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Excimer Laser Lesion Modification to Expand Non-dilatable sTents: The ELLEMENT Registry[☆]

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ABSTRACT

Background/Objectives: Stent underexpansion is a risk factor for in-stent restenosis and stent thrombosis. Existing techniques to optimize stent expansion are sometimes ineffective. The aim of this study was to evaluate the effectiveness and feasibility of Excimer Laser Coronary Angioplasty (ELCA) in improving stent expansion when high-pressure non-compliant balloon inflation was ineffective.

Methods and Results: ECLA ablation was performed at high energy during contrast injection and only within the underexpanded stent. The primary endpoint of successful laser dilatation was defined as an increase of at least 1 mm² in minimal stent cross-sectional area (MSA) on IVUS or an increase of at least 20% in minimal stent diameter (MSD) by QCA, following redilatation with the same non-compliant balloon that had been unsuccessful prior to ELCA. Secondary endpoints were cardiac death, myocardial infarction (MI) and target lesion revascularization. Between June 2009 and November 2011, 28 patients with an underexpanded stent despite high-pressure balloon inflation were included. The mean laser catheter size was 1.2 ± 0.4 (range 0.9–2.0 mm) and a mean of 62 ± 12 mJ/mm² at 62 ± 21 hertz were required for optimal expansion. Laser-assisted stent dilatation was successful in 27 cases (96.4%), with an improvement in MSD by QCA (1.6 ± 0.6 mm at baseline to 2.6 ± 0.6 mm post-procedure) and MSA by IVUS (3.5 ± 1.1 mm² to 7.1 ± 1.9 mm²). Periprocedural MI occurred in 7.1%, transient slow-flow in 3.6% and ST elevation in 3.6%. During follow-up, there were no MIs, there was 1 cardiac-death, and TLR occurred in 6.7%.

Conclusions: The ELLEMENT study confirms the feasibility of ELCA with contrast injection to improve stent underexpansion in undilatable stented lesions.

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1. Introduction

Calcific balloon-resistant coronary stenoses remain a technical challenge and an important cause of stent underexpansion, especially if adequate lesion preparation was not performed. Even in the drug-

eluting stent era, stent underexpansion remains an important risk factor for in-stent restenosis (ISR) and stent thrombosis (ST) [1–4]. Existing techniques to optimize stent expansion are often ineffective and can be harmful such as rotablation within an underexpanded stent which could be associated with serious complications [5]. Implantation of another stent within an underexpanded stent is unlikely to correct the problem and will probably worsen what is primarily a mechanical problem, leading to recurrent restenosis or ST. Excimer laser coronary angioplasty (ELCA) has been previously reported to facilitate stent expansion in balloon-resistant lesions [6–10]. It has been noted that the impact of ELCA on the surrounding tissue is dependent on the

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association with contrast media, saline and blood [11]. In previous studies, the technique of saline “flush and bathe” was used in order to reduce the risk of coronary dissection induced by high-pressure waves [7,12]. However, in patients with underexpanded stents, ELCA using a contrast or blood medium could assist the achievement of optimized expansion for these lesions by disrupting the underlying plaque [13,14]. In this paper, we evaluated the usefulness of high-energy ELCA using contrast media, in patients with underexpanded stents resistant to high-pressure balloon inflation.

2. Methods

We enrolled 28 patients in this prospective, multi-center observational pilot study. In this registry, we included 3 patients with an underexpanded stent implanted in a de novo lesion and 25 patients with ISR lesions due to stent underexpansion despite the use of adequately sized non-compliant balloons at high pressure (≥ 18 atm). Patients presenting with acute MI and any lesions where no stent had been implanted before ELCA were excluded. All patients provided informed consent for both the procedure and subsequent data collection and analysis for research purposes.

