Received: 18 March 2019 | Revised: 16 July 2019 | Accepted: 27 July 2019

DOI: 10.1002/ccd.28435

ORIGINAL STUDIES

WILEY

Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study

John Rundback MD[1] | Pradeep Chandra MD[2] | Marianne Brodmann MD[3] | Barry Weinstock MD[4] | Gino Sedillo MD[5] | Ian Cawich MD[6] | Antonio Micari MD[7,8] | Arthur Lee MD[9] | Chris Metzger MD[10] | Luis Mariano Palena MD[11] | Nicolas W. Shammas MD[12]

[1]Holy Name Medical Center, Teaneck, New Jersey

[2]St. Louis Heart and Vascular, St Louis, Missouri

[3]Medical University of Graz, Graz, Austria

[4]Orlando Heart Specialists, Orlando, Florida

[5]Cardiovascular Solutions Institute, Bradenton, Florida

[6]Arkansas Heart Hospital, Little Rock, Arkansas

[7]Maria Cecilia Hospital, Cotignola, Italy

[8]Gavazzeni Humanitas Hospital, Bergamo, Italy

[9]North Florida Regional Medical Center, Gainesville, Florida

[10]Wellmont CVA Heart Institute, Kingsport, Tennessee

[11]Policlinico Abano Terme, Abano Terme, Italy

[12]Midwest Cardiovascular Research Foundation, Davenport, Iowa

Correspondence
John Rundback, MD, Holy Name Medical Center, 718 Teaneck Road, Teaneck, NJ 07666.
Email: jrundback@aivsllp.com

Abstract

Background: The B-Laser™ atherectomy system (Eximo Medical, Israel) is a 355 nm solid-state Nd:YAG short pulse laser for de-novo and restenotic infrainguinal PAD with enhanced affinity for atheroma and calcified plaque.

Methods: The study was a prospective, single-arm, multi-center, international, open-label study assessing the B-Laser™ in symptomatic (Rutherford 2 to 4) infrainguinal peripheral artery disease. Primary core lab efficacy was mean reduction in diameter stenosis >20% by the B-Laser™ catheter alone. Cardiovascular death, major amputation, target lesion revascularization, WIQ, ABI and Rutherford class were obtained at baseline and out to 6 months. Duplex ultrasound patency (PSVR <2.5), was evaluated by Core Lab.

Results: 97 (77 in USA) PAD subjects (51 male, mean 70.5 years [range 46–86]) with 107 lesions were treated with B-Laser™ (average length 5.4 cm [range 1–24], 29.0% infrapopliteal. 77.6% calcification [26.2% severe], 21.5% chronic total occlusions, 20.6% re-stenotic). Average reduction in residual stenosis post B-Laser™ alone was 33.6 ± 14.2%. Baseline and final stenosis (post laser and adjunctive therapy) were 85.7 ± 12.2% and 17.7 ± 11.0%, respectively. Duplex patency was 96.8% at 30-days and 85.6% at 6 months (95.7% 6-month patency with severe calcification), and did not differ between POBA vs. DCB sub-groups. ABI, Rutherford category and WIQ all improved. There was one MAE and three TLRs out of 101 lesions. No procedural distal embolization was noted and there were no major device-related dissections.

Conclusions: Experience with the B-Laser™ atherectomy system in infrainguinal PAD procedures demonstrates a high level of safety and efficacy for denovo and restenotic infrainguinal arterial lesions.

KEYWORDS

peripheral atherectomy, laser, peripheral artery disease, clinical trials

Abbreviations: ABI, ankle brachial index; BMS, bare metal stent; CD-TLR, clinically driven target lesion revascularization; DCB, drug coated balloon; DES, drug eluting stent; FP, femoropopliteal; IDE, investigational device exemption; ISR, in-stent restenosis; MAE, major adverse event; PAD, peripheral artery disease; POBA, plain old balloon angioplasty; PSVR, peak systolic velocity ratio; RVD, reference vessel diameter; WIQ, walking impairment questionnaire.

1 | INTRODUCTION

Peripheral artery disease (PAD) is characterized by symptomatic occlusive disease of the lower extremities due to mixed histology atherosclerotic plaque containing variable degrees of thrombotic, fibrous, calcific, and hyperplastic morphology. In addition, disease burden may be focal or diffuse and involve single or multiple arterial segments depending on underlying cardiovascular risk factors. Due to this heterogeneity, there are many potential endovascular tools and strategies available for treatment.[1,2]

Atherectomy provides a unique mechanism of therapy through physical debulking of atherosclerotic material, which can facilitate subsequent intervention (i.e., allow easier passage of other therapeutic devices) as well as modify plaque as a mode of vessel preparation for subsequent definitive management with plain old balloon angioplasty (POBA), drug coated balloon (DCB), and bare metal (BMS) or drug eluting (DES) stents. Early data suggests that atherectomy may reduce both the need for bailout stenting and restenosis in long femoropopliteal (FP) lesions,[3] and improved durability in a randomized controlled trial with Excimer Laser Atherectomy (Phillips Vascular Systems) treating FP in-stent restenosis (ISR).[4] In a large registry of isolated tibial interventions on 2,908 patients (1,454 POBA, 1,454 atherectomy and POBA), atherectomy was associated with higher technical success, less bailout stenting, and lower rates of amputation, although vessel patency at 6 months was similar.[5]

The Eximo Medical B-Laser™ is a novel platform with purpose-built catheters designed to treat both above and below knee lower extremity PAD of all morphology, including severely calcific plaque and ISR. We herein present the 6-month pivotal data from the EX-PAD-03 U.S. Investigation Device Exemption (IDE) Trial evaluating the B-Laser™ in patients with symptomatic PAD (Clinicaltrials.gov NCT03157531).

