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Direct selective laser trabeculoplasty: A retrospective study

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Abstract

Purpose: To investigate the effectiveness and safety profiles of Direct Selective Laser Trabeculoplasty (DSLT).

Materials and Methods: Retrospective study of 15 eyes of 10 patients diagnosed with open angle glaucoma (OAG) or ocular hypertension (OHT) who underwent DSLT in June 2023 at University Hospitals of Leicester, UK. We defined success as IOP reduced ≥20% from baseline with no additional medications needed or as a decrease in the number of anti-glaucoma medications while maintaining target IOP. We also considered secondary outcomes such as final BCVA and final number of anti-glaucoma medications.

Results: At the fourth month visit, success was reached in 11 eyes (73.3%). We registered 4 failures (26.7%). Mean IOP at baseline was 22.7 ± 4.4 mmHg and was reduced to 18.7 ± 4.2 mmHg ($p = 0.008$). The absolute mean reduction of IOP in the group of eyes that maintained unchanged the number of medications was 5.4 ± 2.7 mmHg, as baseline IOP was 21.4 ± 4.3 mmHg, and final IOP was 15.9 ± 2.3 mmHg, with a 25.7% reduction ($p = 0.003$). Mean BCVA remained unchanged (0.1 ± 0.1 logMAR, $p = 1.00$). No significant adverse events requiring surgical or clinical intervention were observed.

Conclusion: DSLT showed profiles of effectiveness and safety comparable with those of SLT in the literature and consistent with the results obtained in previous studies on DSLT itself. DSLT may represent a valid alternative to traditional SLT.

Keywords

Laser surgery < GLAUCOMA, GLAUCOMA, glaucoma medical therapies < GLAUCOMA, aqueous humor dynamics < GLAUCOMA, biochemistry/physiology of aqueous < GLAUCOMA

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Introduction

Selective laser trabeculoplasty (SLT) has in the last years acquired an essential role in primary open angle glaucoma (POAG) and ocular hypertension (OHT), as it represents the first line of treatment in these clinical contexts.[1]

Even though at times associated with usually mild inflammatory reactions or post-operative intraocular pressure (IOP) spikes, the safety and efficacy profiles of SLT have solidly been established in a number of previous studies.[2,3] Nonetheless, its use remains largely limited and kept from acquiring widespread accessibility due to several factors (unwillingness to change clinical practice patterns, challenges of talking to patients about new approaches, perceived cost, etc). A novel technique, termed direct selective laser trabeculoplasty (DSLT), uses a translimbal approach, without the use of a goniolens and without touching the cornea, and similarly to SLT, delivers laser energy to the 360 degrees of trabecular meshwork (TM) via a frequency-doubled Q-switched Nd:YAG laser with a wavelength of 532 nm.[4] Differently from SLT, it only requires alignment of the

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device with the patient's eye for the system to automatically recognize and track the target, performing the entire treatment in around 2 s.[5] This allows for a rapid and easy execution of the technique, which only requires minimal training to be performed.

In this retrospective study conducted in a tertiary care glaucoma centre we aim to describe the effectiveness of DSLT considered in terms of IOP reduction, percentage IOP reduction and number of IOP lowering agents required to control IOP before and after the procedure, as well as its safety profiles, considering a follow-up period of four months after the procedure.

Matherials and methods

Population

This was a retrospective, monocentric study. The study included all consecutive patients who underwent DSLT in June 2023 at the Ophthalmology Department, University Hospitals of Leicester NHS Trust, United Kingdom. The laser was performed by a glaucoma consultant (LO). The University Hospitals of Leicester Ethics Committee approved this study, which adhered to the tenets of the declaration of Helsinki. Written informed consent was obtained from all patients before enrolment in this study. Baseline preoperative data were collected in a comprehensive preoperatory visit. Collected data include demographic data (age, sex, ethnicity) as well as laterality and baseline ophthalmological features: baseline best corrected visual acuity (BVCA), preoperative IOP, number and class of IOP lowering agents used before surgery, type of glaucoma and history of previous SLT and ocular surgeries. IOP was measured by an experienced ophthalmologist using a calibrated Goldmann applanation tonometer (Haag Streit, Berne, Switzerland).