2.1. Procedure

The procedure was performed according to standard techniques, with pre-procedural antiplatelet medication according to protocol. Intra-procedural heparin or bivalirudin use was per operator discretion. Glycoprotein 2b/3a administration was discouraged prior to ELCA. It was mandatory to perform pre-dilatation with a non-compliant balloon prior to ELCA of the target lesion. Once balloon underexpansion was found at angiography, intravascular ultrasound (IVUS) of the underexpanded stent was recommended if the lesion was crossable with the IVUS catheter. Calibration of the catheter was then performed and the desired energy level was set up. The ELCA catheter (Turbo Elite catheter®, 0.9 mm to 2.0 mm; Spectranetics Corporation, Colorado Springs, CO, USA) was passed over the guide-wire, then inserted within the stent and advanced slowly toward the underexpanded zone. The catheter tip was maintained in close contact with the undilatable zone without necessarily crossing the lesion. The speed of this advancement was limited to 0.5 to 1.0 mm per second to avoid dotter effects, dissections and suboptimal ablation. Laser energy was applied in several trains of pulses of 3 to 5 seconds each. To maximize debulking, several passes are commonly performed. The procedure was then finalized by laser catheter removal and additional balloon and stent use according to standard practice.

Importantly, laser energy was never delivered outside the stent, particularly when contrast media was injected. The fluency and repetition rates were increased at the discretion of the operator but we advised that if optimal expansion of the lesion was not achieved, ELCA was to be performed **with contrast injection** at the highest fluency and repetition rates (i.e. 80 mJ/mm² and 80Hz for the 0.9 mm catheter).

2.2. Study endpoints and definitions

To determine if ELCA was effective in improving stent expansion, we defined success as an increase of at least 1 mm² for minimal stent cross-sectional area (CSA) as measured by IVUS; or an increase of at least 20% in minimal stent diameter (MSD) as measured by quantitative coronary angiography, when IVUS was not available. Coronary angiograms were analyzed offline using a validated edge detection system (CMS, version 5.2, MEDIS, The Netherlands) by an expert not involved in any of the procedures. Minimal stent diameter (MSD), reference vessel diameter, and percent diameter stenosis were measured at baseline and post-procedure. The endpoints to assess the safety of this novel procedure included: vessel perforation,

dissection in an uncovered segment of the target vessel, slow-flow or no-reflow, and periprocedural myocardial infarction (MI). During follow-up, we also evaluated the occurrence of target lesion revascularization, MI, death, and ST. The standardized definitions of the Academic Research Consortium were applied for MI, revascularization, and ST [15].

2.3. Statistical analysis

Continuous variables are expressed as mean \pm SD. Categorical variables are presented as absolute numbers and percentages. All analyses were conducted using SPSS software version 18.0. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

3. Results

Between June 2009 and March 2011, 28 patients with an underexpanded stent despite high-pressure balloon inflation were included. The mean age was 71.5 ± 10.5 years, 19 patients (67.9%) were male, and diabetes mellitus was present in 12 patients (42.9%). Seven patients (25.0%) presented with unstable angina (Table 1). Target lesions occurred in the following coronary arteries: 1 (3.6%) in the distal left main, 15 (53.6%) in left anterior descending artery, 6 (21.5%) in left circumflex, 5 (17.9%) in right coronary artery and 1 in a saphenous vein graft. In patients with restenotic lesions, index procedures were performed successfully in all patients. The mean stent size was 3.2 ± 0.4 mm and postdilatation was performed using a 3.3 ± 0.5 mm non-compliant balloon at 22.8 ± 4.8 atm. The mean catheter size was 1.2 ± 0.4 (range 0.9–2.0 mm) and a mean fluency of 62 ± 12 mJ/mm² at 62 ± 21 Hz were required for optimal expansion. Rotational atherectomy was performed in 2 patients (7.1%) and cutting balloon in 1 patient (3.6%) before ELCA treatment. IVUS was performed in 21 (75%) patients (Table 2). However, in 4 patients (14.2%), it was not possible to advance the IVUS catheter through the lesion before ELCA. In all patients, expansion of the stent with a non-compliant balloon at high pressure was attempted before ELCA and with the same balloon after ELCA.

