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RESEARCH

First in man: a novel 355 nm laser plaque ablation system for peripheral artery disease

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Abstract

Objectives A New Ultra-Low Pulse width 355 nm Solid-State Laser Shows Superior Performance to 308 nm Lasers in Preclinical Trials. Real-world statistics, however, are currently scarce. The purpose of this study is to assess the CLA-355 nm laser system's clinical safety and feasibility in human trials.

Methods This study is a prospective, non-randomized, first-in-human trial. The main inclusion criterion was patients with peripheral artery disease (PAD), and the main exclusion criterion was the presence of vascular grafts in the target vessel. Enrolled patients received treatment with the 355 nm Laser Plaque Ablation System (Shenzhen Vivolight, China) in combination with a drug-coated balloon (Endovastec, China) during hospitalization. Efficacy was assessed by the improvement in the percent diameter stenosis (DS) of the target vessel after laser ablation. The primary endpoint was the 6-month primary patency, while secondary endpoints included 6-month clinically driven target lesion revascularization (CD-TLR), amputation, and death. Safety endpoints included device-oriented clinical events (MoCEs) and major adverse cardiovascular events.

Results Nine patients (10 limbs affected) were enrolled in this study; their average age was 69.55 ± 7.99 years, and 44.44% of the patients were male. The femoral artery contained 60% of the lesions, 70% of which were eccentric, and the average lesion length was 49.13 ± 53.87 mm. Chronic occlusive lesions accounted for 40% of lesions. One patient had vascular lesions that were extensively calcified, and the other patient had an aneurysm. Thrombosis and ulcerative lesions were absent from every lesion. Prior to the treatment, the minimal vessel diameter was 0.53 ± 0.68 mm, and the DS was 88.09 ± 15.26%. The reference vessel had a diameter of 4.22 ± 0.69 mm. The residual stenosis after laser atherectomy was 47.94 ± 16.78%, with a minimum lumen diameter of 2.26 ± 0.75 mm. Following the procedure, after subsequent DCB angioplasty, the DS was reduced to 26.07 ± 6.411% with a minimal vessel diameter of 3.00 ± 0.54 mm. During the perioperative phase, there were no MoCEs (distal embolization, perforation, acute occlusion, vasospasm, or intravascular thrombosis). 90% of patients remained patent after six months, and CD-TLR was 100% free. None of the patients experienced MACEs, amputations, or any other problems.

Conclusions This is the first exploratory study on treating PAD in people using the CLA-355 nm laser plaque ablation device. According to preliminary findings, this device exhibits good safety and feasibility in plaque ablation.

Keywords CLA-355 · Laser · Atherosclerosis · Peripheral arterial disease

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Introduction

Peripheral artery disease (PAD), is characterized by the formation of atherosclerotic plaques on the arterial walls of the lower limbs, leading to arterial narrowing or occlusion and consequently impairing distal blood flow. Epidemiological studies indicate that with an aging population, the incidence of PAD is steadily increasing, currently affecting over 200 million middle-aged and elderly individuals worldwide [1–3]. PAD can result in severe consequences, including persistent pain, ulcers, gangrene, and amputation [4, 5]. Additionally, patients with PAD often have concurrent cardiovascular diseases such as coronary artery disease and stroke, which further increase the risk of mortality. This significantly impacts the quality of life for patients and their families and imposes a substantial burden on socioeconomic development [6, 7].

In recent years, minimally invasive endovascular treatments have progressively replaced highly invasive open bypass surgeries for lower limb arterial occlusive lesions. The mainstream endovascular approach is stenting, which, while effective in the short term, presents issues such as stent fracture and restenosis that severely compromise long-term vessel patency. These issues are particularly pronounced in the joint regions of the lower limbs [8]. With the introduction of the "leave nothing behind" concept aimed at restoring natural lumens and minimizing stent implantation, debulking technologies have become a focus of clinical research. Commonly used intravascular debulking techniques include Rotational Atherectomy, Orbital Atherectomy, Laser Atherectomy, and Mechanical Thrombectomy [9, 10]. Among these, excimer laser atherectomy (ELA) has shown utility in modifying plaque morphology and improving lesion preparation, potentially facilitating better outcomes when used in conjunction with balloon angioplasty and drug coated balloon [11].

