Hydrus microstent compared to selective laser trabeculoplasty in primary open angle glaucoma: one year results

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ABSTRACT

Background: To compare the reduction of intraocular pressure (IOP) and glaucoma medications following selective laser trabeculoplasty (SLT) versus stand-alone placement of the Hydrus microstent, a microinvasive glaucoma surgery device.

Design: Prospective interventional case-series. University practice.

Participants: Fifty six eyes (56 patients) with uncontrolled primary open-angle glaucoma.

Methods: Patients received either SLT (n = 25) or Hydrus implantation (n = 31) in two centres. Patients were evaluated at baseline and 1, 7 days, 1, 3, 6 and 12 months after surgery.

Main Outcome Measures: Intraocular pressure and number of glaucoma medications variations inter-groups and intra-groups.

Results: There were no significant differences at baseline between groups, but the mean deviation was worse in the Hydrus group (−8.43 ± 6.84 dB, confidence limits (CL)−2.8/−3.3 vs.−3.04 ± 0.65 dB, CL−6/−10.8; P < 0.001). After 12 months, there was a significant decrease in IOP and medications in the Hydrus group compared with baseline values. In the SLT group, only the decrease in IOP was significant. There was 3-fold greater reduction in medication use in the Hydrus group compared with SLT (−1.4 ± 0.97 vs.−0.5 ± 1.05, P = 0.001). 47% of patients were medication free at 12 months in the Hydrus group (4% in the SLT group). No complications were recorded in the SLT group. In the Hydrus group, three patients experienced a temporary reduction of visual acuity post-operatively, and two patients had post-operative IOP spikes that resolved within one week.

Conclusions: Both SLT and Hydrus implantation reduced IOP without serious adverse events. Hydrus implantation led to a significant and further reduction in medication dependence at 12 months.

Key words: glaucoma, Hydrus, minimally invasive glaucoma surgery, SLT, trabecular surgery.

INTRODUCTION

Medical therapy is the most common treatment modality worldwide to reduce intraocular pressure (IOP) in primary open angle glaucoma (POAG) and ocular hypertension.1, 2 However, medication noncompliance, ocular surface disease caused by medication and preservatives, tachyphylaxis and medication side effects all pose significant limitations to medical therapy-especially in patients requiring multiple glaucoma medications.3-5 As a result, several alternative IOP lowering procedures have been developed as either an adjunct or replacement to medical therapy.

Since 1999, frequency doubled Nd:YAG laser (selective laser trabeculoplasty, SLT, Santa Clara, CA, USA) has been demonstrated to lower IOP as well as argon laser trabeculoplasty with a lower thermal damage to surrounding tissues and hence, the theoretical benefit to apply multiple treatments.6-12 Micro-invasive glaucoma surgery (MIGS) are a group of surgical procedures that share the common features of an ab interno approach, no or minimal manipulation of the conjunctiva and sclera, and a high safety profile. Randomized clinical trials have shown that MIGS devices lower IOP and medication use when combined with cataract surgery compared with cataract surgery alone.13, 14 However, there are a limited number of studies that describe the use of MIGS devices as a solo, or stand-alone procedure.15, 16

Both SLT and MIGS procedures have potential applications in mild to moderate POAG patients.

The Hydrus Microstent (Ivantis, Inc. Irvine, CA) is an emerging MIGS device (Figs 1, 2) that serves as an intracanalicular scaffold once implanted into Schlemm's canal. By dilating and stenting a large circumferential area of the canal, the Hydrus Microstent maintains aqueous flow through the trabecular meshwork and conventional outflow system.17, 18

The aim of the present study is to compare patients with POAG who underwent either a 360 degree-SLT procedure or the implantation of the Hydrus Microstent. We are unaware of previous reports directly comparing SLT and Hydrus and could find no reference to it in a computerized search (PubMed).

METHODS

This prospective, comparative case series was conducted on consecutive patients at two sites: the Glaucoma Center of the Ophthalmology Unit of Siena University Hospital, Italy and the ‘Clinica Oculistica’ of the Department of Surgical Sciences of Turin University, Italy.

The study and data accumulation were carried out with approval from both Siena and Torino Ethics Committees and has therefore been performed in accordance with the ethical standards laid down in the Declaration of Helsinki (2013). Proper informed consent for the research was obtained from all patients.

This study is registered on ClinicalTrials.gov (Identifier: NCT02512133).