Successful laser-assisted stent dilatation was achieved in 27 cases (96.4%), with an 82.1% improvement in MSD as measured by QCA and an absolute increase of 1.1 ± 0.7 mm ($p < 0.001$). In the 17 patients in whom IVUS was possible before and after ELCA, the minimum stent area increased from 3.5 mm² to 7.1 mm² ($p < 0.001$) (Fig. 1 and Table 3). No deaths occurred during the procedure, while periprocedural MI was observed in 1 patient (3.6%) with a peak CK elevation of 1000U/L and transient ST elevation was observed in 2 patients (7.1%). During follow-up at 6-months, cardiac death occurred

Table 1
Baseline Characteristics.

	n = 28
Age (years)	71.5 \pm 10.5
Male gender	19 (67.9)
LVEF	49.0 \pm 10.5
Previous MI	14 (50.0)
Previous CABG	9 (32.1)
Previous PCI	26 (92.9)
Diabetes Mellitus	12 (42.9)
Hypertension	21 (75.0)
Dyslipidemia	14 (50.0)
Smoker	4 (14.3)
Unstable angina	7 (25.0)

Data are presented as absolute numbers and percentages or means \pm standard deviation, unless otherwise specified. LVEF = Left ventricular ejection fraction; CABG = Coronary artery bypass graft surgery; MI = Myocardial Infarction.

Table 2
Angiographic and Procedural Characteristics.

	n = 28
LAD/LCx/RCA/LM/SVG	15 (53.6)/6 (21.5)/5 (17.9)/1 (3.6)/1 (3.6)
AHA Lesion type: A/B1/B2/C/ISR	0/1 (3.6)/1 (3.6)/1 (3.6)/25 (89.3)
De novo/DES-ISR/BMS-ISR	3 (10.7)/15 (53.6)/10 (35.7)
Ostial Lesion	9 (32.1)
Bifurcation lesion	7 (25.0)
Calcification	25 (89.3)
Tortuous	2 (7.1)
IVUS	17 (60.7)
Rotational Atherectomy	2 (7.1)
Cutting balloon	2 (7.1)
Maximum balloon diameter, mm (Pre Laser)	3.5 ± 0.6
Maximum balloon diameter, mm (Post Laser)	3.5 ± 0.5
Maximum dilation pressure, atm (Pre Laser)	22.4 ± 4.5
Maximum dilation pressure, atm (Post Laser)	22.4 ± 5.4
Size of Excimer laser, mm	1.2 ± 0.4
Excimer laser, 0.9 mm	18 (64.2)
Excimer laser, 1.4 mm	7 (25.0)
Excimer laser, 1.7 mm	1 (3.6)
Excimer laser, 2.0 mm	2 (7.1)
Fluency, mJ/mm ²	62.3 ± 12.3
Repetition rate, Hz	61.7 ± 20.6

Data are presented as absolute numbers and percentages or means ± standard deviation, unless otherwise specified. CABG = Coronary artery bypass graft surgery. LAD = Left Anterior Descending Artery; LCx = Left Circumflex Artery; RCA = Right Coronary Artery; LMT = Left Main Trunk; SVG = Saphenous Vein Graft; IVUS = Intravascular Ultrasound.

in 1 patient and TLR in another patient (Table 4). The patient who died had severe left ventricular dysfunction (LVEF of 20%) and suffered a sudden death 105 days after the treatment of an ostial left circumflex stenosis.

Table 3
Quantitative Coronary Angiography and Intravascular ultrasound.

Patients:	QCA (Pre ELCA), n = 28	QCA (Post ELCA), n = 28
Reference diameter, mm	3.0 ± 0.6	3.2 ± 0.5
MSD, mm	1.6 ± 0.6	2.6 ± 0.6
% stenosis	48.3 ± 18.6	17.9 ± 14.3
Δ MSD mm	1.1 ± 0.7	
Δ MSD (%)	86.0 ± 71.0	
Patients:	IVUS (pre ELCA), n = 17	IVUS (post ELCA), n = 17
CSA, mm ²	3.5 ± 1.1	7.1 ± 1.9
Δ CSA mm ²	3.7 ± 1.6	
Δ CSA (%)	117.7 ± 76.4	

Data are presented as absolute numbers and percentages or means ± standard deviation, unless otherwise specified. MSD = Minimal Stent Diameter; IVUS = Intravascular Ultrasound, CSA = Cross-Sectional Area.