Currently, the commonly used laser source for laser atherectomy is the excimer xenon chloride (XeCl) laser, which emits a 308 nm wavelength excimer laser in pulsed mode. This laser is transmitted through intertwined optical fibers within a catheter. The radiation from the laser operates through three primary mechanisms: photothermal energy, photochemical energy, and photomechanical energy. Most of the laser radiation is absorbed by chromophore-containing tissues such as hemoglobin, proteins, and cholesterol, leading to the breaking of molecular bonds and ionization of atoms within the plaque, resulting in laser ablation. This process fragments the plaque into micro-particles smaller than 25 μm, carbon dioxide, and water, which are then safely expelled from the body via the kidneys or respiratory system. Thus, it effectively ablates and dissolves intravascular thrombi and atherosclerotic plaques [12–14]. Although the 308 nm laser is widely used, it still has several unresolved limitations. The penetration depth of the 308 nm excimer laser is relatively shallow, primarily affecting the skin and superficial tissue layers. This limits its effectiveness in treating deeper arterial plaques, potentially failing to eliminate deep-seated plaques effectively [15]. Additionally, when the laser radiation interacts with blood or contrast agents, these liquid media, having a high absorption coefficient at 308 nm, absorb a significant amount of radiation and convert it into mechanical energy. This increases the risk of intimal rupture, vessel dissection, or arterial perforation [16].

In recent years, the use of 355 nm solid-state lasers (third harmonic of Nd) has been proposed as a new laser source for intravascular plaque ablation. According to the literature, compared to the 308 nm excimer laser, this laser offers higher ablation efficiency, causes less damage to the vessel wall, and can operate compatibly in the presence of contrast agents [17–19]. Given this, we designed a novel 355 nm solid-state laser (third harmonic of Nd). This study is the first prospective human trial evaluating the use of this laser for the treatment of newly developed PAD.

Materials and methods

Materials

The laser device utilized in this experimental study is the ultra-low pulse width 355 nm solid-state laser (CLA-355) independently developed by Shenzen Vivolight Medical Device & Technology Co. Ltd., China. (Fig. 1). The system comprises a laser emitter and a laser catheter. The laser emitter uses a frequency-tripled solid-state Nd laser with a wavelength of 355 nm, a pulse width of 15 ± 10ns, and a photon energy of 3.5 eV, delivering a maximum energy density of 60 mJ/mm². The custom-developed laser catheter features outer diameters of 1.2 mm, 2.0 mm, and 2.5 mm in an over-the-wire (OTW) structure, recommended for use in vessels with diameters of $\geq$1.8 mm, $\geq$3.0 mm, and $\geq$3.5 mm, respectively, with a maximum working length of 150 cm.

Methods

Study design and patient selection

Based on the safety and efficacy of the system and technology, a prospective, non-randomized, single-center first-in-man (FIM) study was designed to further evaluate the feasibility of this device in human patients. This trial was designed in accordance with the Declaration of Helsinki and has been registered on ClinicalTrial.gov (registration