2 | PATIENTS AND METHODS

2.1 | Study design

The EX-PAD-03 was a prospective, single-arm, international, multi-center, open-label, clinical study assessing the safety and efficacy of the Eximo Medical's B-Laser™ in subjects with symptomatic (Rutherford 2 to 4) infrainguinal peripheral artery disease (PAD) at eight U.S. and three EU sites. Patients were included if they had an infrainguinal lesion of ≥70% diameter stenosis in a native artery and excluded if lesion length was >15 cm in a native artery, or > 25 cm in ISR. The protocol was approved by the Food and Drug Administration (FDA), as a pivotal study under an investigational device exemption, and by each investigational site's Institutional Review Board, as well as by the relevant Competent Authorities and local ethics committees in the European sites. The study is also registered in the US National Library of Medicine ClinicalTrials.gov website (Identifier: NCT03157531). The study was conducted in accordance with Good Clinical Practice. An angiographic core laboratory (SynvaCor, Springfield, IL) and a Duplex ultrasound Core Laboratory (Vascore, Boston, MA) provided independent analyses of angiographic and duplex ultrasound images. An independent Clinical Events Committee (CEC) adjudicated all endpoint related adverse events, and an independent Data Safety Monitoring Board (DSMB) supervised the study safety.

2.2 | Investigational device

The B-Laser™ atherectomy system (Eximo Medical, Israel) is a 355 nm solid-state Nd:YAG short pulse laser, containing an array of optical fibers surrounded by a blunt blade for atherectomy, developed for treatment of de-novo and restenotic infrainguinal PAD, including in-stent restenosis. Four catheter sizes (2.35 mm with off center alignment, 2.0, 1.5, and 0.9 mm) are available for treatment of FP and tibial arteries; the larger two catheters have an aspiration feature to limit procedural embolization. The system has approximately threefold higher affinity for atheroma than for endothelium and is indifferent to the presence of contrast material.[6,7] The currently commercial B-Laser™ system and catheters line are shown in Figures 1 and 2, respectively.

2.3 | Procedure

All patients signed an informed consent prior to undergoing any study procedures. Between September 2017 and March 2018, 97 patients were enrolled after angiographic evaluation during the index procedure confirmed that the lesion characteristics met study requirements per the operating physician. Significant stenoses or occlusions of inflow lesions required successful revascularization before treatment of the target lesion. Under core laboratory angiographic protocol, images were captured before and after guidewire crossing of the entire lesion, after the treatment with B-Laser™, and after final adjunctive

FIGURE 1 Front side of the laser system [Color figure can be viewed at wileyonlinelibrary.com]

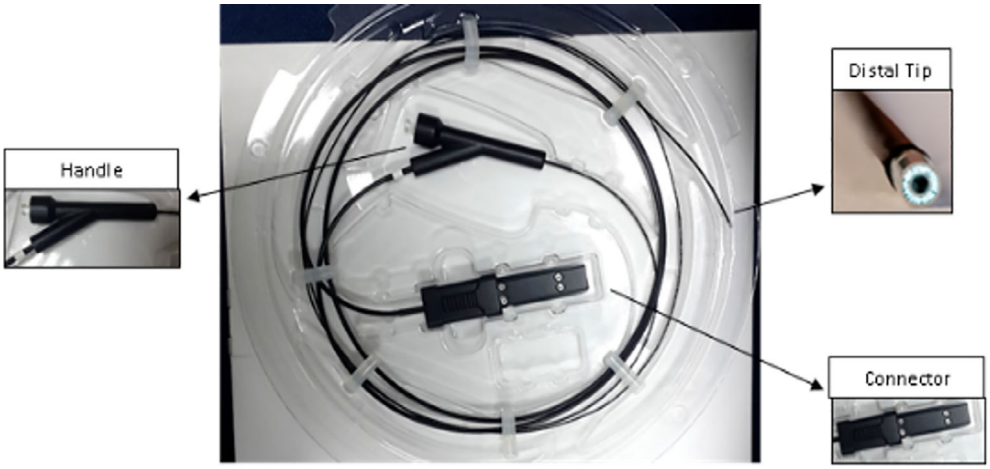

FIGURE 2 B-Laser™ line of catheters [Color figure can be viewed at wileyonlinelibrary.com]

therapy, including run-off after each of these time-points, for evaluation of distal embolization. Procedural angiograms were evaluated quantitatively and qualitatively by the Core Laboratory for Reference Vessel Diameter (RVD), lesion morphology and length, calcification level, residual diameter stenosis, number of distal run-off vessels to the foot, and any perioperative complications. Subjects were hospitalized according to each site's practice. Post-procedural follow-up through 30 days and 6 months consisted of a physical examination, assessment of a validated Walking Impairment Questionnaire (WIQ),[8] Ankle Brachial Index (ABI), Rutherford classification, duplex ultrasound for patency and adverse event evaluation.

2.4 | Study endpoints, definitions and statistics

The primary efficacy endpoint was acute technical success defined as the average reduction from baseline in residual diameter stenosis, achieved by the B-Laser™ catheter alone prior to any adjunctive therapy, for the entire study group. The efficacy null hypothesis of a mean reduction in residual diameter stenosis from baseline ≤20% against the alternative hypothesis of a mean reduction from baseline >20%, with a one-sample two-sided *t*-test, at a one-sided 2.5% level of significance and 90% power, was tested using analysis of covariance (ANCOVA) with center and subject as a categorical covariate.

