4 ± 18.6
Male gender, n (%)	10 (90.9%)
Body mass index (kg/m^2)	25.9 [23.5-27.5]
Hypertension, n (%)	8 (72.7%)
Dyslipidemia, n (%)	8 (72.7%)
Diabetes, n (%)	4 (36.4%)
Peripheral vascular disease, n (%)	2 (18.2%)
Previous PCI, n (%)	9 (81.8%)
Previous CABG, n (%)	1 (9.1%)
Previous CAD, n (%)	10 (90.9%)
Left ventricular ejection fraction (%)	53.5 [46.2-55]
Glomerular Filtration Rate (mL/min)	66 [46-80]
Three-vessel disease	4 (36.4%)
SYNTAX score	16 [9-31]
Indication for PCI, n (%)	
ACS: NSTEMI/STEMI	5 (45.5%)
Unstable angina	1 (9.1%)
Stable angina	5 (45.5%)

Data are presented as median [interquartile range] or values (%). PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; CAD, coronary artery disease; ACS, acute coronary syndrome; NSTEMI, non-ST segment elevation infarction; STEMI, ST segment elevation infarction.

result. Most patients only required one burr (mainly a 1.5 mm diameter one in 45.5%) during the intervention. However, upsizing to a larger burr was required in 36.4% of cases. All lesions were post-dilated with non-compliant balloons. All patients but one had a properly expanded stent implanted after stentablation (procedural success = 90.9%). After the procedure, minimal percentage of residual stenosis measured increased significantly in all patients (54.4% [42.2-63.3] vs 7.6% [0.33-16.67]); P < 0.001).

The only patient who did not undergo a new stent implantation presented hemodynamic instability in context of no-reflow due to under expanded stent in the left main coronary artery. Vasoactive drugs and intra-aortic balloon support were required. After stent ablation and non-compliant balloon dilatations, the angiographic result was acceptable with TIMI 3 flow and the operator considered a stent implantation was unsafe in this setting. The patient had an uneventful evolution after the procedure. To date, 3 months after the procedure, this patient remains free from MACE and chest pain. An angiographic control is scheduled at 6 months.

In another patient, cardiac tamponade due to type 3 coronary perforation developed after a super high-pressure dilatation balloon at 35 atmospheres was used. This complication was solved with pericardiocentesis and implantation of a covered stent with favorable evolution. Other intra-procedural complications encountered in this study included: one patient who required vasoactive drugs and one patient who had burr entrapment solved with the use of an extension catheter to recover the burr.

TABLE 2 Procedural characteristics

	Total (n = 11)
Radial approach, n (%)	7 (63.6%)
Successful procedure, n (%)	10 (90.9%)
BMS/DES/BVS, n (%)	1 (9.1%)/9 (81.8%)/1 (9.1%)
Coronary artery treated, n (%):	
LM	1 (9.1%)
LAD	4 (36.4%)
LCX	2 (18.2%)
RCA	4 (36.4%)
Contrast amount (mL)	215 [120-270]
Radiation dose (mGy)	1838.5 [762.2-3505.2]
Burr/Lumen radio	0,93 [0,76-1.07]
Burr size 1.5mm, n (%)	5 (45.5%)
Burr upsizing need, n (%)	4 (36.4%)
Residual diameter stenosis (%)	54.4 [42.2-63.3]
Post-RA stent diameter, (mm)	3.5 [3.25-4]
Post-RA stent length, (mm)	23 [15.5-38]
Post-dilatation balloon diameter, (mm)	4 [3.5-4.5]
Final residual diameter stenosis (%)	7.6 [0.33-16.67]
Acute lumen gain (%)	42.7 [30.7-61.49]
Peak TnT levels (ng/L)	263 [100.1-3629.5]
Complications, n (%)	
No reflow	1 (9.1%)
Perforation	1 (9.1%)
Balloon rupture	1 (9.1%)
Burr entrapment	1 (9.1%)
Vasoactive drug needed	2 (18.2%)
IABP needed	1 (9.1%)
RBC transfusion needed	1 (9.1%)
AKIN 2/3	2 (18.2%)

Data are presented as median [interquartile range] or values (%). BMS, bare metal stent; DES, drug eluting stent; BVS, bioresorbable vascular scaffold; LM, left Main coronary artery; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; RCA: right coronary artery; RA, rotational atherectomy; IABP, intra-aortic balloon pump; RBC, red blood cells; AKIN, acute kidney injury.