We included patients aged 18 or more and eyes with a previous diagnosis of primary open angle glaucoma (POAG) including normal tension glaucoma (NTG), or with a previous diagnosis of primary open angle glaucoma suspect (POAGS) or ocular hypertension (OHT). These eyes had an IOP above target with or without antiglaucoma medications or an IOP on target and on medications. We excluded all patients with secondary open angle glaucoma and closed angle glaucoma. We excluded eyes that received previous glaucoma surgeries, eyes with baseline BCVA less than 20/200, eyes that underwent cataract surgery less than 1 year prior to DSLT as well as eyes that underwent SLT less than 1 year prior to DSLT.

Laser technique

The Belkin Eagle (BELKIN Laser Ltd., Yavne, Israel) is the first DSLT laser, and it is currently available in Europe. Laser energy is delivered directly to the TM through the peripheral cornea and the limbus.

It uses a Q-switch, frequency-doubled Nd:YAG laser with a wavelength of 532 nm. It directs the 7-nanoseconds pulse, 400-µm laser beam, to the limbus region. The Eagle delivers 120 pulses of 1.8 mJ in an automated circular and consecutive pattern. Treatment requires setting up the patient and adjusting the target, as the device algorithm does the rest at the touch of a button. The laser is equipped with eye-tracking technology (SureTrac), which helps the laser to locate the intended treatment area at all times. The process is highly automated and operator independent, so that the influence of user-related variability is negligible. As a result, the training required to perform the procedure is minimal, and there is no significant learning curve associated with its implementation. Nevertheless, it cannot be stressed enough that, despite the ease with which DSLT can be performed, the decision to treat must come from specialized medical personnel with adequate experience, and cannot disregard a comprehensive ophthalmological examination – inclusive of gonioscopy – prior to treatment administration.

Post-laser management

Each patient received one drop of apraclonidine hydrochloride 0.5% immediately after the laser treatment was performed. IOP was measured 30 min after the procedure to assess possible IOP spikes. No patient received additional anti-inflammatory drops. Patients were followed with a comprehensive visit at 1 and 4 months postoperatively. During each of these visits, BCVA and IOP were measured, and comprehensive anterior and posterior segment examinations (dilated fundoscopy) were performed. The number and class of anti-glaucoma medications used by each patient was also recorded. All possible complications and complaints presenting at any time during the follow-up were accurately recorded and addressed. At each follow-up visit, IOP was measured with a calibrated Goldman applanation tonometer. The measurement was performed by an experienced ophthalmologist, and the IOP was recorded as the IOP value at 1 or 4 months of follow-up. The IOP at 4 months was referred to as final IOP.

Definition of outcomes and success

Primary outcome was defined as a success if, after four months from the procedure, IOP showed a reduction $\geq$20% from preoperative levels with no additional medications needed to achieve this target or if the technique made it possible to decrease the number of anti-glaucoma medications needed while maintaining target IOP. Primary outcome was defined as failure when the technique failed to achieve the abovementioned results. Furthermore, mean final IOP, mean number of anti-glaucoma medications and mean final BCVA were also considered. The safety profile of this technique was analysed, and all

postoperative adverse events and complications were recorded, as well as all the possible postoperative interventions needed.

Statistical analysis

Descriptive data were presented as mean and standard deviation (SD). Generalized Estimated Equations were used to calculate p-values for a mix of one or two eyes per patient in the analysis of results in IOP reduction at different time points. SPSS version 28.0 IBM was used for data analysis. A p-value <0.05 was considered significant.

Results

15 eyes of 10 patients fulfilled inclusion criteria. Mean age was 69.8 ± 10.7 years (range 49–80) and 7 subjects were male (70%) with 8 right eyes (53.3%). Most patients were of white Caucasian (90%) and Asian (10%) ethnicity. Eyes included in this study were diagnosed with OHT in 7 eyes (46.7%), POAG in 7 eyes (46.7%) and primary open angle glaucoma suspect (POAGS) in 1 eye (6.6%). At baseline, mean best corrected visual acuity (BCVA) was 0.1 ± 0.1 logMAR, mean preoperative IOP was 22.7 ± 4.4 mmHg, and mean number of glaucoma medications was 0.9 ± 0.8, with most eyes on one medication (40%, $n = 6$). Of the 15 eyes included in our study, only one eye underwent previous SLT. Table 1 describes ocular features and clinical characteristics of patients involved in the study.

Outcomes

At the fourth month visit, success was reached in 11 eyes (73.3%). Of these eyes, 7 showed a reduction of baseline IOP ≥20%, without the use of any additional medication. 4 eyes showed a reduction in the number of medications needed, maintaining target IOP (in each of these 4 cases, one drug was removed from their initial IOP-lowering therapeutic regimen).

