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First results of direct selective laser trabeculoplasty for the treatment of glaucoma

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ABSTRACT

Aim To evaluate the efficacy and safety of direct selective laser trabeculoplasty (DSLT) on eyes with primary open-angle glaucoma (POAG) and on primary angle closure glaucoma (PACG) eyes at 1 year follow-up.

Methods In this study, 54 patients affected by POAG (76) or PACG (28) undergoing DSLT were enrolled, for a total of 104 eyes. Before each treatment and at each follow-up visit, all subjects underwent a complete eye visit, including the collection of data regarding the number and type of topical medications prescribed for glaucoma. The patients treated underwent 30–2 standardised automated perimetries prior to DSLT, at 6 months and 12 months post DSLT procedure. Each patient was checked at 1 week and subsequently at 1, 3, 6 and 12 months.

Results At 1 month follow-up, both the eyes affected by POAG and those affected by PACG showed significantly ($p<0.01$) lower mean intraocular pressure (IOP) (−3.67±2.95 mm Hg and −3.93±2.36 mm Hg, respectively) and lower mean number of IOP-lowering topical drugs taken (−0.62±0.57 and −0.78±0.64, respectively) after DSLT. These reductions remained significant until the 1 year follow-up, both for IOP (−3.76±2.84 mm Hg and 3.67±2.46 mm Hg, respectively) and for drugs assumed (−0.79±0.53 and 0.96±0.47, respectively). The mean deviation mean values showed perimetry stability both in POAG and in PACG eyes at 1 year follow-up. No major complications were observed in the eyes included in this study.

Conclusions Although this study has some limitations such as the retrospective design, the lack of comparison with standard selective laser trabeculoplasty (SLT) and the relatively short follow-up, the results observed require confirmation through further studies, with extended follow-up and larger cohorts. This study suggests that DSLT would be a useful tool for the management of patients with glaucoma.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Glaucoma is one of the most complicated eye diseases to manage.
⇒ Selective laser trabeculoplasty (SLT) is an intraocular pressure (IOP) lowering procedure recognised to be safe and effective in patients with glaucoma.
⇒ Recently, a device able to perform SLT in an alternative way has been released. It is able to target directly (direct-SLT (DSLT)) the trabecular meshwork without using gonioscopic lens. Studies evaluating DSLT are needed to check safety and effectiveness.

WHAT THIS STUDY ADDS

⇒ Data from this study suggest DSLT to be a safe and effective IOP-lowering procedure both in primary open-angle glaucoma (POAG) and in primary angle closure glaucoma (PACG) eyes.
⇒ After 1 year of treatment, a significant reduction of IOP-lowering drugs has been detected.
⇒ The efficacy of the IOP-lowering effect appears to be related to the IOP and the number of drugs assumed before treatments.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Results of this study suggest that DSLT could be used as a routine IOP-lowering procedure both in POAG and in PACG eyes.
⇒ Further studies need to confirm the results observed in this one in larger populations and longer follow-up.
⇒ More studies are needed to understand the role of DSLT in the overall glaucoma care.

INTRODUCTION

The term glaucoma is used to identify a group of optic nerve diseases characterised by optic neuropathy and progressive visual field (VF) loss, a multifactorial disease which, if left untreated, can lead to blindness.[1] Elevated intraocular pressure (IOP) is the greatest risk factor for the disease, but it must be remembered that IOP can also be normal or relatively low.[2 3] Other risk factors for glaucoma onset are ageing, surgery, drugs and laser treatments. Therapeutic strategies for glaucoma target IOP lowering, which is essentially the only modifiable risk factor, include topical drugs, laser treatments or surgery.[2 3]

The latest European Glaucoma Society guidelines suggest that selective laser trabeculoplasty (SLT) be considered a first-line treatment option in primary open-angle glaucoma (POAG) eyes due to its widely proven efficacy and safety.[4] A further, great advantage of this procedure is a reduction in the use

Table 1 Main characteristics of patients included in the study, affected either by primary open-angle glaucoma (POAG) or primary angle closure glaucoma (PACG)