The primary safety endpoint was freedom from major adverse events (MAE), defined as a composite of cardiovascular death, amputation above the ankle and clinically driven target lesion revascularization (CD-TLR) throughout 30 days post procedure. The safety null hypothesis of the percent of subjects free from 30 days MAE ≤85% versus the alternative hypothesis that percent of subjects free from 30 days MAE > 85%, based on the lower limit of the one-sided 97.5% exact binomial confidence interval of the percent of subjects free from MAE, was tested with statistical significance level of 0.025 and 70.6% statistical power. The sample size has been calculated in order to test each of the hypotheses independently and the higher sample size was selected. The efficacy sample size of 97 treated subjects was selected to provide at least 90% power against the predefined performance goals of 25% mean with 15% standard deviation in diameter stenosis reduction, assuming one lesion per subject, while the safety sample size was calculated for 76 patients, therefore the final sample size chosen was 97 subjects.

Predefined secondary endpoints included[1] ≤30% final residual diameter stenosis (including any adjunctive therapy), with no flow limiting dissection[2]; Freedom from perioperative and up to 30 days device related complications in the target vessel (defined as perforation, dissection, distal embolization, in-situ thrombus or pseudo-aneurysm); as well as[3] clinical outcome at 30 days and 6 months compared to baseline, as assessed by WIQ, ABI, Rutherford and duplex ultrasound patency (PSVR < 2.5). All angiographic cines and duplex films were evaluated by the respective core laboratories for the respective endpoints and all endpoints adverse events were adjudicated by CEC. Analyses such as baseline covariates, secondary endpoints, data after 30 days follow up, subgroup analyses, and secondary analysis set, were not planned to be analyzed with inferential statistics as the primary endpoints, but rather summarized by descriptive statistics by data type. For categorical variables, the number and percentage within each category of the parameter was calculated, and for continuous variables, the N, median, interquartile range (IQR), mean, standard deviation (*SD*), minimum and maximum values were presented. Data regarding stenosis reduction, patency and clinical outcomes, is also presented stratified by certain key subgroups (e.g., calcification level; lesion type: native artery vs. ISR; adjunctive treatment: POBA vs. DCB). As this study is not powered to explore these subgroups, no formal hypothesis testing was performed and therefore subgroup analyses data is presented by descriptive statistics. All statistical analyses were performed on the intent-to-treat population using the statistical analysis system (SAS) software package, Version 9.4 (SAS Institute, Cary, NC). All data were monitored with 100% source data verification (SDV) for data related to endpoints.

3 | RESULTS

Patient and lesion characteristics: A total of 97 (77 in USA) PAD subjects (51 males, mean age 70.5 years [range 46, 86]) were enrolled; 107 evaluable lesions were treated with B-Laser™. Calcification was

TABLE 1 Patient characteristics

PATIENTS	*n* (%)
Subjects (male/female)	97 (51/46)
HTN	89 (91.8%)
Dyslipidemia	83 (85.6%)
DM	41 (42.3%)
Active or prior smoking	78 (80.4%)
CAD	53 (54.6%)
Rutherford grade	
R2	31 (32%)
R3	57 (59%)
R4	9 (9%)
ABI < 0.9	73/88[a] (82.9%)
WIQ <39[18]	76/93 (81.7%)

[a]There were only 88 ABI measured as baseline, since in few patients, baseline ABI was attempted but was unobtainable due to non-compressible arteries. The presence of poorly compressible arteries (PCA) in the lower extremities has been found to be highly specific for calcification of the medial layer in these arteries.[9]

seen in 83/107 (77.6%) and 26.2% were severe (defined as involving more than 50% of the lesion length and visible on both sides of the treated artery). Twenty-three out of 107 lesions (21.5%) were chronic total occlusions, and 22 (20.6%) were re-stenotic (of which 17 [15.9%] were ISR). Average lesion length was 5.4 cm [range 1–24 cm] and anatomical locations were femoropopliteal (88/107) and tibial (19/107). 47.7% lesions received only POBA while 51.4% received DCB, and in one (0.9%) lesion, balloon angioplasty was not performed. Additional patient and lesion features are shown in Tables 1 and 2, respectively.

Acute (initial) and follow-up (6 m) results are shown in Tables 3 and 4, respectively. Core Lab evaluation demonstrated average baseline stenosis and RVD of 85.7 ± 12.2% and 4.5 ± 1.1 mm, respectively. A typical angiograms at baseline, post B-Laser™ and post-adjunctive therapy is shown in Figure 3. Average reduction in residual stenosis post B-Laser™ alone prior to any adjunctive therapy was 33.6 ± 14.2% and was not affected by degree of calcification nor lesion type, or length (Figure 4a–c, respectively). The percentage of lumen gain prior to any adjunctive therapy was comparable with all four B-Laser™ device sizes (Figure 5). Average final