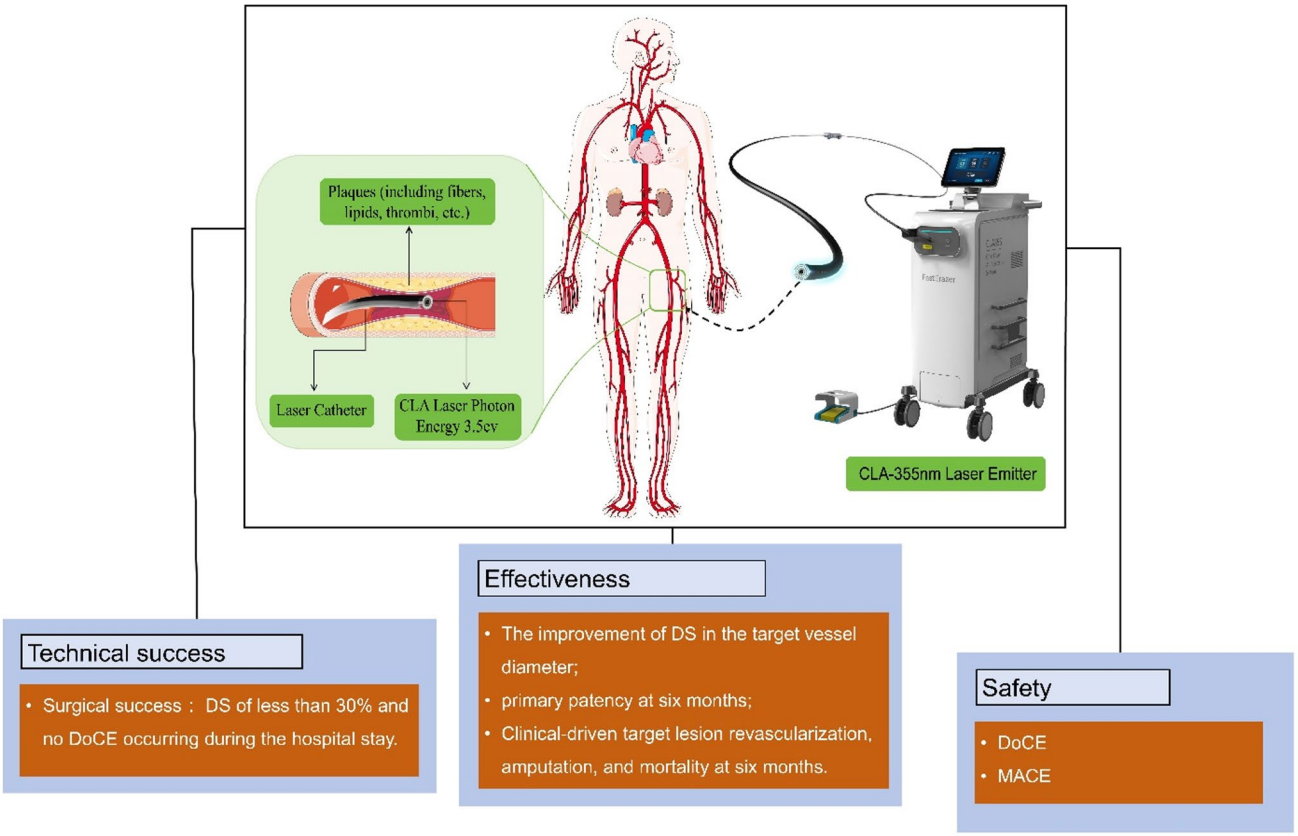

Fig. 1 355 nm Molecular Laser System and Major Evaluation Metrics. DoCEs: Device-oriented Clinical Events, DS: diameter stenosis, MACEs: Major Adverse Cardiovascular Events

number: NCT06211127). The trial was approved by the Ethics Committee of Xuanwu Hospital, Capital Medical University ([2022]054). The inclusion criteria were divided into general and intraoperative angiographic inclusion criteria. The general inclusion criteria were: (1) Age between 18 and 85 years (inclusive), irrespective of gender; (2) Patients with PAD, with a Rutherford classification of grades 2 to 5; (3) Willingness to participate in the study, with signed informed consent and a commitment to follow-up as required; Intraoperative angiographic inclusion criteria were: (1) A reference vessel diameter≥1.8 mm at the proximal end of the target lesion; (2) Target lesion vessel stenosis≥70%. The protocol was approved by the Ethics Committee of Xuanwu Hospital, Capital Medical University. Patients meeting all criteria provided written informed consent to participate in the trial. The main exclusion criteria were: (1) Presence of vascular grafts in the target vessel; (2) History of target vessel aneurysm, intracranial or gastrointestinal hemorrhage, intracranial aneurysm, myocardial infarction, or stroke within the past 2 months; (3) Flow-limiting dissection in, proximal, or distal to the target lesion; (4) Uncorrectable coagulopathy (platelet count≤75×10^9/L or INR≥2.0), bleeding diathesis, or history of heparin-induced thrombocytopenia (HIT); (5) Known allergy to contrast agents or perioperative medications; (6) Subjects participating in other drug or medical device clinical trials; (7) Pregnant or lactating women.

Study procedure

Preoperatively, all patients received dual antiplatelet therapy (aspirin 100 mg/day and clopidogrel 75 mg/day) for at least three days. CT angiography was performed preoperatively to assess vascular lesions, and either ipsilateral common femoral artery antegrade puncture or contralateral common femoral artery retrograde puncture was selected. Using the "crossover" or "subintimal tracking and reentry" technique, the catheter was advanced to the affected limb, and angiography of the diseased artery was performed to delineate the extent of the lesion. A Treasure 12 guidewire (Asahi, Japan) or V18 guidewire (Boston Scientific, USA) was used in conjunction with a TrailBlazer support catheter (EV3, USA) to traverse the stenotic or occlusive lesion. The true lumen was confirmed by angiography via the support catheter at the distal end of the lesion, considering laser ablation treatment for the patient. An EV3 SpiderFX protection device was placed at the distal end of the lesion along the guidewire for protection, and the CLA-355 system, along with a single-use