	POAG	PACG
Age (years)	61.55±15.30 (from 21 to 87)	57.45±14.63 (from 27 to 75)
CCT (µm)	539.41±46.26 (from 382 to 644)	541.80±43.18 (from 471 to 642)
Visual acuity (Snellen lines)	0.81±0.90 (from 0.3 to 1)	0.85±0.27 (from 0.3 to 1)
Phakic eyes	93 (76.9%)	18 (90%)
Pseudophakic eyes	28 (23.1%)	2 (10%)
Hodapp's severity classification		
Early	42	15
Moderate	23	9
Advanced	11	4
Drugs assumed		
None	8	4
Timolol	8	0
Bimatoprost 0.1%	13	8
Tafluprost	8	0
Travoprost	8	4
Latanoprost	4	2
Brimonidine	4	1
Brinzolamide	2	1
Dorzolamide	2	2
Fixed combination timolol brimonidine	7	6
Fixed combination timolol brinzolamide	12	4
Fixed combination timolol dorzolamide	32	16
Fixed combination timolol tafluprost	34	4
Fixed combination timolol bimatoprost	36	20

CCT, central corneal thickness.

of topical antiglaucoma drugs which is, in turn, linked to a lower percentage of patient failure in adhering to medical therapy and to an improvement of the overall clinical conditions of the ocular surface, which can strongly condition surgical outcomes.[5 6] SLT has also been proven to be more effective than medical therapy in reducing diurnal IOP fluctuation,[7] and some studies have also reported SLT's effectiveness in lowering IOP, even in primary angle closure glaucoma (PACG).[8–11] However, due to the complexities of visualisation and treatment of the trabecular meshwork (TM) in these patients, which arise from anatomical characteristics, it has not been widely adopted in clinical practice.[8–11]

Recently, certain studies have reported the first data regarding the use of a new device with a patient with POAG in performing a translimbal automatic SLT called direct SLT (DSLT).[12 13]

DSLT is an innovative and contactless procedure that automatically delivers laser energy through the corneal limbus overlying the TM, treating the entire 360 degrees in just a few seconds.[12]

The purpose of this study is to evaluate the efficacy and safety of DSLT on eyes with POAG and PACG, and it is one of the first studies to report a 1 year follow-up.

METHODS

This prospective single-centre study was conducted at the Eye Unit of University della Campania Luigi Vanvitelli with 104 eyes of 54 patients affected by POAG (76) or PACG (28) who underwent DSLT between February 2023 and May 2024.

It was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Every patient enrolled in the study had previously been treated or newly diagnosed in the Glaucoma Office. POAG was defined as the presence of an open irido-corneal angle evaluated on gonioscopy associated with typical VF

Table 2 Values of intraocular pressure (IOP), number of topical drugs taken and mean defect (MD) measured on standardised automated perimetry (SAP) in the primary open-angle glaucoma (POAG) eyes and the primary angle closure glaucoma (PACG) eyes included in this study, measured before treatment, after 3 hours and at 1, 3, 6 and 12 months

POAG						
	Before	3 hours later	1 month FU	3 months FU	6 months FU	12 months FU
IOP (mm Hg)	17.36±3.20 (from 10 to 30)	18.06±4.16 (from 10 to 24) p=0.23	13.69±2.78 (from 8 to 25); p<0.05	12.79±1.89 (from 10 to 16); p<0.05	12.74±1.66 (from 11 to 16); p<0.05	13.63±1.39 (from 10 to 18); p<0.05
Drugs	2.1±0.81 (from 0 to 4)		1.48±0.57 (from 0 to 2); p<0.05	1.42±0.62 (from 0 to 2); p<0.05	1.29±0.63 (from 0 to 2); p<0.05	1.31±0.61 (from 0 to 2); p<0.05
MD (dB)	−6.34±7.55 (from −25.30 to 1.53)				−6.55±7.68 (from −24.41 to 2.10); p=0.17	−7.02±7.36 (from −24.92 to 1.85); p=0.22
PACG						
IOP (mm Hg)	17.05±3.06 (from 10 to 23)	17.05±2.09 (from 14 to 23) p=0.16	13.12±2.03 (from 9 to 18); p<0.05	13.33±1.72 (from 10 to 16); p<0.05	13.42±2.54 (from 9 to 18); p<0.05	13.38±1.98 (from 10 to 18); p<0.05
Drugs	2.2±0.83 (from 1 to 3)		1.42±0.5 (from 0 to 3); p<0.05	1.27±0.46 (from 0 to 2); p<0.05	1.32±0.52 (from 0 to 3); p<0.05	1.24±0.48 (from 0 to 3); p<0.05
MD (dB)	−5.61±7.05 (from −23.18 to 1.44)				−6.06±7.54 (from −24.55 to 0.42); p=0.12	−5.83±7.21 (from −23.48 to 1.85); p=0.14