No surgical intervention was conducted for any of the patients, no rhythm disturbances requiring atropine and no indications for pacemaker implantation were identified.

In-hospital and long-term outcomes are presented in Table 3. No in-hospital deaths or MACE were documented. During hospitalization, two patients required a punctual renal replacement therapy with posterior stabilization of initial renal function (Baseline glomerular filtration rate 16 and 22 mL/min, respectively). One of these cases, also required a red blood cells transfusion due to gastrointestinal bleeding.

Median follow up time was 26 months [5-32]. No deaths were documented. Only one patient (9.1%) had a MACE. He was admitted
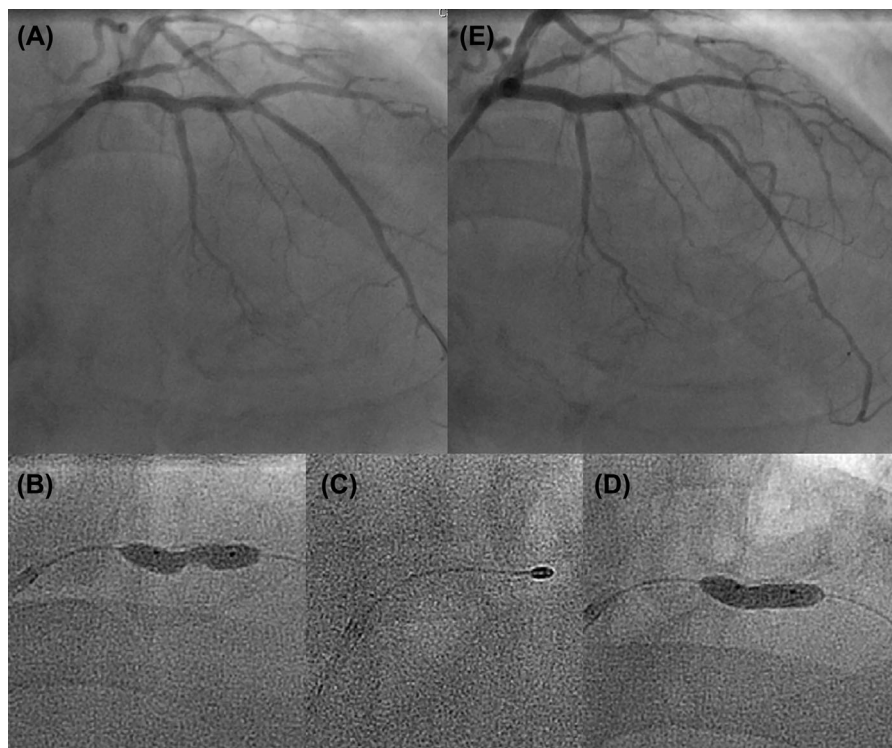
FIGURE 1 Underexpansion of a drug eluting stent (DES) implanted in the left anterior descending artery. After dilatation with a non-compliant ballon, a DES (4 × 18 mm) was implanted with an evident underexpansion despite aggressive post-dilatation: "dog-bone effect" (A and B). Rotational atherectomy was then performed, at first, with a 1.5 mm burr, before upsizing to a larger burr (1.5 mm to 1,75 mm) was required (C). A dilatation with a non-compliant balloon of 4 mm at 20 atm expanded correctly the stent (D). Implantation of a DES (4 × 20 mm) with excellent angiographic result (E)

4 months after the procedure in context of non-ST myocardial infarction and required a percutaneous coronary intervention in the left main coronary artery (non-TLR). Another patient required chronic total occlusion recanalization in the follow up period, that is, a total of 2 non-TLR (18.2%) patients were reported. Three patients underwent a negative stress-test during follow-up (27.2%). Invasive follow-up by coronary angiogram was performed in 6 patients (50.5%): no in-stent restenosis or thrombosis were found.