We registered 4 failures (26.7%). In detail, in one eye, final IOP was reduced, but by less than 20%. Additionally, 2 eyes required the introduction of supplementary anti-glaucoma drugs to their regimen to reach target IOP. One eye stopped one glaucoma medication of its therapeutic regimen, but the final IOP was 2 mmHg above baseline. Table 2 shows the primary outcomes of our study and the associated percentages.

Overall, mean IOP showed a reduction from 22.7 ± 4.4 mmHg at baseline to 20.8 ± 3.8 mmHg at the first postoperative month (this reduction was not statistically significant, $p = 0.1$), and a further reduction to 18.7 ± 4.2 mmHg, at four months after DSLT (Figure 1). This final reduction was statistically significant ($p = 0.008$). Considering only those eyes that maintained the same number of drugs at baseline and at 4 months ($n = 8$, 53.3%), baseline IOP was 21.4 ± 4.3 mmHg, and it was reduced to 15.9 ± 2.3 mmHg at the final follow-up visit (Figure 2), with an absolute mean IOP reduction of 5.4 ± 2.7 mmHg (25.7% reduction). This reduction was also statistically significant ($p = 0.003$). Overall, at baseline, mean number of anti-glaucoma medications was 0.8 ± 0.9. During the follow-up period it remained stable at 0.7 ± 0.8 (first postoperative month, $p = 0.49$) and at 0.8 ± 1.0 at the fourth postoperative month (Figure 2). The number of glaucoma medications per patient was therefore not significantly reduced from baseline ($p = 0.69$). Table 3 shows individual data of each single eye examined.

Baseline mean BCVA was 0.1 ± 0.1 logMAR and remained unaltered at 0.1 ± 0.1 logMAR at the first and fourth month of follow-up ($p = 1$).

Table 1. Clinical characteristics of patients and their eyes.

Parameter	Value
Mean Age (years) ± SD	69.8 ± 10.7
Sex % (n)	
Male	70% (7)
Female	30% (3)
Laterality % (n)	
Right eye	53.3% (8)
Left eye	46.7% (7)
Race % (n)	
White Caucasian	90% (9)
Asian	10% (1)
Type of glaucoma % (n)	
OHT	46.7% (7)
POAG	46.7% (7)
POAGS	6.6% (1)
Mean BCVA logMAR ± SD	0.1 ± 0.1
Mean IOP mmHg ± SD	22.7 ± 4.4
Mean no. of glaucoma medications ± SD	0.9 ± 0.8
No. of glaucoma medications % (n)	
0	33.3% (5)
1	40.0% (6)
2	26.7% (4)
3	0% (0)
4	0% (0)

Legend: OHT: ocular hypertension; POAG: primary open angle glaucoma; POAGS: primary open angle glaucoma suspect.

Table 2. Success and failure of direct SLT at fourth month.

Total Success % (n)	73.3% (11)
IOP baseline reduced ≥20%	46.6% (7)
Target IOP mantained reducing medications	26.7% (4)
Total Failure % (n)	26.7% (4)
IOP not reduced ≥20%	6.7% (1)
Introduction of additional glaucoma drugs to reach the target IOP	13.3% (2)
Reduction of one drug, but IOP over target	6.7% (1)