laser plaque ablation catheter, was used, ensuring proper device connection. After manually powering on the device, the catheter tip was slowly advanced at a speed of 0.5 cm/s along the guidewire to perform intravascular lesion debulking. After one operation, the catheter was withdrawn and flushed with heparinized saline. If the debulking effect was unsatisfactory, as shown by angiography, a second operation could be performed. Subsequently, the target lesions were pre-dilated using a plain balloon angioplasty (POBA, Batai, China), followed by angioplasty with a 4.0–5.0 mm drug-coated balloon (DCB, Endovastec, China) inflated for three minutes at the lesion site. If there was residual stenosis greater than 30% or a flow-limiting dissection, a bare metal stent implantation was performed.

Study endpoints

The primary efficacy endpoint is the improvement in the percent diameter stenosis (%DS) in the target vessel diameter post-laser ablation. The primary endpoint event is the six-month initial patency rate. Secondary endpoints include clinical-driven target lesion revascularization, amputation, and mortality at six months. Safety endpoints encompass device-related composite endpoints and major adverse cardiovascular events. Device-oriented composite endpoints (DoCEs) are defined as intravascular thrombosis, vasospasm, acute occlusion, perforation, and distal embolization. Major adverse cardiovascular events (MACEs) are defined as acute myocardial infarction and ischemic stroke during the perioperative period. Device success is defined as achieving DS < 30% at the target site using the 355 nm laser. Procedural success requires DS < 30% with no occurrence of DoCEs during hospitalization. All patients undergo vascular ultrasound examinations at a six-month outpatient follow-up.

Table 1 Baseline patient characteristics

Variables	*N* = 9
Age(years)	69.55 ± 7.99
Male, n (%)	4 (44.44%)
Weight(kg)	65.11 ± 8.41
Hight(cm)	167.67 ± 5.66
Body Mass Index (Kg/m2)	23.19 ± 3.20
Diabetes, n (%)	6 (66.67%)
Hypertension n (%)	7 (77.78%)
Hyperlipidemia, n (%)	3 (33.33%)
Coronary Artery Disease	4 (44.44%)
Cerebrovascular Disease, n (%)	0
Chronic renal dysfunction, n (%)	0
Rutherford Category	3.89 ± 0.33
TASC II	
A	5(55.56%)
B	2(22.22%)
C	2(22.22%)
Critical Limb Ischemia	8 (88.89%)
Ankle Brachial Index	
Left	0.65 ± 0.22
Right	0.69 ± 0.19
Current Smokers, n (%)	3 (33.33%)

Statistical analysis

Discrete variables are presented as counts and percentages. Continuous variables are reported as mean ± standard deviation (SD). A Student's t-test was employed to compare pre- and post-treatment data. A *P*-value < 0.05 was considered statistically significant. This study is a FIM and single-arm study; the sample size was not defined based on the endpoint hypothesis but to provide preliminary information on device safety. The primary endpoint and all imaging-based findings were analyzed based on the actual treated population. Statistical analysis was performed using SPSS version 23.0 (IBM Corporation, Armonk, NY, USA).

Results

Baseline clinical characteristics

From August 2023 to September 2023, a total of 9 subjects were recruited at our center. All patients met the inclusion criteria and did not meet any exclusion criteria. All patients underwent CLA-355 nm molecular laser treatment for lower limb vascular lesions. The demographic data of the patients are shown in Table 1. Among them, 44.44% were male, with an average age of 69.55 ± 7.99 years. Most patients had comorbidities such as diabetes (66.67%) and hypertension (77.78%). All patients had a Rutherford classification of grade 3 or higher, with no concurrent coronary artery disease or renal insufficiency.