FU, follow-up.

alteration of glaucoma disease from at least two reproducible, consecutive standardised automated perimetries (SAP) performed over 2 months using Humphrey Field Analyzer (HFAII, Carl Zeiss Meditec, Dublin, California, USA), standard 30–2 or 24–2 programme.[14] PACG was defined as the presence of a synechial angle closure of 180 degrees or more, associated with a II grade angle of over 90 degrees according to the Shaffer classification on gonioscopy, and with significant glaucomatous damage to the optic nerve detected through two or more reproducible, consecutive SAP performed over 2 months using Humphrey Field Analyzer (HFAII, Carl Zeiss Meditec, Dublin, California), standard 30–2 or 24–2 programme.[15]

Reliability criteria for VF were the following: fixation losses<20%; false-negative error<33%; false-positive error<33% as reported in other, similar studies.[14]

Before treatments, all subjects included in the study underwent a complete eye visit, including Scheimpflug camera scan of the anterior segment (Pentacam HR, Oculus, Wetzlar, Germany), IOP assessment with Goldmann applanation tonometry (Haag Streit, Koeniz, Switzerland), perimetry report evaluation, fundus examination with indirect ophthalmoscopy and gonioscopy, performed with Gonio-4 lens (Volk Enterprise, mentor, USA). In addition, data regarding the number and type of topical medications for glaucoma were collected for each patient.

The patients included were 18 years or over (mean age of 61.12±11.82 years, from 39 to 87 years old) and affected by POAG or PACG. Patients who had previously undergone cataract surgery were included only if the surgery had been performed at least 1 year before treatment.

Every patient with PACG included in the study had had peripheral laser iridotomy and/or cataract surgery in both eyes. Other exclusion criteria were: previous glaucoma or vitreoretinal surgery, prior corneal refractive surgery, prior SLT and dense pigmentation or perilimbal conjunctival haemorrhage. Any participant requiring ocular surgery or additional laser procedure for glaucoma of any kind was excluded from the study, and only presurgery follow-up data for those patients were included. DSLT was offered either as first-line treatment or for patients who had been taking IOP-lowering drugs. The main characteristics of patients included in the study are shown in table 1.

For patients with POAG, DSLT procedures were performed with the objective of reaching the Canadian Target IOP Workshop specified Targets, based on disease severity stratification (ocular hypertension (OHT) and mild, moderate or severe POAG).[16] Eye-specific target IOP was determined in relation to single untreated baseline (month 0) IOP measurement: eyes with mild POAG had baseline minus 20% target IOP or below 21 mm Hg (whichever was lower), eyes with moderate POAG had baseline minus 30% target IOP or below 18 mm Hg (whichever was lower) and eyes with advanced POAG had baseline minus 30% target IOP or below 21 mm Hg (whichever was lower). For patients affected by PACG, the IOP target was less than 18 mm Hg or reduced at least

20% from baseline.[4] Achievement of these parameters or a reduction in medical therapy was classified as successful treatment.

When an IOP reduction of over 20% was observed in both eyes after treatment, compared with target values, with the patient's consent, the less hypotensive drug was discontinued. IOP was checked again after 2 weeks and, if the Canadian Target IOP Workshop specified targets continued to be reached, the patient continued not to take that drug until the next follow-up.