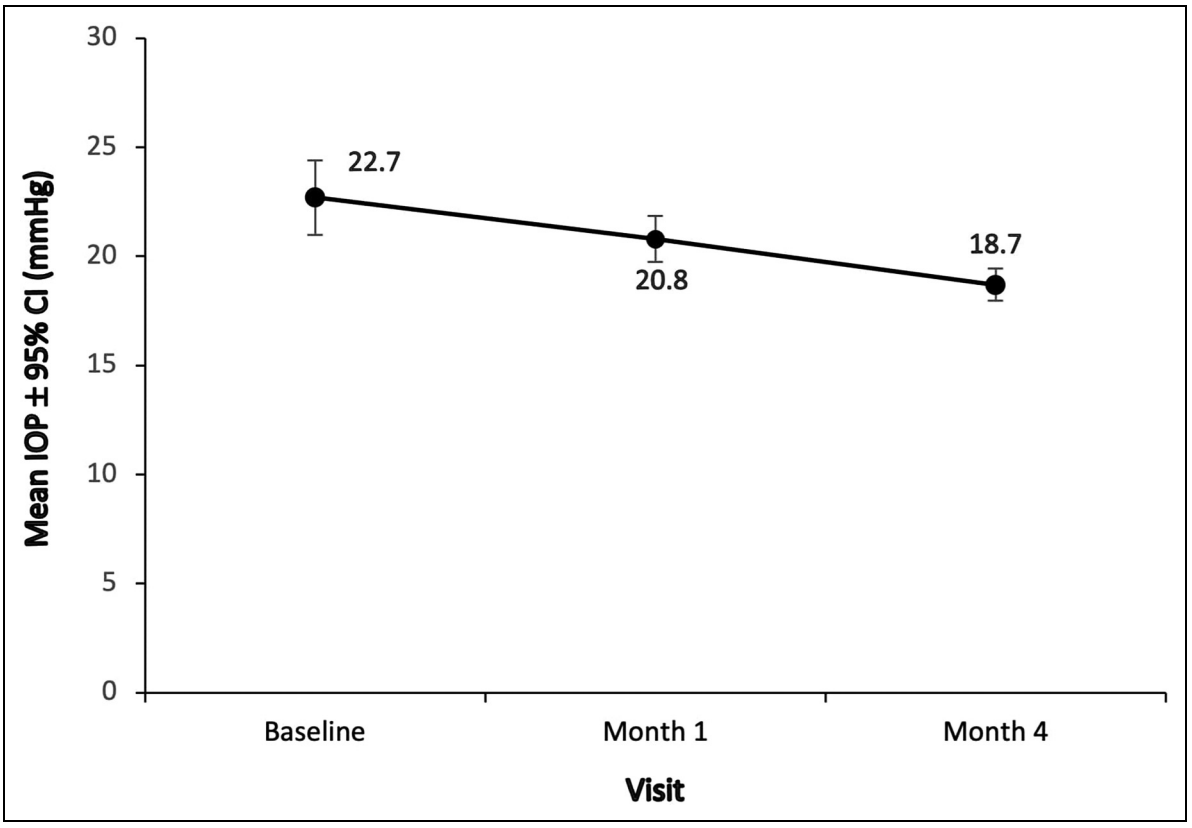

Figure 1. Mean change in baseline IOP (y-axis) at 1 month and at 4 months (x-axis) considering all patients. (IOP = intraocular pressure)

No adverse events were recorded after the DSLT treatment in our study. In only one eye IOP increased by 8 mmHg from baseline levels. This case was successfully treated with the help of a short course of IOP-lowering medications, IOP decreased, and target levels were reached by the time of the final follow-up visit without any additional drop to its preoperative therapeutic regimen.

Discussion

As elucidated in the LiGHT study, both SLT and anti-glaucoma medications have a similar IOP-lowering profile of effectiveness.[6] Over time, however, patients treated with SLT have a better stability at the visual field testing than patients on medical therapy.[6] Furthermore, patients treated with SLT are less prone to undergo subsequent glaucoma surgery and have a better quality of life than those on IOP-lowering agents.[7]

After the evidence put forward by the LiGHT study, the use of SLT as a first-line treatment for OAG or OHT, or its use in conjunction with topical IOP-lowering therapy, has rapidly increased.[7] However, in many countries, SLT fails to acquire the popularity it deserves probably because of the closed mindset and reluctancy of clinicians to change traditional approaches based on IOP-lowering agents, or for the ease of prescribing topic therapies instead of performing a laser procedure. On the other hand, in countries where SLT has already acquired widespread usage, the main limitation to treatment access might be represented by the mismatch between the high demand and the capability of the healthcare system to provide timely access to the treatment for all those who need it.

A novel therapeutic approach, the DSLT, is a highly automated process and approximately requires 2 s per eye to be performed, thereby potentially overcoming the challenges that traditional SLT poses.[8]

DSLT allows the treatment of patients with open iridocorneal angles that result difficult to visualize in primary position, as well as of patients with unfavourable anatomic characteristics, such as prominent facial and orbital bones, that make the procedure difficult to be performed. It also facilitates treatment in non-collaborative patients or in patients with photophobia or that do not tolerate being touched on the cornea with a gonioscopy lens. System automation should make treatment delivery more standardized and less user dependent. Additionally, DSLT uses a lower amount of total energy per treatment compared to traditional SLT; this element, combined with it being a no-touch technique, may imply a lower rate of infective, inflammatory and IOP spikes-related complications.[4,9]