4 | DISCUSSION

The main findings of the present study can be summarized as follows: (i) RA of underexpanded stents is a feasible option with a high rate of procedural success. (ii) At long-term follow-up of 26 months, 90.9% of patients remained free from MACE and all of them were alive.

Calcified coronary lesions remain challenging to deal with, even for experienced operators. Current available options to deal with under-expanded stents include: aggressive dilatation with super high-pressure[20,21] or cutting balloons,[22] laser excimer therapy and RA. The first one, has showed favorable safety profile and reached 92% of acceptable post-dilatation luminal gain in a recent registry of 91 lesions.[21] Nevertheless, only 30% of the lesions were in context of stent optimization and in case of failure RA was used. The ELLEMENT registry[23] demonstrated feasibility and efficacy of contrast-enhanced laser excimer therapy to treat underexpanded stents in 28 patients.

Reported procedural success with this device ranges from 84% to 96% and mid-term outcomes are also acceptable.[23,24] However, a lack of experience and the limited availability of this technique in numerous centers restrain its widespread use.

Quang et al performed stentablation in a porcine model using microscopy and X-ray mammography to analyze the deposit of pulverized metal particles in the myocardium. They found that over 95% of these particles measured less than 15 μm suggesting that they were small enough to be removed by the reticuloendothelial system.[25]

TABLE 3 Clinical outcomes during hospitalization and at long-term follow-up

	Total (N = 11)
In-hospital MACE, n (%)	0
In-hospital death, n (%)	0
Mean time follow-up (months)	26 [5-32]
MACE, n (%)	1 (9.1%)
MI, n (%)	1 (9.1%)
TLR, n (%)	0
Non-TLR, n (%)	2 (18.2%)
Death, n (%)	0

Data are presented as median [interquartile range] or values (%). MACE, mayor adverse cardiac events; MI, myocardial Infarction; TLR, target lesion revascularization.

Various mechanisms have been proposed to explain the facilitation of expansion of the stent. The most plausible of them seems to be heat generation leading to liquefaction of the calcified atheroma behind the stent struts that would facilitate the balloon expansion.[18,26,27] Other possible cause may be the direct ablation of the metallic stent and fibrocalcific tissue.[8]

Previous reports on stentablation are summarized in Table 4. The first case was reported by Kobayashi et al in 2001.[7] Several cases were described afterwards in various clinical scenarios and over variable follow-up periods (3 months to 2 years). Most of them had an excellent clinical outcome. However, a publication bias cannot be ruled-out since no published case reports presenting negative results are available.

Recently, two new series of cases were reported in the literature:

Édes et al published a study on the outcomes of 12 patients. They described a high rate of procedural success without any in-hospital MACE nor mortality, as found in our analysis. However, a 6-month follow-up revealed that 50% of the patients had a MACE and 25% of them were dead. These different follow-up results could be explained by a higher rate of diabetic and prior coronary artery bypass surgery patients compared to our population.

In contrast, Ferri et al reported more favorable outcomes at one-year follow-up with a 26.6% rate of MACE and 13.3% of TLR. Acute procedural results were also favorable despite isolated complications such as coronary dissection and burr entrapment that were correctly solved. More than half of the patients were studied with intravascular ultrasound.[18]

The present paper brings more evidence of the benefits of RA as a treatment strategy of under expanded stents and supports favorable long-term outcomes. Moreover, we describe the first "scaffold-ablation" with positive results. Procedural complication rates were similar among the three working groups and were included into the expected rate of complex coronary interventions. Also, when feared complications such as coronary artery dissection, perforation, and burr entrapment presented, the three interventional groups were able to manage them percutaneously without surgical intervention.