Compared with the traditional SLT, DSLT uses the same laser wavelength of 532 nm, identical spot size of 3 nm and identical target on TM but does not require the lens.[13 17] DSLT treatment aims to reach the TM via the conjunctiva and scleral limbus, by applying 120 Yttrium Aluminum Garnet (YAG) laser spots of 400 nm diameter and 3 ns duration at the limbus.[18]

DSLT was delivered in accordance with the predefined protocol to 360° of the TM through about 120 shots and about 240 mJ of total energy.[13]

All treatments were performed under topical anaesthesia with oxybuprocaine eye drops. A speculum was applied, and both eyes of every patient were planned to be treated. IOP was checked 3 hours post-treatment in order to detect eventual spikes, and the following therapy was prescribed: acetazolamide 250 mg tablets, 2 times a day for 3 days and diclofenac 0.1% eye drops, 3 times a day for a week; this treatment is in accordance with the hospital guidelines for patients undergoing SLT, regardless of the IOP value detected 3 hours after treatment, in order to avoid IOP spikes in the days following procedures. Each patient was checked at 1 week and subsequently at 1, 3, 6 and 12 months follow-ups. The patients treated underwent 30–2 SAP at 6 and 12 months post DSLT procedure.

Statistical analysis

The fulfilment of the data requirements for parametric analysis (normality and homogeneity of variance) was assessed by specific tests (Kolmogorov-Smirnov and Levene). Both eyes of the patients were included, but Bonferroni correction was applied to the statistical analysis to avoid any potential bias due to inner correlations in parameters of pair organ bias. Differences between IOP, mean deviation (MD) values and the number of drugs taken by patients before and after treatment were evaluated with paired student's t-test. Univariate correlations among parameters were performed using Regression Analysis. For all tests, the level of significance was set at $p<0.01$. All analyses were performed using SPSS software (IBM, Armonk, New York, USA) V.26.0.

RESULTS

At the 1-month follow-up, both the eyes affected by POAG and those affected by PACG showed a significant reduction in mean IOP after DSLT. These reductions remained stable until the last follow-up at 1 year post laser treatments, both in the POAG and PACG eyes (table 2). The number of medications used by patients affected by POAG and by PACG was significantly lower after 1 month, remaining stable until 1 year follow-up in both groups (table 2). MD values showed stability of perimetry both in POAG and in PACG eyes (table 2).

In POAG, a mean of 118.49±6.43 laser spots with a mean total energy of 211.02±23.00 mJ were used, whereas in PACG a mean of 116.85±13.85 laser spots with a mean total energy of 207.38±28.00 mJ were used. According to the data in this study, IOP reduction showed significant correlation with IOP values at baseline (figures 1 and 2), whereas no significant correlations were observed with mean central corneal thickness, mean MD, mean number of spots used or mean energy delivered. What is more, a reduction in the need for IOP-lowering drugs after 1 year of treatment showed significant correlation with higher IOP values and higher number of drugs used before DSLT (figures 1 and 2).

The percentage of successful treatment observed both in POAG and in PACG eyes at every follow-up is represented in figure 3, patients not reaching a successful result were managed, according to their condition, with other medical, laser or surgical therapies.

In four patients, bilateral treatment was not performed because of a large gerontoxon that prevented the software of the laser device from recognising the limbus and tracking the eye.

In all the DSLT-treated eyes, a conjunctival haemorrhage of varying dimensions was observed, subsequently disappearing with no additional therapy.

The cells detected immediately after DSLT in the anterior chamber in all eyes treated disappeared after 1 week with no additional therapy.

No IOP spikes, peripheral anterior synechiae developed after treatments or other kinds of complications were detected in the patients included in the study.

Gonioscopy was repeated 1 month after DSLT in all PACG eyes in order to identify any post-laser anomalies of the angle. On comparison with the pretreatment situation, no changes were detected.

DISCUSSION

Laser selective trabeculoplasty is a well-established, well-evaluated treatment option for patients affected by OHT and POAG,[3 14 19–25] but it has also been demonstrated to be effective in PACG eyes.[9 26 27]

Particularly when proposed in early-stage glaucoma,[3] this kind of treatment has also demonstrated clear cost/benefit ratio advantages.