TABLE 2 Lesion characteristics

Lesions & treatment	All	Native	ISR	POBA alone[a]	DCB
n	107	90	17	51	55
Length (mean ± *SD*), cm	5.4 ± 4.3	5.0 ± 3.7	7.6 ± 6.1	4.6 ± 3.1	6.3 ± 5.0
Baseline stenosis (mean ± *SD*)	85.7 ± 12.2	85.7 ± 12.1	85.8 ± 12.8	84.3 ± 11.2	86.9 ± 13.0
Moderate–Severe calcification	41 (38.3%)	35 (38.9%)	6 (35.3%)	21 (41.2%)	20 (36.4%)
CTO	23 (21.5%)	20 (22.2%)	3 (17.6%)	9 (17.6%)	14 (25.5%)
Restenosis/ISR	22 (20.6%)	0 (0%)	17 (100%)	6 (11.8%)	16 (29.0%)
Location					
Femoral	79 (73.8%)	64 (81.0%)	15 (19.0%)	28 (35.4%)	51 (64.6%)
Popliteal	9 (8.4%)	8 (88.9%)	1 (11.1%)	7 (77.8%)*	1 (11.1%)
Tibial	19 (17.8%)	18 (94.7%)	1 (5.3%)	16 (84.2%)	3 (15.8%)
Adjunctive inflow treatment	18 (16.8%)	17 (94.4%)	1 (5.6%)	9 (50.0%)	9 (50.0%)

[a]Lesions treated with both POBA and DCB, were counted as DCB, were compared to lesions treated with POBA alone. One patient did not receive balloon angioplasty.

TABLE 3 Initial (acute technical outcome) results

Initial *n*	All 107	Native 90	ISR 17	POBA alone 51	DCB 55
Baseline stenosis (mean ± *SD*)	85.7 ± 12.2	85.7 ± 12.1	85.8 ± 12.8	84.3 ± 11.2	86.9 ± 13.0
Stenosis post B-laser (mean ± *SD*)	52.1 ± 14.6	52.0 ± 15.3	52.9 ± 11.7	47.6 ± 16.2	57.0 ± 10.7
Final stenosis after PTA (mean ± *SD*)	17.7 ± 11.0	18.0 ± 11.1	17.1 ± 9.9	14.7 ± 11.2	20.8 ± 9.8
Stenosis post B-laser in moderate–severe calcification (mean ± *SD*)	54.3 ± 12.6	53.3 ± 14.8	59.8 ± 14.8	53.4 ± 17.8	55.2 ± 17.8
Stenosis post B-laser in severe calcification (mean ± *SD*)	53.4 ± 13.3	53.0 ± 14.8	56.0 ± 14.8	53.2 ± 17.1	53.6 ± 17.1
Embolization	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade A/B dissection	16 (14.9%)[a]	15 (93.8%)	1 (6.3%)	9 (56.3%)	7(43.8%)
Grade C–E dissection	0 (0%)[b]	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bail-out stenting	1 (0.9%)	1 (1.1%)	0 (0%)	0 (0%)	1 (1.8%)

[a]Sixteen A/B dissections were reported post B-Laser™, 11 dissections grade A and 5 dissections grade B.
[b]No >C dissections were reported post B-Laser™ alone; 14 dissections grade C and 2 dissections grade D were noted only post balloon inflation.

stenosis post adjunctive therapy was 17.7 ± 11.0%, and was similar between the subgroups of lesion types and the type of adjunctive therapy administrated.

ABI, Rutherford category and WIQ all improved from baseline versus 30 days and 6 months (0.7 vs. 1.0 vs. 0.9; 2.8 vs. 1 vs. 0.7; and 23.4 vs 50.9 vs. 50.2, respectively) (Figure 6a–c, respectively). Patency by Duplex evaluation at 30-days and 6 months was 96.8% and 85.6% (n = 93, n = 90 assessable lesions), respectively (Figure 7), with 96% patency at 6 months in the severe calcification sub-group. Clinically driven TLRs occurred in 3/101 lesions (3.0%) and 3/91 subjects (3.3%). For the cohort with ISR, 6-month duplex patency was seen in 11/13 (84.6%) evaluable lesions (four lost to follow-up) similar to the native artery cohort which was with 66/77 (85.7%) patent lesions, and the CD-TLR rate in the ISR cohort was 0%. Also, in the adjunctive therapy sub-groups (POBA vs. DCB regardless the presence of a stent), the patency was comparable between lesions treated with POBA and the lesions treated with DCB post B-Laser™, with 36/41 (87.8%) versus 41/48 (85.4%) respectively.

Per CEC, there was one MAE up to 30 days (non-device related death), no perioperative device-related complications requiring intervention, and no dissections greater than grade C (NHLBI Classification) post balloon in the atherectomy treated areas. No perioperative distal embolization was noted by Corelab with only two filters used. Bailout stenting was reported in one case but was adjudicated as unrelated to the atherectomy in the treated index lesion but to the subsequently inflated drug coated balloon, per investigator and CEC.

TABLE 4 Results of 6 month follow-up

SIX-MONTH	*n* (%)
CD-TLR	
Per subject (*N* = 91)	3 (3.3%)
Per lesion (*N* = 101)	3 (2.9%)
Rutherford class (*N* = 88)	
R0	44 (50%)
R1	31 (35%)
R2	9 (10%)
R3	2 (2%)
R4	1 (1%)
R5/6	1 (1%)
ABI < 0.9 (*N* = 85)	40 (47%)
WIQ < 39 (*N* = 83)	34 (41.0%)

4 | DISCUSSION

The endovascular management of PAD remains challenging due to complex patterns of disease, including frequent multilevel involvement, occlusions, and the high prevalence of arterial calcification. Consequently, definitive therapy often involves the utilization of multiple adjunctive technologies to optimize both initial and late results. Although the value proposition of atherectomy remains controversial,[10] there are numerous studies showing clinical advantage across a broad spectrum of patients.