We strongly recommend performing a careful plaque preparation before stenting in order to avoid stent underexpansion in severe CCL. Indeed, the use of intravascular ultrasound can help identify a CCL hardly detectable in angiography. Nevertheless, when SU is present, the use of stent ablation seems to be a valuable bail-out strategy for operators with experience in RA. When needed, special considerations should be taken into account: (i) Ensure burr/reference <0.7 and start with initial burr 1.25-1.5 mm; (ii) Slow advancement and stepped burr approach are necessary to avoid excessive thermal injury and trapped burr. Use periods of less than 15 s of lesion contact and avoid deceleration inside the lesion; (iii) Aggressive dilatation with non-compliant balloons and evident expansion should follow RA before stenting; (iv) Cover the entire ablated portion with the new stent and post-dilatation with non-compliant balloon is strongly recommended; (v) Tools like microcatheters, extension catheters, and equipment necessary to manage complications should be easily available.

At last, additional data about long-term outcomes are needed. While future randomized trials are not likely, larger multicenter registries would confirm these findings.

TABLE 4 Overview of published reports about stentablation

Authors	n	Follow-up	Comments
Koyabasi et al[7]	1	3 months	First case report, IVUS confirmed good post-stentablation expansion. FU-angiography discarded restenosis
Medina et al[12]	2	6 months	IVUS and GP IIb/IIIa inhibitor were used used in one case, no MACE mentioned.
Fournier et al[13]	1	5 months	No restenosis in FU-angiography, no MACE mentioned.
Mokkaberi et al[15]	1	No	STEMI with presence of thrombus and intracoronary dissection. Good acute outcome.
Herzum et al (2005)[16]	1	No	Direct stenting in STEMI. Good acute outcome.
Akin et al[8]	1	6 months	FU-angiography revealed 25% restenosis, no MACE mentioned.
Lee et al[9]	1	18 months	IVUS confirmed good post-stentablation expansion. FU-angiography discarded restenosis. No MACE mentioned.
Vales et al[10]	1	2 years	Angina free. No FU-angiography.
Kawata et al[11]	1	6 months	Three times restenosis due to US stent, IVUS confirmed good post-stentablation expansion. Transient ST elevation but no other complications. FU-angiography discarded restenosis.
Devidutta et al[4]	1	6 months	Acute stent thrombosis due to underexpanded stent, IVUS showed 5% residual stenosis after stentablation, GP IIb/IIIa inhibitor was used. No FU angiography. No MACE mentioned
Frisoli et al[14]	1	NS	RA of three-overlapped stent layers. IVUS and FFR confirmed good result.
Édes et al[17]	12	6 months	100% procedural success. No in-hospital MACE but adverse events present in every case. FU-MACE in 50% of patients and 25% of them were death. No IVUS used. No FU-angiography.
Ferri et al[18]	16	12 months	87.5% Procedural success. No in-hospital detah or MACE. 26.6% MACE. TLR 13.3% and one non-cardiac death. 56.3% IVUS.
Present paper (2017)	11	26 months	90.9% procedural success. No in-hospital MACE. No mortality and 90.1% free from MACE in FU. No IVUS used. FU angiography in 6 patients and negative stress test in 3.

IVUS, intravascular ultrasound; FU, follow-up; GP IIb/IIIa, glycoprotein IIb/IIIa; MACE, mayor adverse cardiac events; STEMI, ST elevation myocardial Infarction; NS, not specified; RA, rotational atherectomy; FFR, fractional flow reserve. IVUS, intravascular ultrasound.

4.1 | Limitations

This study was small, single center, and retrospective. No intravascular images were used in any of the patients. Angiographic follow-up was available only in half of the patients. However, the other half of them were evaluated in a non-invasive manner or clinically driven, and the main objective of this study was to evaluate safety and long-term clinical outcomes.

5 | CONCLUSION

RA of underexpanded stents is a feasible option with a high rate of procedural success as a bail-out strategy. At long-term follow-up, 90.9% of patients remained free from MACE and all of them were alive. Further analysis in multicenter registries are required to confirm these findings.

ORCID

Marco Hernández-Enríquez iD http://orcid.org/0000-0003-0073-455X

Francisco Campelo-Parada iD http://orcid.org/0000-0003-1821-0658

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