The device evaluated in this study aims to perform the same procedure in a different way: by targeting the TM through the conjunctiva and the sclera.[13] Despite the limited cohort and relatively short follow-up evaluated, initial reports regarding safety and efficacy of this procedure have produced interesting results.[13]

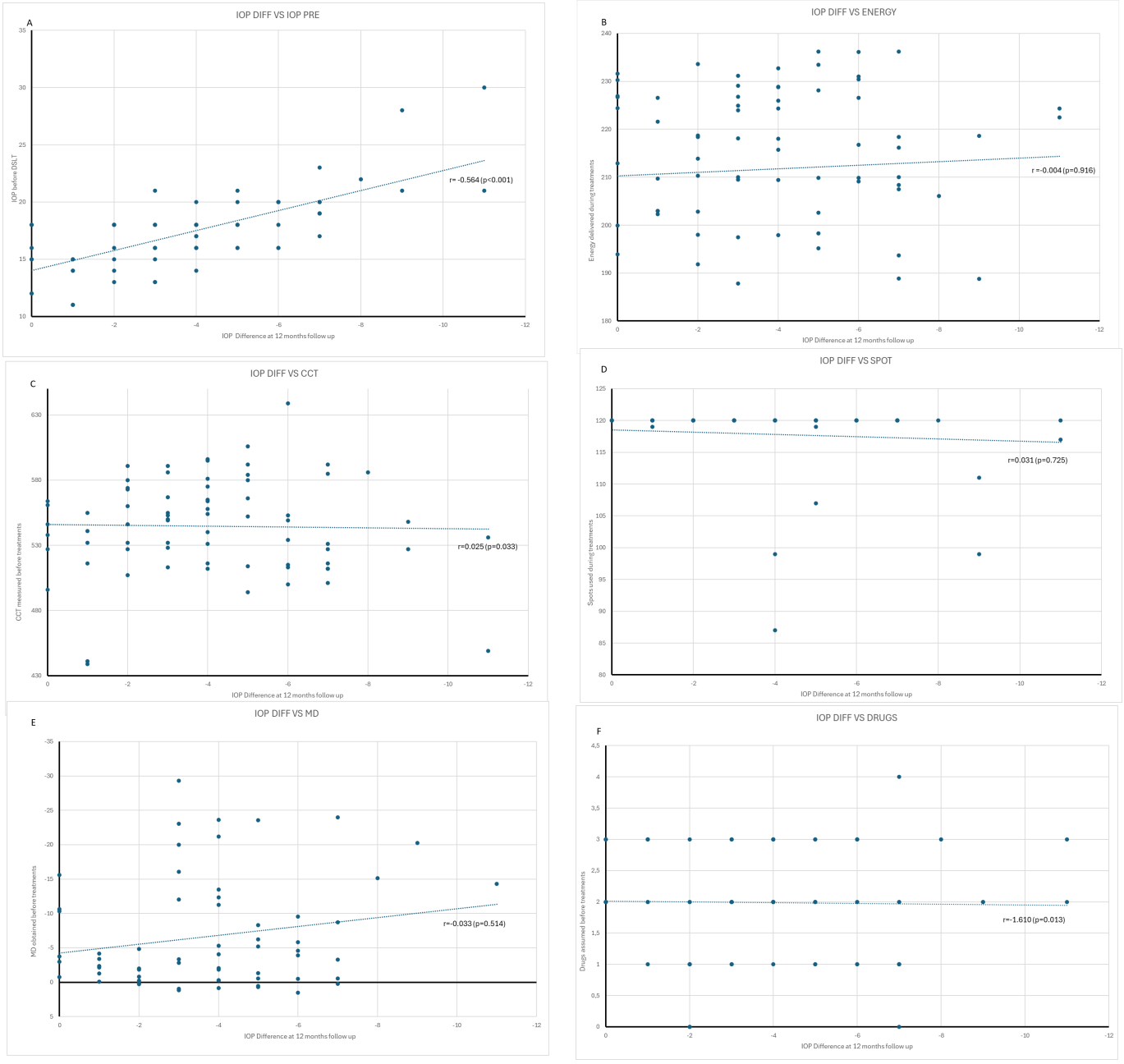

Figure 1 Scatterplot representing the regression analysis performed to evaluate correlations between intraocular pressure (IOP) differences measured at 12 months and IOP measured before treatments (A), energy delivered during treatments (B), central corneal thickness (C), spots used during treatments (D), mean deviation of the standardised automated perimetry before treatments (E) and drugs taken before treatments (F), in patients affected by primary open-angle glaucoma. CCT, central corneal thickness; DSLT, direct selective laser trabeculoplasty; MD, mean deviation.