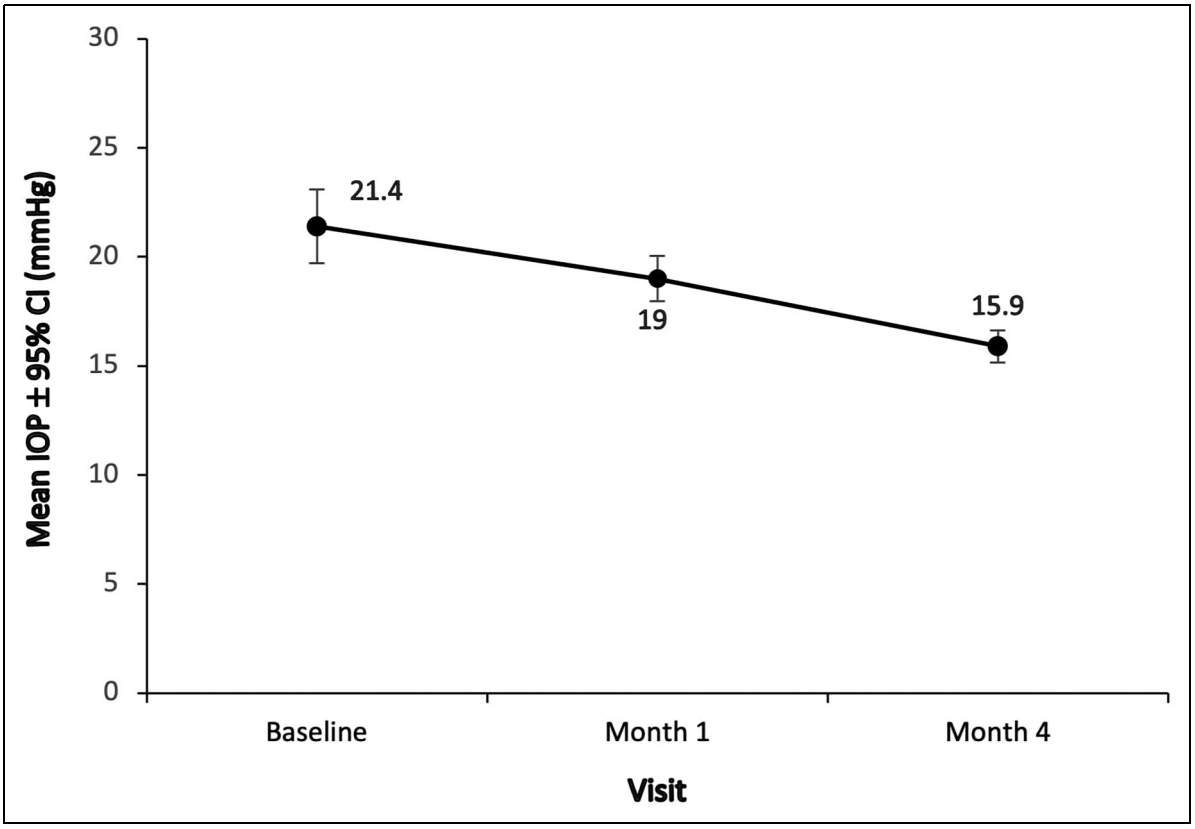

Figure 2. Mean change in baseline IOP (y-axis) at 1 month and at 4 months (x-axis) considering only those eyes that maintained the same number of drugs. (IOP = intraocular pressure)

Table 3. Individual data (IOP mmHg and number of glaucoma medications) of each single eye at baseline, first month and fourth month.

	Baseline		Month 1		Month 4	
Eyes	IOP	N. Med	IOP	N Med	IOP	N Med
1	24	0	21	0	17	0
2	24	0	19	0	16	0
3	18	0	15	0	14	0
4	20	0	15	0	14	0
5	18	1	26	1	15	3
6	24	1	25	0	21	0
7	22	1	21	0	21	0
8	22	1	22	1	24	0
9	24	1	17	1	22	0
10	15	2	18	2	15	2
11	18	2	18	2	13	2
12	28	2	26	1	24	1
13	28	2	20	2	19	2
14	31	0	23	1	26	1
15	24	1	26	0	19	1

DLST also presents some disadvantages, as it is not possible to adjust laser energy according to trabecular meshwork tissue response. This is feasible with traditional SLT, in which laser energy is often titrated so to produce an optimal TM response and set 0.1 mJ below the threshold energy at which the formation of cavitation bubbles is observed.[10]

We report that, at least in a follow-up period of 4 months, DSLT seems to offer a percentage of success (73.3%) comparable with that attributed to SLT. Barkana et al.[11] evaluated in a meta-analysis the success rate that SLT had in 20 reference studies, and they showed that it ranged between 10 and 96%. Damji et al.[12] reported the percentage of SLT success, defined as a reduction in IOP $\geq 20\%$ without any additional medication, was 53.9% at 3 months, and 61.5% at 6 months. Moreover, Hodge et al.[13] showed that the percentage of success, defined as a reduction in IOP $\geq 20\%$ without any additional medication, was 60% at 1 year of follow-up.