In two randomized multicenter studies on a total of 100 patient with confirmed calcified lesions, the CALCIUM 360 (CLI patients) and COMPLIANCE 360 trials, demonstrated advantage of atherectomy and balloon angioplasty compared to balloon angioplasty alone.[11,12] In a study of 80 CLI patients with tibial CTO's by Sultan et al., laser atherectomy significantly improved 3-year amputation free survival compared with PTA alone (95.2% vs. 89.4%, p = .02) with sustained benefit through 3 years.[13]

A principle limitation of currently available laser atherectomy is vascular calcification. The B-Laser™'s unique physical properties (355 nm wavelength, 10–25 ns pulse width) allows successful luminal gain despite lesion morphology, including moderate and severe calcific plaque (Figure 4a). In this study, there was similar luminal gain after B-LaserTM in lesions without visible calcium (34.3% gain residual stenosis reduction) compared to severe calcium (34.5% gain residual stenosis reduction). Only type A/B dissections were seen after B-Laser™ therapy, with few type C dissection demonstrated following adjunctive balloon angioplasty within areas treated previously with B-Laser™; in contrast, more frequent and severe dissections occurred after angioplasty in vessel segments not treated previously with B-Laser™. Also, no differences in CD-TLR were noted in

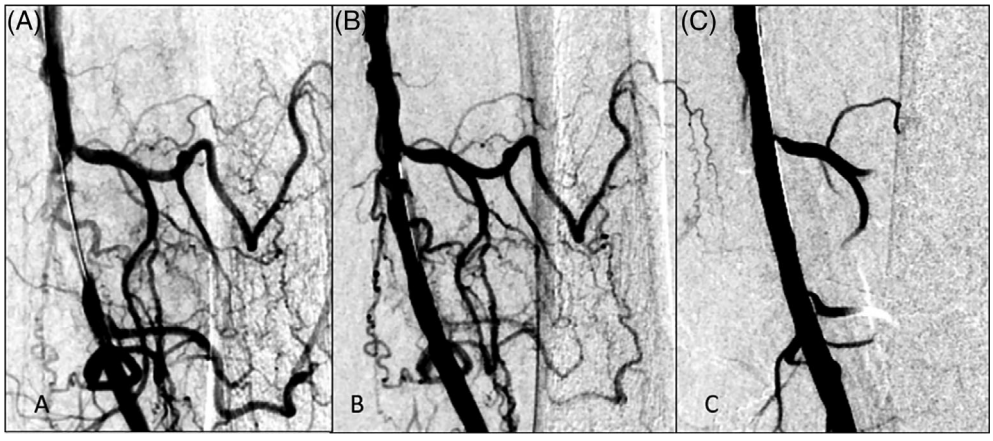

FIGURE 3 B-Laser™ treatment of a femoropopliteal calcified CTO. Initial angiography (a) shows an occlusion of the SFA at the adductor canal. Patency is restored after B-Laser™ atherectomy (b) and subsequent PTA (c)