4. Discussion

Laser-facilitated angioplasty of undilatable or calcified coronary stenoses has been well described in the past [7,8]. The occurrence of moderate coronary dissection was reported from 5% to 7% with the use of the saline injection method. On the other hand, the occurrence of perforation was very low (0 to 1.4%), if the optimal ELCA size was selected. However, the application of excimer laser to expand an undilatable stent is limited to case reports [6,10,13,14,16]. In 1998, Goldberg et al. was the first to describe the use of contrast injection during laser angioplasty to amplify the energy and shock waves to successfully expand a stent refractory to balloon dilatation [6]. This technique was not studied further probably due to the availability of non-compliant balloons which allowed high pressure postdilatation. A decade later, Noble et al. described laser treatment within a blood medium to modify a calcified, balloon refractory lesion beneath an

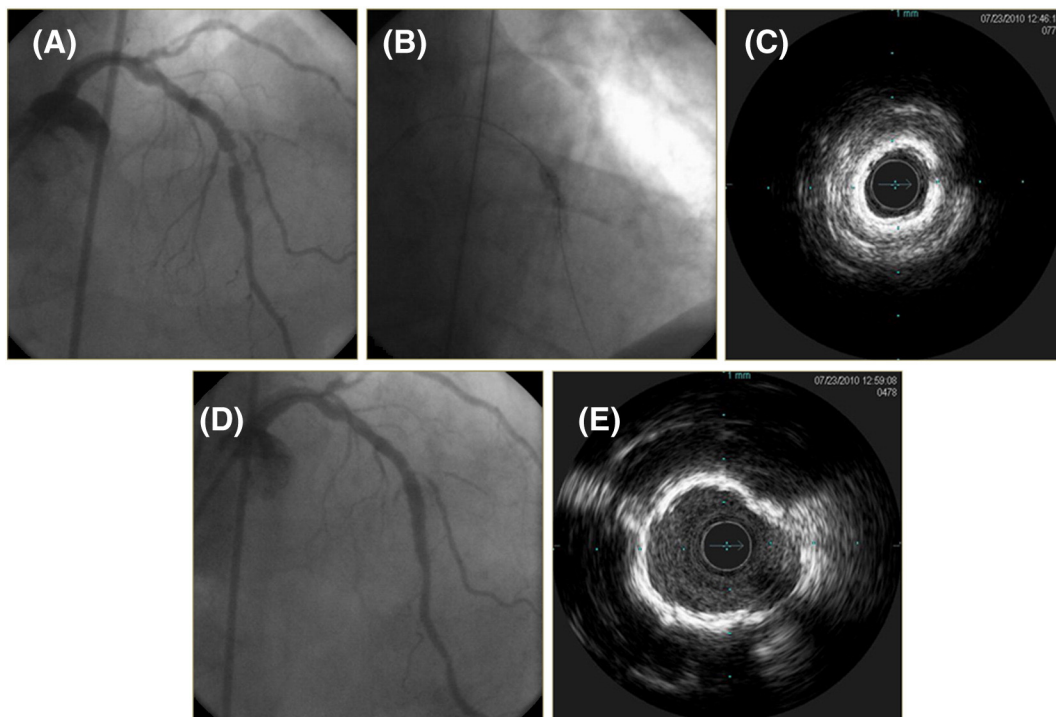


Fig. 1. A 75-year-old man presented with focal restenosis of the mid-LAD with a history of previous PCI at the point of severe stent underexpansion (1-A). Despite dilatation with a 3.75 mm non-compliant balloon at 30 atm, it was unable to expand the stent (1-B). IVUS showed that the minimum stent area (MSA) was 3.8 m² with severe stent underexpansion due to a severely calcified lesion behind the stent (1-C). ELCA with a 1.4 mm laser catheter at a fluency of 40 mJ/mm² and repetition rate of 80Hz was performed during contrast injection within the stent. Following ELCA, the same 3.75 mm non-compliant balloon inflated at 24 atm resulted in successful stent expansion (1-D). IVUS confirmed excellent stent expansion with a MSA of 10.7 m² (1-E).