Angiographic and procedural characteristics

Baseline angiographic characteristics are shown in Table 2. The trial included a total of 10 affected limbs, with 60% of lesions located in the femoral artery and 70% being eccentric. The average lesion length was 49.13 ± 53.87 mm, with 40% being chronic occlusions. One patient had an associated aneurysm, and another had severely calcified vascular lesions. None of the lesions were associated with thrombus or ulcerative lesions. All patients successfully underwent revascularization using the CLA-355 nm molecular laser. The preoperative reference vessel diameter was 4.22 ± 0.69 mm, the minimum preoperative vessel diameter was 0.53 ± 0.68 mm, and the preoperative stenosis degree was 88.09 ± 15.26%. After 355 nm laser ablation, the minimum

Table 2 Baseline angiographic characteristics

Variables	*N* = 10
Target vessel, n (%)	
Femoral Artery	6(60%)
Popliteal Artery	2(20%)
Tibiofibular Artery	2(20%)
Moderate to heavy calcification, n (%)	1(10%)
Eccentric Lesions, n (%)	7(70%)
Chronic Total Occlusion, n (%)	4(40%)
Associated Aneurysm, n (%)	1(10%)
Associated Thrombus and Ulceration, n (%)	0
Associated Intimal Tear, n (%)	0
Lesion Length (mm)	49.13 ± 53.87
Calcified Lesions, n (%)	1(10%)
Flow-Limiting Dissection, n (%)	0
Distal Embolization, n (%)	0
Perforation, n (%)	0

Table 3 Pre and post treatment vessel measurements

Variables	Pre-Treatment	Post laser treatment	Post laser + DCB treatment
RVD (mm)	4.22 ± 0.69	-	
MLD (mm)	0.53 ± 0.68	2.26 ± 0.75	3.00 ± 0.54
DS (%)	88.09 ± 15.26	47.94 ± 16.78	26.07 ± 6.41

MLD, minimum luminal diameter; DS, percent diameter stenosis; RVD, reference vessel diameter; DCB, drug coated balloon

lumen diameter (MLD) increased to 2.26 ± 0.75 mm, and the residual stenosis was reduced to 47.94 ± 16.78%. Following adjunctive treatment with a DCB, the MLD further increased to 3.00 ± 0.54 mm, and stenosis degree decreased to 26.07 ± 6.41% (Table 3). Figure 2 presents pre- and post-operative optical coherence tomography (OCT) imaging of a patient treated with the CLA-355 nm molecular laser. The treatment effectively expanded the minimum lumen area. Figure 3 displays representative angiographic images of a patient treated with the CLA-355 nm molecular laser, showing significant restoration of blood flow in the lower limb post-procedure.

Device-oriented composite endpoints (DoCEs) and six-month follow-up results

No DoCEs such as intravascular thrombosis, vasospasm, acute occlusion, perforation, or distal embolization occurred during the perioperative period, achieving a device success rate of 100%. All patients were followed for more than six months. The primary patency at six months was 90%, and the CD-TLR was 0%. Additionally, no amputations or adverse cardiovascular events were observed, and the overall mortality rate was 0% (0/9) (Table 4).

Discussion

In this FIM study, the use of CLA-355 did not result in any MoCEs, achieving a device success rate of 100%. Preoperative vessel stenosis was 88.09 ± 15.26%, which reduced to 25.04 ± 4.31% postoperatively. There were no occurrences of amputation, adverse cardiovascular events, or mortality. The six-month follow-up showed an initial patency rate of 90%, with no instances of CD-TLR, confirming the safety and efficacy of this device in human trials.

Compared to the commonly used 308 nm excimer laser, the CLA-355 has demonstrated superior clinical performance. The LACI (Laser Angioplasty for Critical Ischaemia) trial, a multicenter feasibility study, aimed to assess the safety and efficacy of ELA for patients with peripheral arterial critical limb ischemia (CLI) [20]. This trial included 23 CLI patients (25 limbs) who underwent ELA-assisted percutaneous transluminal angioplasty (PTA) with selective stent implantation, achieving a procedural success rate of 88% (22/25). At the six-month follow-up, the limb salvage rate was only 90%. Based on the LACI trial results, Laird et al. [21] conducted the LACI Phase II prospective study across 14 sites in the USA and Germany, enrolling 145 CLI patients who were unsuitable for surgical bypass. The treatment involved ELA-assisted PTA with selective stent implantation when necessary. Postoperatively, 89% of patients restored direct blood flow to the foot. At the six-month follow-up, the patency rate was 83%, the limb salvage rate was 93%, and the amputation rate was 8%. In our study, 88.9% of the patients had severe limb ischemia, and the initial clinical outcomes exceeded those of the 308 nm excimer laser. Moreover, the complication rate related to ELA treatment is approximately 14%, mainly involving flow-limiting dissection, distal embolization, and vascular perforation [22, 23].