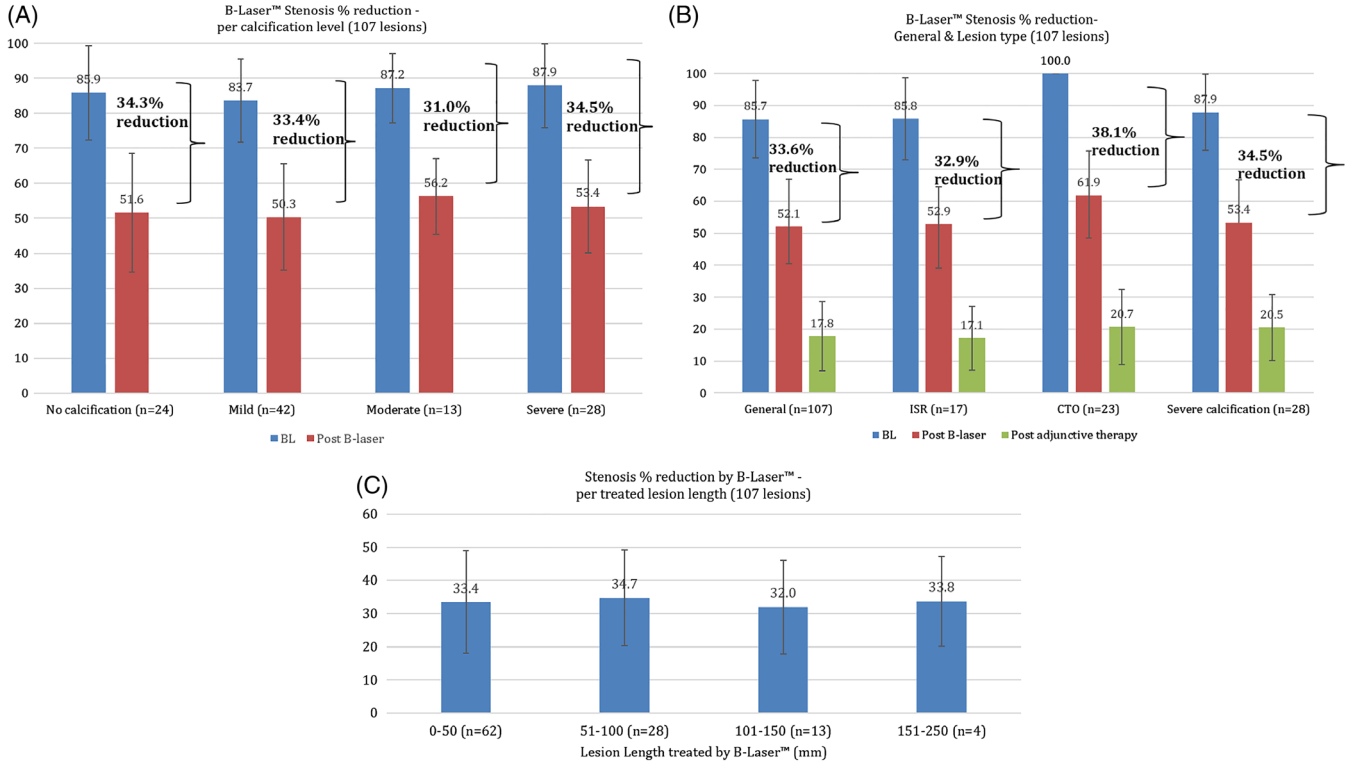

FIGURE 4 Debulking with the B-Laser™ as a function of calcification severity (a), lesion type (b) and lesion length (c) [Color figure can be viewed at wileyonlinelibrary.com]

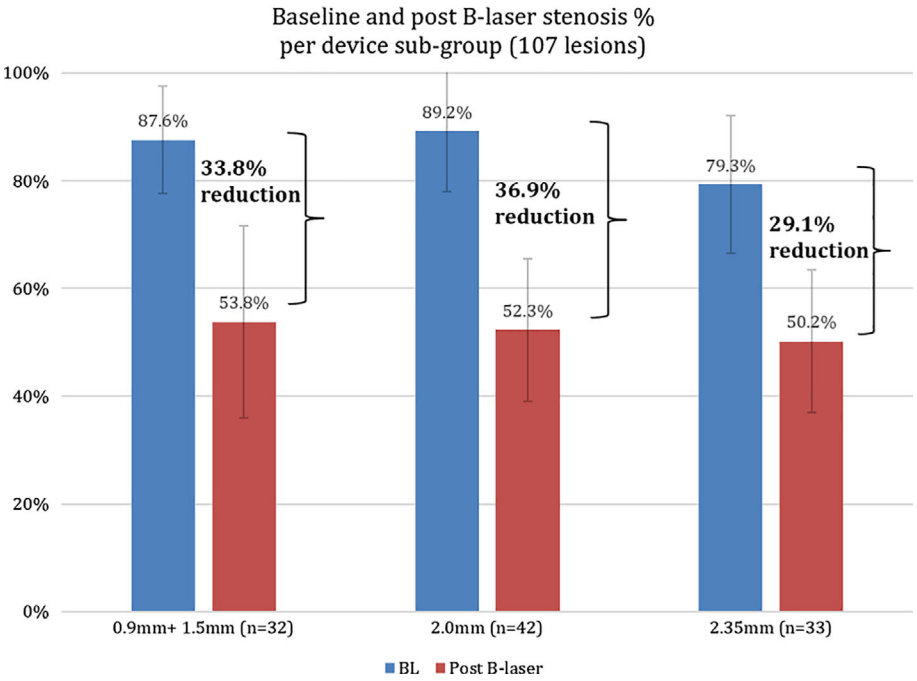

FIGURE 5 Baseline and post B-Laser™ stenosis % per device sub-group [Color figure can be viewed at wileyonlinelibrary.com]

patients with calcific atherosclerosis with unusual, very low CD-TLR across all patient and lesion cohorts. Calcium burden has been demonstrated to impact clinical results with DCB,[14] and vessel preparation to ablate this calcium may improve results particularly in longer lesions.[3] Our current data supports further investigation with debulking of calcific lesions with the B-Laser™ technology prior to arterial drug delivery. However, it is noteworthy to see that in this study high patency rates at 6-months were achieved in both POBA and DCB sub-groups.

The B-Laser™ also demonstrated effectiveness for ISR. Despite there being only a small number of ISR patients in this study, the primary six-month patency rate of 84.6% was comparable to the entire study cohort,