Table 4

Clinical outcome following CABG, POBA and DES.

	n = 28
Hospital MI/CABG/death	1 (3.6)
CPK (periprocedural MI)	1 (3.6)
Dissection/perforation	0
Bradycardia and ST elevation	1 (3.6)
ST elevation alone	1 (3.6)
6 month follow-up after ELCA	
MACE at 6-months	2 (7.1)
TLR at 6-months	1 (3.6)
Death/MI at 6 months	1 (3.6)

Data are presented as absolute numbers and percentages or means \pm standard deviation, unless otherwise specified. MI = Myocardial Infarction. CABG = Coronary artery bypass graft surgery. MACE = major adverse cardiac event. TLR = Target Lesion Revascularization

underexpanded stent [10]. The ELLEMENT registry is the first large case series to evaluate contrast-enhanced laser therapy to modify plaques that are stented but resistant to balloon expansion despite the use of high pressures. Although this is a niche application for ELCA, the alternative for these patients would have been either coronary artery bypass surgery or rotational atherectomy. There have been published case reports of successful rotational atherectomy within under-expanded stents [5], however this procedure is not without risk and may result in burr entrapment, distal embolization of microparticles resulting from stent destruction, or even severe vessel damage.

The ELLEMENT registry demonstrates the feasibility and efficacy of contrast-enhanced ELCA to facilitate the expansion of undilatable stents. This novel technique was associated with a relatively low incidence of peri-procedural complications, particularly if the complexity of the lesions treated is considered. Furthermore, the occurrence of TLR at 6-months following combination of ELCA and POBA was 4.3%, which may be acceptable considering that the majority of lesions were restenotic and severely calcified.

An explanation of the mechanisms of ELCA is essential for an understanding of why contrast-enhanced ELCA may be effective in improving stent underexpansion. Absorption of excimer laser by tissue may lead to photochemical, photomechanical, or photothermal interactions but the predominant effect of ELCA involves a thermo-mechanical process of rapidly expanding and imploding vapor bubbles [9,16–20]. The rapid conversion of water to water vapor produces an explosive increase in volume and generates acoustic shock waves up to tens of kbars that propagate away from the irradiated tissue [9,19]. This pulse pressure generation is responsible for both the detrimental and beneficial effects of laser angioplasty. Tchong et al demonstrated that no pressure waveforms are generated upon exposure to saline while substantial pulse pressure is generated in a concentration of 25% vol/vol blood in saline or in as little as 1% vol/vol contrast [11]. Thus, the “flush and bathe” technique was designed to replace all blood and contrast with crystalloid before activating the laser, in order to decrease vapor bubble formation and its corresponding acoustomechanical trauma, and in this manner reducing the incidence of laser-induced dissections [12]. In the presence of contrast media, pressure pulses >100 atm can be generated, and in the ELLEMENT registry it was this powerful photomechanical effect that was used to modify and disrupt the balloon-resistant plaque beneath the stent. This also highlights the most important caveat of this technique, that contrast-enhanced ELCA should only be performed within the stent to minimize the risk of vessel injury. Secondly, we recommend that only smaller laser catheters such as the 0.9 mm be used for this technique as the vapor bubbles generated during ELCA are three times greater than the diameter of the laser catheter [9]. Thus, the use of larger size laser catheters in a blood or contrast medium can result in macro-bubble formation (Fig. 2), and increase the risk of

slow flow or transient ST elevation. Furthermore, the smaller catheter is more deliverable and can be utilized in more complex lesions. Finally, this technique may be limited in the treatment of aorto-ostial lesions due to the technical difficulties in maintaining the catheter tip at the ostium, which is the explanation for the only case of failure that we had in this study.

Finally, in order to reduce serious complications, we strongly recommend that this technique is only done within a stent. Furthermore, the laser should be avoided in very tortuous vessels and if there is a history of previous dissection or perforation.

4.1. Limitations

The main limitations of this study are the small sample size and lack of randomization. However, this is a niche treatment of a complex problem, which fortunately occurs rarely. To confirm the safety of this technique, a larger sample size would be necessary. Randomization for balloon resistant under-expanded stents would be challenging as it may be considered unethical to have a control arm with no treatment and the only other potential treatment would be rotational atherectomy with its inherent risks in this subset. Furthermore, this study might be limited value because ELCA is not regularly available worldwide.

5. Conclusions

The importance of good lesion preparation and debulking of calcified lesions prior to stent implantation should not be underestimated, as once a stent has been deployed it may be impossible to optimally expand if the underlying lesion is severely fibrotic or calcified. The ELLEMENT registry confirms the efficacy and reproducibility of ELCA with contrast injection to modify the underlying plaque and improve stent expansion in undilatable lesions.



Fig. 2. Laser angioplasty performed with a 1.7 mm laser (black arrow) created visible vapor macrobubbles (white arrows) during contrast injection.

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