Increasing the number of effective safe options available for the management of glaucoma eyes is a priority with the foreseen increase in life expectancy worldwide, with a resulting dramatic increase in the number of patients affected in the near future.[28] It is even more important to find alternative treatment options for PACG, which is associated with a higher risk of loss of vision.[26 27]

Although wider evaluation is required, DSLT appears to be an interesting tool for glaucoma specialists and eye care physicians. The data observed in this study demonstrate that it reduces both IOP and the medications required in both POAG and PACG eyes, with no mean reduction in retinal sensitivity as evaluated on SAP at 1 year post-treatment in both groups. The rate of success of this procedure observed in this study (figure 3) is very satisfying and, interestingly, it is increasing during the first year of follow-up. This is due to the fact that in the success criteria, reduction in medical therapy was included and, sometimes, the drugs were discontinued later in the follow-up to avoid some IOP rebound spikes. A decrease in the rate of success is expected, as for SLT, in the next few years,

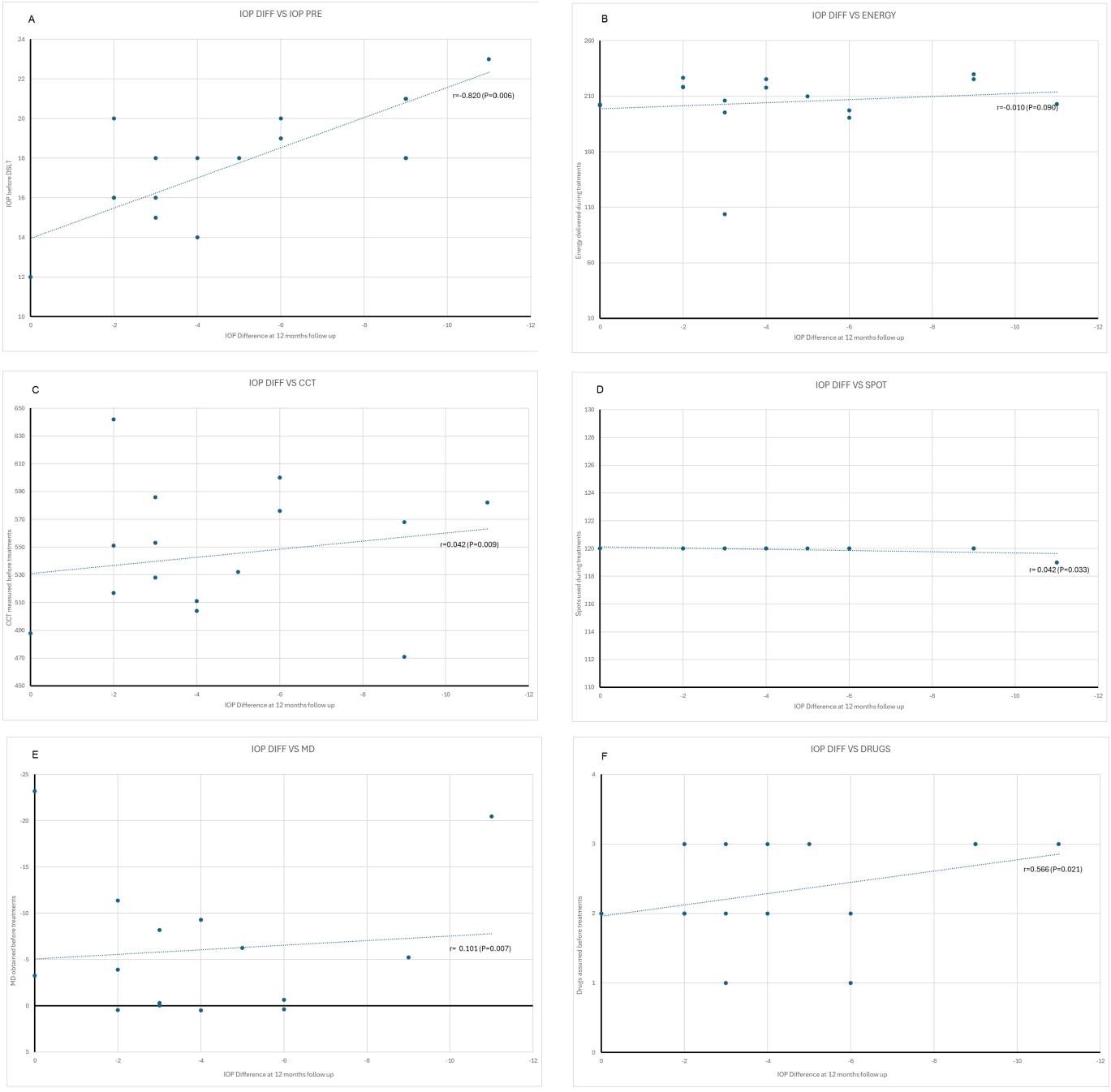

Figure 2 Scatterplot representing the regression analysis performed to evaluate correlations between intraocular pressure (IOP) differences measured at 12 months and IOP measured before treatments (A), energy delivered during treatments (B), central corneal thickness (C), spots used during treatments (D), mean deviation of the standardised automated perimetry before treatments (E) and drugs taken before treatments (F), in patients affected by primary angle closure glaucoma. CCT, central corneal thickness; DSLT, direct selective laser trabeculoplasty; MD, mean deviation.

and it will be very interesting to compare it with the available data regarding SLT.

The device has some ergonomic disadvantages, at times making treatments less comfortable, both for physicians and patients. In addition, it requires wide 360° limbus exposure, so in cases where a large gerontoxon is present, the software fails to scan the eye and treatment cannot be carried out. In this study, four patients did not receive the bilateral treatment because the software did not recognise the limbus. Consequentially, in these cases, the first eye underwent DSLT and the other SLT a few minutes later.

This limitation needs to be taken into account during patient selection. Patients also need to be informed that they will have post-treatment ocular haemorrhage. The cells detected in the anterior chambers post-treatment may have been related to an inflammatory reaction and/or pigmented epithelium cell movement just after the procedure, but this produced no vision impairment and resolved without any additional therapy within 1 week.