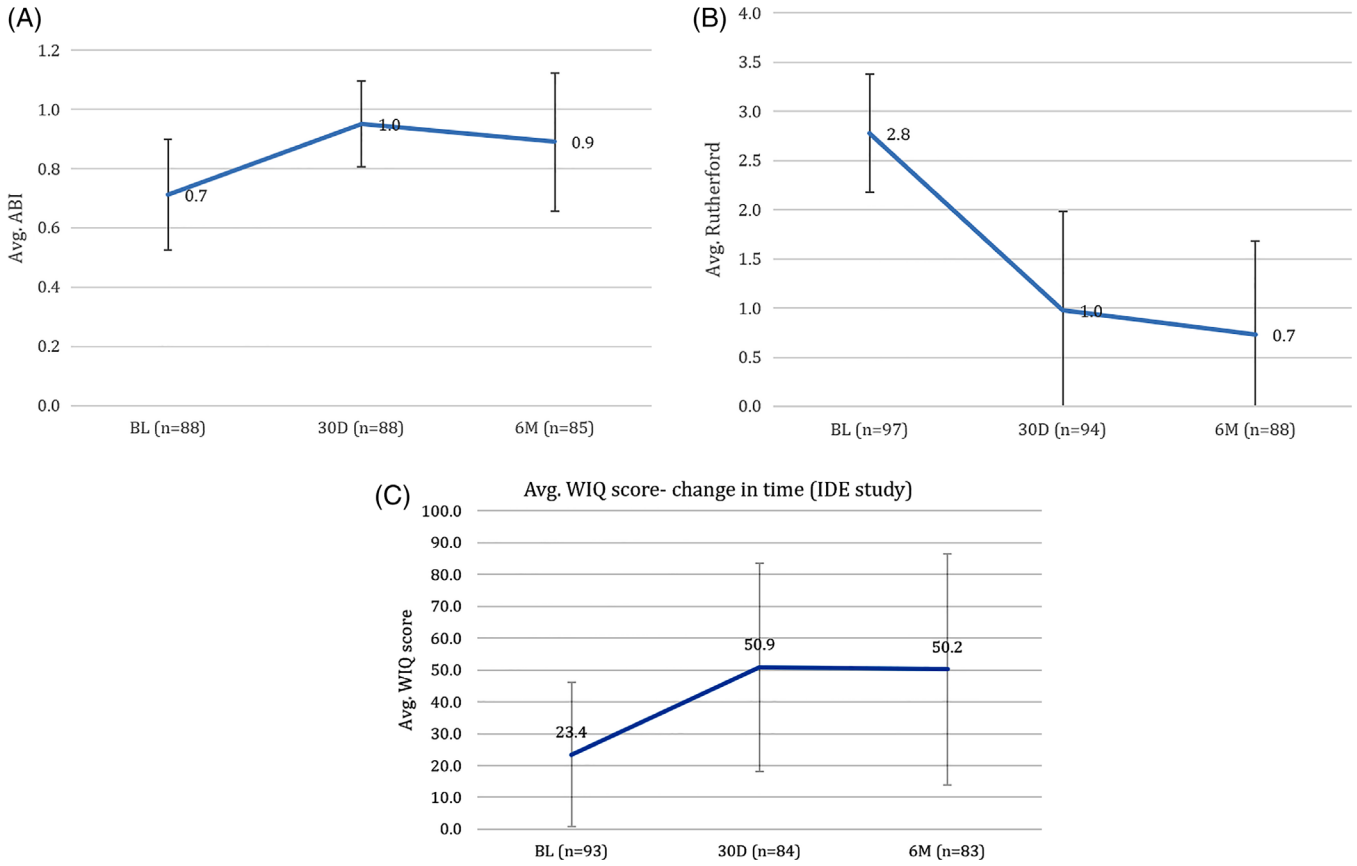

FIGURE 6 Clinical outcomes after B-Laser™ treatment [Color figure can be viewed at wileyonlinelibrary.com]

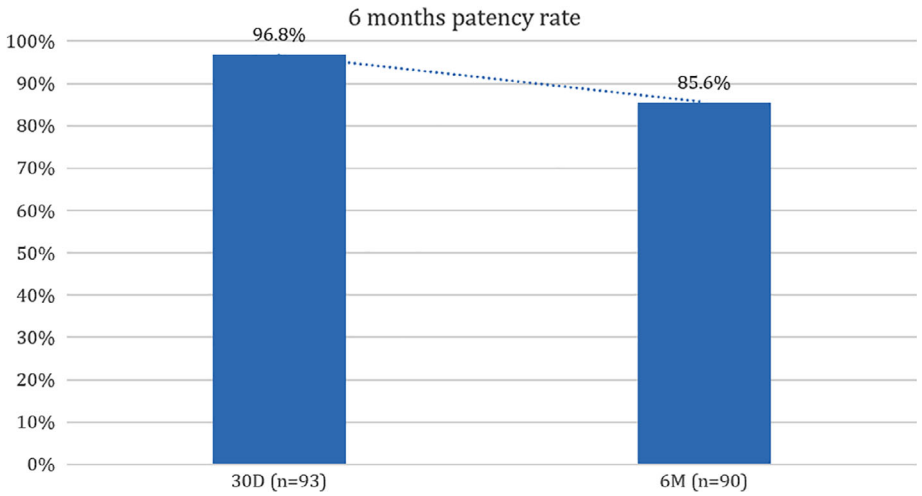

FIGURE 7 B-Laser™ patency rate (PSVR <2.5) for the combined European CE and global IDE studies. For the IDE, PSVR is per Core lab. For the CE study, PSVR is per sites sonographer's physicians [Color figure can be viewed at wileyonlinelibrary.com]

and there were no CD-TLRs. This compares favorably with the 20% CD-TLR rate observed in a study treating ISR with a 308 nm laser.[4]

Atherectomy may potentially cause distal embolization that can compromise results, occurring in 3–10%.[4,15–19] The lack of observed device related distal embolization in this IDE study with the B-Laser™ compares very favorably to these previous reports, despite the inclusion of a moderately complex overall pattern of disease, including severely calcified lesions, and the low number of embolic protection device used. Further, no device related emboli were noted in the previous European Union CE study with 50 patients treated with B-Laser™, resulting in a complete absence of distal embolization in the 147 initial patients treated with B-Laser™ in the combined European and US IDE studies.

This current IDE study extends upon the early results using the B-Laser™ performed in Poland.[20] Combining the 85.6% (77/90 lesions) six-month patency rate (PSVR < 2.5) in this IDE study (Figure 7) with

the CE study, sums to 86.6% (97/112) patent lesions at 6-months (for the IDE, PSVR is per Core lab. For the CE study, PSVR is per sites sonographer's physicians). The combined 6-months CD-TLR rate for both this IDE (91 subjects) and the CE studies (50 subjects) was 2.1%.