Additionally, we observed that DSLT could have IOP lowering effects comparable to those observed with traditional SLT in the literature, as we registered a significant reduction of final IOP from preoperative levels, both numerically and in terms of percentage reduction. In particular, Wong et al.,[14] in a meta-analysis, considered 35 studies which assessed SLT efficacy. In terms of percentage IOP reduction, it was reported that, after at least 12 months of follow-up, mean percentage IOP reduction

ranged from 6.9 to 35.9%, with a mean reduction among the studies of 21.50%. Babighian et al.[15] showed a mean IOP reduction from 23.9 ± 0.9 mmHg at baseline to 19.1 ± 1.8 mmHg at the final follow-up visit with a final mean percentage reduction of 21%. Accordingly, in our study we observed a reduction of IOP from baseline (22.7 ± 4.4 mmHg) to the final follow-up visit (18.7 ± 4.2 mmHg). In eyes that maintained the same number of medications pre and postoperatively, the baseline IOP of 21.4 ± 4.3 mmHg decreased to 15.9 ± 2.3 mmHg, with a 25.7% IOP reduction. In our study, eyes that maintained unchanged the number of antiglaucoma therapeutic agents, showed a mean absolute IOP reduction of 5.4 ± 2.7 mmHg. This result is also similar with those in the existing literature on SLT.[16–18]

Furthermore, in our study, DSLT showed optimal safety profiles, comparable in terms of nature with those offered by SLT.[18] In our study, no significant side effects or complications were observed; therefore, no clinical or surgical intervention was needed in our cohort of patients. Only one eye in our study had a post-DSLT IOP elevation. In this case, IOP elevation over baseline was observed, but was then resolved by a short course of medical therapy.

The results obtained in our study are comparable with the two existing pilot studies on DSLT. Geffen et al.,[5] in the first clinical study on DSLT, reported a 23.4% and a 20.83% IOP reduction at 6 and 12 months, respectively, in a group of 14 eyes diagnosed with POAG or pseudoexfoliation glaucoma that received treatment with DSLT. Goldenfeld et al.,[8] in the second clinical study on DSLT, showed that this technique determined a reduction of IOP, from baseline values of 26.7 ± 2.3 mmHg to 21.5 ± 4.1 mmHg (18.8% reduction) at 6 months. Preliminary results from the GLAUrious trial, a large, multicentre, randomized clinical trial, presented in April 2023, showed that DSLT can determine a reduction of unmedicated IOP at 6 months of 5.46 ± 0.51 mmHg (our study showed a reduction of 5.4 ± 2.7 mmHg at 4 months).[19] In these preliminary results it was showed that the mean number of medications used by patients who received DLST treatment was reduced by approximately 50%, from 1.19 ± 1.01 at baseline to 0.63 ± 0.94 at 12 months. In addition, over half of patients (61.7%) who underwent DSLT did not need to use anti-glaucoma medications at 12 months. Our results seem therefore comparable with previous findings in the existing literature.

Our study has several limitations, including the limited sample size and the relative diversity of the cohort of patients included in the study, who varied, among other factors, for use or not of antiglaucoma medications prior to treatment. Other limitations include the short follow-up period considered, as well as the nature itself of the study. Large randomized, controlled clinical trials are needed to shed further light on the role that DSLT could have in the treatment of glaucomatous patients.

As a study group, we desire to extend the use of DSLT in clinical practice, and we could bring more interesting results in the future relative to a greater number of patients and to longer follow-ups. In conclusion, this study investigated the role of DSLT in patients with OAG and OHT, its efficacy and safety profiles. The promising results we obtained in our study may elicit further enthusiasm for DSLT and pave the way for large, randomized and controlled clinical trials.

Declaration of conflicting interests

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Informed consent statement

A written informed consent form was obtained from the patient to publish these data.

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