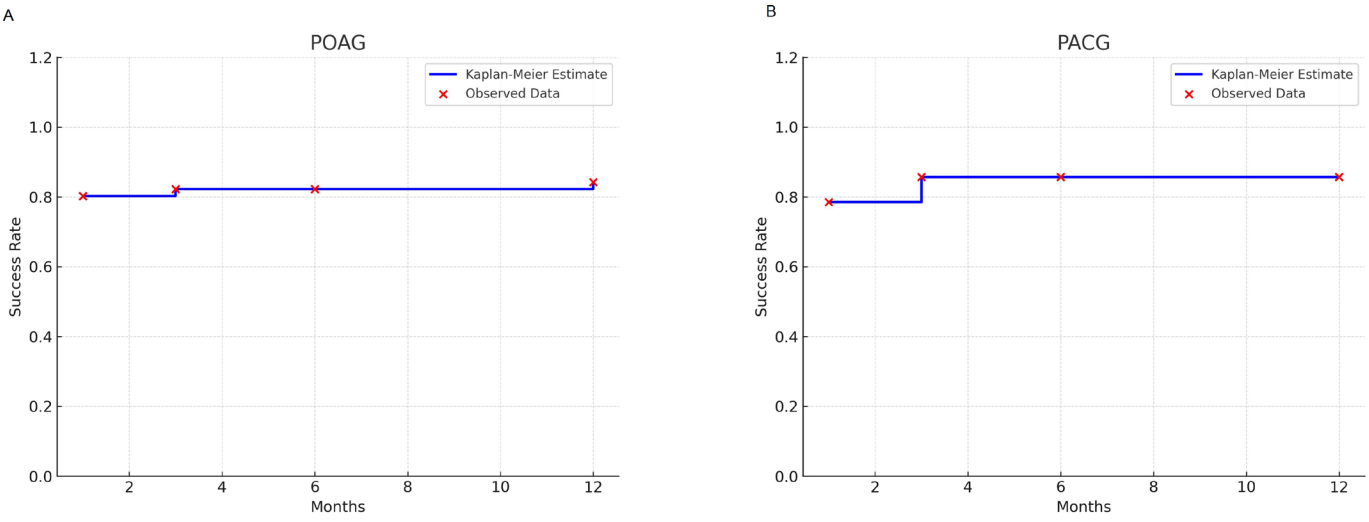

Figure 3 Scatterplot representing the Kaplan-Meier survival curve both for (A) primary open-angle glaucoma (POAG) and for (B) primary angle closure glaucoma (PACG) during the 1 year follow-up from direct selective trabeculoplasty.

Although no IOP spikes were detected in the patients included in this study, oral acetazolamide was, nevertheless, prescribed for all patients prior to leaving the hospital, as suggested in various papers.[29] This is part of the routine treatment approved by hospital guidelines in order to avoid IOP spikes after SLT procedures, so it was also adopted for DSLT.

The limitations of this study are mainly design-related: although a randomised study, evaluating DSLT with other therapies, would have provided comparative data, our main objective was to assess safety and effectiveness of this new device, rather than compare DSLT to SLT or other therapies. Moreover, a randomised study would not have permitted the collection of data regarding the number of eyes and months of follow-up shown here. This is the first study to provide such a large cohort of eyes treated with DSLT, with 1 year follow-up, in a real-life scenario, and much useful information has been garnered, from both a clinical and research point of view.

It should be noted, however, that 1 year follow-up is a brief time period for the evaluation of disease progression with SAP, thus the values observed require careful interpretation.

The IOP and reduction in medications shown in this study are similar to those reported after SLT, the lowering effect being more evident in patients with higher initial IOP (table 3) as previously reported in SLT studies.[2 3] The greatest difference between SLT and DSLT seems to be the speed of the procedure. Treatment duration, after the eye has been locked by the eye-tracker, is just 2 s. The procedure itself is extremely straightforward and could even be carried out by a first or second-year resident in ophthalmology. These aspects would allow large volumes of DSLT treatments to be carried out in a relatively short time, should the data observed here be confirmed by further studies. The IOP lowering and drug reduction in PACG is very interesting because these data would open the possibility of another option in the management of these eyes that are more challenging for a glaucoma specialist.

In conclusion, the preliminary data coming from this study suggest that DSLT is a safe procedure, effectively reducing both IOP and the medications required, not only in POAG but also in PACG. Further evaluations, including larger cohorts and longer follow-up, would be required to assess the role of this procedure in overall glaucoma care, but this study suggests that it is a potentially valuable tool for glaucoma physicians in the management of their patients.

Table 3 Percentages of eyes with successful direct selective trabeculoplasty (DSLT), according to Canadian Target IOP Workshop specified Targets, at 1, 3, 6 and 12 month follow up (FU). Primary open angle glaucoma (POAG), primary angle closure glaucoma (PACG)

	1 month FU	3 months FU	6 months FU	12 months FU
POAG				
Successful treatment	80.26%	82.29%	82.29%	84.21%
PACG				
Successful treatment	78.57%	85.71%	85.71%	85.71%

Contributors ML (guarantor): research design, data analysis and interpretation, manuscript preparation; LS: data acquisition, research execution and data analysis; RB: research execution and manuscript preparation; TC: data acquisition and data interpretation; IF: data analysis, data interpretation and manuscript preparation; SA: data acquisition and research execution; FS: research design, manuscript preparation, supervision.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by AziendaOspedalieraUniversitaria, 'Università degli Studi della Campania Luigi Vanvitelli', 0012575/2022. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request.

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