Preclinical results of this study demonstrated that compared to the 308 nm excimer laser, the CLA-355 nm laser effectively reduces the incidence of such events. The 308 nm excimer laser has a pulse width of 125-250ns, whereas the CLA-355 used in this study has a pulse width of 15 ± 10ns. A more minor pulse width results in a more significant photomechanical effect, leading to higher plaque ablation efficiency and less vascular wall damage; it also minimizes thermal effects, reducing vascular wall injury. Furthermore, the ELA laser energy is 4.0 eV, while the CLA-355 laser energy is only 3.5 eV. The dissociation energy threshold for vascular wall chemical bonds C-O and C-N is 3.6 eV, whereas the dissociation energy threshold for plaque (including fibrous, lipid, thrombus, etc.) chemical bonds C-N is 3.0 eV. The photon energy of the CLA-355 laser exceeds the dissociation energy threshold of plaque molecular bonds. Still, it is lower than that of vascular wall

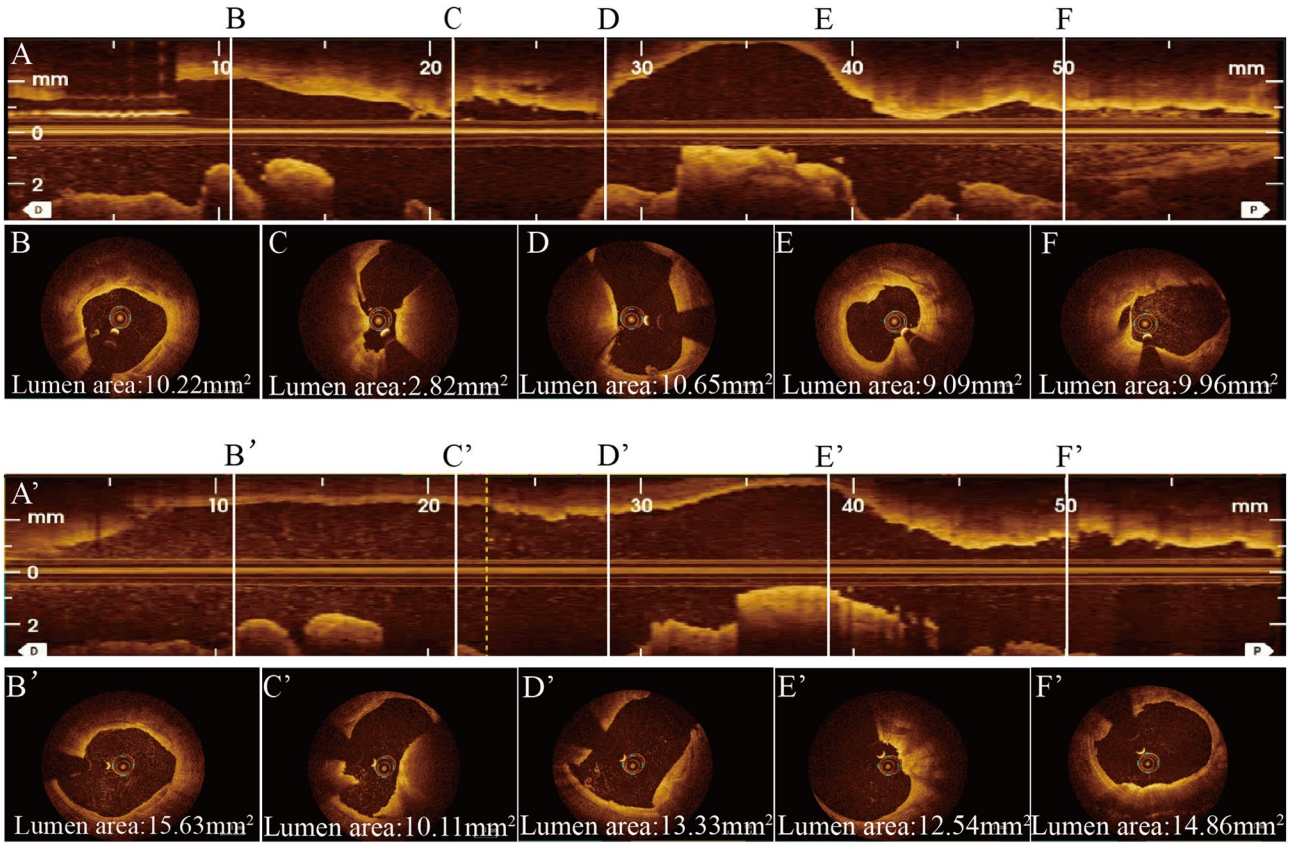

Fig. 2 Optical Coherence Tomography (OCT) Imaging Pre- and Post-Procedure Comparison. OCT imaging (longitudinal view: **A**, cross-sections: **B**-**F**) shows the baseline condition, which is used to compare with the post-laser ablation OCT images. The corresponding longitudinal and cross-sectional views after laser ablation are shown in **A**' and **B**'-**F**,' respectively. Panel C shows the preoperative minimum lumen area of 2.82 square millimeters, while the corresponding post-laser ablation area in **C**' shows a minimum lumen area of 10.11 square millimeters