5 | CONCLUSION

Atherectomy provides a unique mechanism of action for the treatment of a wide range of lower extremity atherosclerotic lesions. The B-Laser™ in this study provided reproducible results in calcified and non-calcified native arterial lesions as well as ISR in a single platform, with low rates of adverse events and sustained clinical benefits out to 6-months of evaluation. Larger and long-term studies including more diverse patients and adjunctive therapies including DCBs are needed.

6 | DISCLOSURE

This study was supported by Eximo Medical. Dr. Rundback was compensated as Principal Investigator for this study. All authors received investigational support from Eximo Medical.

ORCID

John Rundback https://orcid.org/0000-0001-6843-7506
Marianne Brodmann https://orcid.org/0000-0001-6493-3799
Barry Weinstock https://orcid.org/0000-0002-8211-5471
Nicolas W. Shammas https://orcid.org/0000-0001-8279-0111

REFERENCES

1. Rundback JH, Herman KC, Patel A. Superficial femoral artery intervention: creating an algorithmic approach for the use of old and novel (endovascular) technologies. Curr Treat Options Cardiovasc Med. 2015;17(9):400.
2. Shishebor MA et al. Critical limb ischemia: an expert statement. JACC. 2016;68(18):202-215.
3. Zeller J et al. Directional Atherectomy followed by a paclitaxel-coated balloon to inhibit restenosis and maintain vessel patency: twelve-month results of the DEFINITIVE AR study. Circ Cardiovasc Interv. 2017;10(9):e004848.
4. Dippel EJ, Makam P, Kovach R, et al. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial results from the EXCITE ISR trial (EXCImer laser randomized controlled study for treatment of FemoropopliTEal in-stent restenosis). JACC Cardiovasc Interv. 2015;8:92-101.
5. Sharma P, Nfor T, Ortiz D, et al. TCT-113 Effectiveness of Atherectomy Vs. Balloon Angioplasty for Limb Salvage in Occlusive Tibioperoneal Arterial Disease. J Am Coll Cardiol. 2018;72(Supplement):B49.
6. Herzog A, Oszkinis G, Planer D, et al. Atherectomy using a solid-state laser at 355 nm wavelength. J. Biophoton. 2017;10:1-8. https://doi.org/10.1002/jbio.201600209.
7. Herzog A et al. A route to laser angioplasty in the presence of fluoroscopy contrast media, using a nanosecond-pulsed 355-nm laser. IEEE J Sel Top Quantum Electron. 2016;22(3):342-347. https://doi.org/10.1109/JSTQE.2015.2487889
8. Sagar SP, Brown PM, Zelt DT, Pickett WL, Tranmer JE. Further clinical validation of the walking impairment questionnaire for classification of walking performance in patients with peripheral artery disease. Int J Vasc Med. 2012;2012:190641. https://doi.org/10.1155/2012/190641.
9. Arain FA, Ye Z, Bailey KR, et al. Survival in patients with poorly compressible leg arteries. J Am Coll Cardiol. 2012;59(4):400-407.
10. Feldman DN, Armstrong EJ, Aronow HD, et al. SCAI Consensus for device selection in femoral-popliteal arterial interventions. Catheter Cardiovasc Interv. 2018;92(1):124-140.
11. Shammas NW, Lam R, Mustapha J, et al. Comparison of orbital atherectomy plus balloon angioplasty vs. balloon angioplasty alone in patients with critical limb ischemia: results of the CALCIUM 360 randomized pilot trial. J Endovasc Ther. 2012;19(4):480-488.
12. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. J Invasive Cardiol. 2014;26(8):355-360.
13. Sultan S, Tawfick W, Hynes N. Cool excimer laser-assisted angioplasty (CELA) and tibial balloon angioplasty (TBA) in management of infragenicular arterial occlusion in critical limb ischemia (CLI). Vasc Endovasc Surg. 2013;47(3):179-191.
14. Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37(4):898-907.
15. McKinsey JF, Zeller T, Rocha-Singh KJ, Jaff MR, Garcia LA, Definitive LE Investigators. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv. 2014;7(8):923-933.
16. Zeller T, Krankenberg H, Steinkamp H, et al. One-year outcome of percutaneous rotational Atherectomy with aspiration in Infrainguinal peripheral arterial occlusive disease: the Multicenter pathway PVD trial. J Endovasc Ther. 2009;16:653-662.
17. Schmidt A, Zeller T, Sievert H, et al. Photoablation using the turbobooster and Excimer laser for in-stent restenosis treatment: twelve-month results from the patent study. J Endovasc Ther. 2014;21:52-60.
18. Laird JR, Zeller T, Gray BH, et al. Limb salvage following laser-assisted angioplasty for critical limb ischemia: results of the LACI multicenter trial. J Endovasc Ther. 2006;13:1-11.
19. Shrikhande GV, Khan SZ, Hussain HG, Dayal R, McKinsey JF, Morrissey N. Lesion types and device characteristics that predict distal embolization during percutaneous lower extremity interventions. J Vasc Surg. 2011;53:347-352.
20. Kuczmik W et al. Laser atherectomy using the B-Laser™ Catheter for the treatment of femoropopliteal lesions: twelve-month results from the EX-PAD-01 study. (to be published)

How to cite this article: Rundback J, Chandra P, Brodmann M, et al. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study. *Catheter Cardiovasc Interv*. 2019;1–8. https://doi.org/10.1002/ccd.28435