molecular bonds. Thus, the photochemical effect ablates the tissue plaque selectively without affecting the vascular endothelium, achieving "selective" ablation [18, 24]. The divergence angle of the ELA catheter is only 9.4°, whereas the divergence angle of the CLA catheter is 25°, nearly three times that of ELA. Therefore, the tissue ablation range of CLA is much more extensive than that of ELA, a finding corroborated by our previous animal studies [19, 25].

Previous similar clinical reports have confirmed the efficacy of the 355 nm laser for lower limb arterial lesions. Herzog et al. [26] A 355 nm laser was used for revascularization in two cases of chronic total occlusion (CTO) with severe calcification above and below the knee (ATK and BTK). Both patients successfully restored lower limb perfusion without any adverse events such as dissection, perforation, or embolization. The EX-PAD-03 IDE trial, a prospective, single-arm study on the Auryon laser—a novel laser system with a long wavelength and short pulse width—treated 60% of lesions with a drug-coated balloon, achieving a low CD-TLR rate of only 3.3%. However, one case of distal embolization occurred. In contrast, our study found no thrombus or distal embolization in the filters, and all patients underwent subsequent dilation with a drug-coated balloon to maintain long-term patency. This may have contributed to the superior six-month freedom from CD-TLR in our study compared to the EX-PAD-03 trial [27]. In summary, the short-term clinical safety and efficacy of the 355 nm laser have been validated.

Study limitations

Several limitations of this study need to be acknowledged: (1) Insufficient study population size: As this trial is a FIM study, the scale of the study population is insufficient to address efficacy questions comprehensively; (2) This study represents the first human evaluation of the CLA-355 device for the treatment of PAD. It was designed as a single-center, small-sample, single-arm trial without a control group. In addition, all included lesions in this study were less than 10 cm in length. According to the TASC II classification, these correspond to TASC A–B lesions for stenosis and

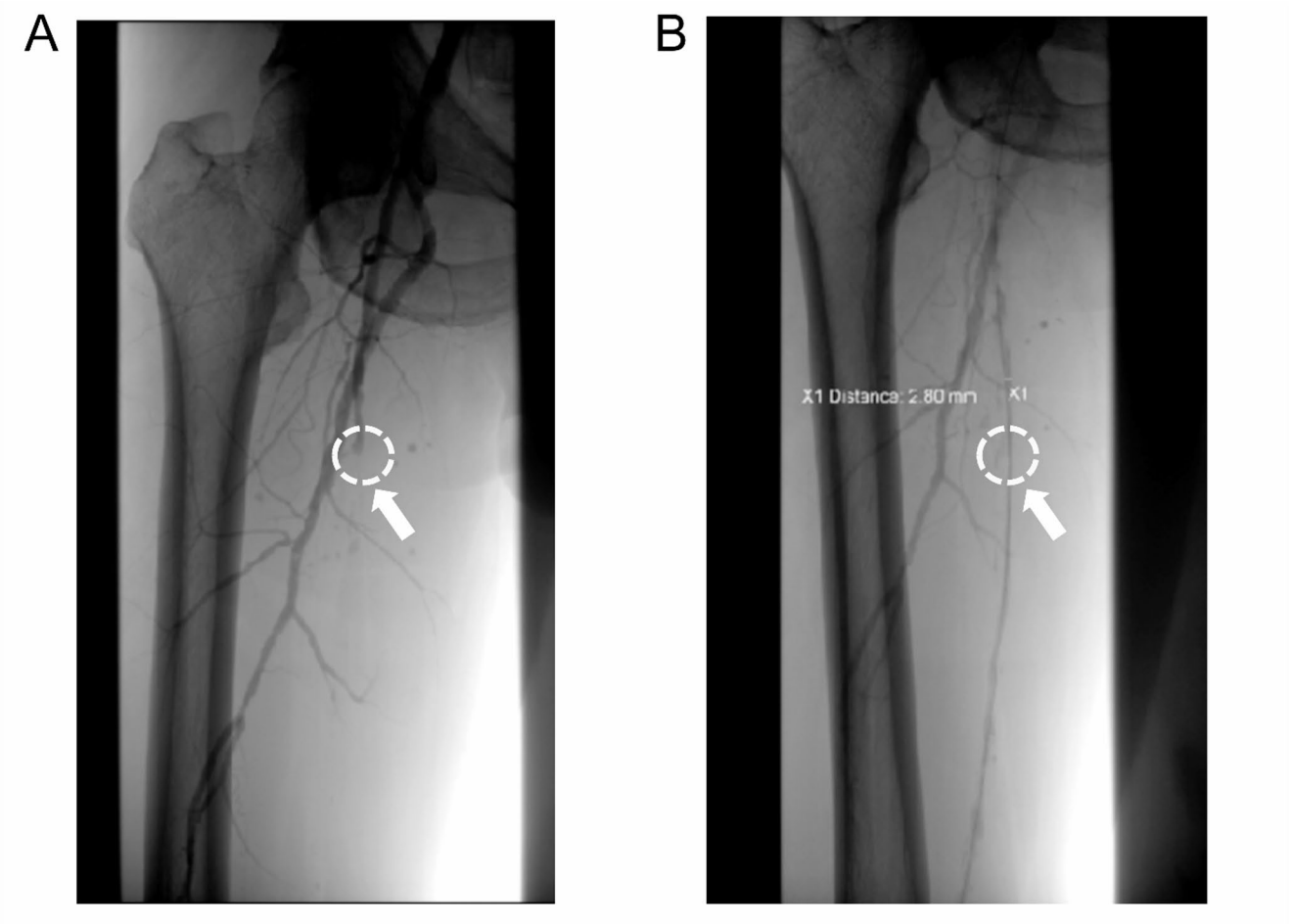

Fig. 3 Angiographic Images of CLA-355 nm Laser Treatment. (**A**) Pre-laser treatment (arrows indicating interrupted blood flow); (**B**) Post-laser treatment (arrows indicating restored blood flow)

Table 4 Device evaluation and 6-Month Follow-Up results

Variables	Values
Device-Related Adverse Events	0(0%)
Device Procedural Success Rate	100(100%)
6-Month Follow-Up Results	
Primary patency	90%
Freedom from CD-TLR	100%
Major amputation	0(0%)
MACEs	0(0%)
Death	0(0%)

CD-TLR: clinically driven target lesion revascularization, MACEs: Major Adverse Cardiovascular Events,

Categorical data are given as the counts (percentage),

Continuous data are presented as the mean ± standard deviation

TASC C for total occlusion. Based on previous literature, DCB angioplasty alone has demonstrated favorable outcomes in the treatment of such short, focal atherosclerotic lesions. Therefore, the 6-month early clinical outcomes observed in this study may largely reflect the therapeutic effect of DCB alone, rather than any additional benefit from laser atherectomy. Future randomized controlled trials comparing laser + DCB with DCB alone are warranted to clarify the true clinical value of adjunctive laser treatment; (3) The follow-up period in this study is relatively short, making it impossible to predict long-term outcomes at this stage fully. Therefore, the preliminary clinical experience of using the CLA-355 nm device for patients with lower limb arterial lesions needs to be validated in larger-scale, multicenter studies. These studies should include extensive long-term clinical follow-up and objective assessment of target lesion patency rates.

Conclusion

This study represents the first exploratory application of the CLA-355 nm laser plaque ablation system for treating lower limb atherosclerosis in humans. Preliminary results indicate that this system is highly feasibility in plaque ablation and demonstrates a high safety profile. Despite certain

limitations, the study shows promising potential for application. Future large-scale studies are necessary to verify the long-term efficacy and safety, providing more robust evidence for clinical use.

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Author contributions H.W. and J.G. initially conceptualized and designed the project, R.Z., Y. Z. and H.W. were major contributors to data collection and the writing of the manuscript, H.W., J.G., and L.G. participated in data interpretation and contributed to the writing of the manuscript. All authors have read and approved the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate All patients signed an informed written consent for participation. The trial was approved by the Ethics Committee of Xuanwu Hospital, Capital Medical University ([2022]054).

Competing interests The authors declare no competing interests.

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