Study patients were diagnosed with POAG and were not sufficiently controlled by, were intolerant of, or were non-compliant with their current IOP-lowering regimen. All patients presented with IOP > 21 mmHg on at least two consecutive measurements. Study subjects had typical glaucomatous visual field loss on Octopus or Humphrey automated perimetry (Carl Zeiss Meditec, Dublin, CA) and glaucomatous alterations to the optic nerve head. The visual field was classified as glaucomatous according to the European Glaucoma Society guidelines.19

Exclusion criteria were the following: eye surgery in the previous 6 months, any previous incisional surgery for glaucoma, evidence of glaucoma of a type other than POAG, Shaffer angle grade of two or less, and medication with systemic or topical steroids.

Prior to surgery, a full ophthalmological examination was performed including best-corrected visual acuity, IOP measurement using Goldmann applanation tonometry and slit lamp examination with gonioscopy. The cup-to-disk ratio was evaluated using indirect slit lamp biomicroscopy, and the median of at least three preoperative IOP values taken in the week before the treatment was used as baseline. Age, sex, angle width, visual acuity, lens status, previous glaucoma procedures and number of IOP-lowering medications were also recorded. Patients compliant with inclusion and exclusion criteria were enrolled in the study and underwent either SLT procedure in Siena or Hydrus implantation in Turin. The main investigators (Antonio Fea and Paolo Frezzotti) agreed upon the target IOP for each patient on the basis of their previous clinical history and on the European Glaucoma Society guidelines prior to their recruitment. If agreement could not be reached for a patient, he/she was not enrolled in the study.

Selective laser trabeculoplasty procedure

On the day of SLT, the only pre-treatment preparation was topical anaesthesia with benoxinate hydrochloride 0.4% (Novesina 0.4%, Novartis Farma S.p.A., Italy) eye drops. We used a Laser Solutis SLT laser (Quantel Medical, Clermont-Ferrand, France): this frequency-doubled, Q-switched Nd:YAG laser emits light at a wavelength of 532 nm, with a pulse duration of 4 ns, a spot size of 400 µm and pulse energy ranging from 0.2 to 2 mJ.

One experienced glaucoma specialist (PF) performed the laser procedure in all cases. The patient was seated at the slit lamp, and using the Ocular Latina SLT laser lens (Ocular, Bellevue, WA, USA), the laser was focused on the trabecular meshwork. The entire vertical width of the trabecular meshwork was irradiated with each pulse, using a 400-µm spot size. The laser energy was initially set at 0.5 mJ and a single pulse was delivered at the 12 o'clock position. If cavitation bubbles appeared, the energy was reduced by 0.1 mJ increments until no bubble formation was observed and treatment continued at this energy level. If no cavitation bubbles occurred, the energy was increased by increments of 0.1 mJ until bubble formation and then decreased as described earlier. The entire 360° of the distal pigmented trabecular meshwork was treated with 100 non-overlapping spots. After SLT, a drop of nonsteroidal anti-inflammatory agent was instilled and patients were prescribed diclofenac sodium ophthalmic solution 0.1% eye drops (Voltaren Ofta, Novartis Farma S.p.A., Italy) bis in die for 5 days.

Hydrus Microstent procedure

One experienced surgeon performed all Hydrus procedures (AF). Patients were administered topical 3rd-generation fluoroquinolone eye drops ter in die (Oftaquix, Bausch & Lomb, Rochester, NY) starting 3 days prior to surgery. Before surgery, the microscope was repositioned and patients' head was tilted nasally to allow a clear view of the angle structures with a gonioprism. A 1.5 mm corneal temporal incision was performed to access the target for microstent placement. High molecular weight viscoelastic was introduced for chamber maintenance and to achieve an optimum view. The Hydrus delivery cannula was then inserted through the corneal incision. The bevelled tip of the cannula was used to perforate the trabecular meshwork, and the microstent was implanted into Schlemm's canal by advancing the tracking wheel, leaving 1–2 mm (the inlet segment) remaining in the anterior chamber. Upon gonioscopic confirmation of microstent positioning in the canal, the delivery system was withdrawn and high molecular weight viscoelastic removed; the anterior

chamber was inflated with balanced salt solution to achieve normal IOP. Post operative care included a topical antibiotic (Oftaquix) ter in die for 7 days and a tapering dose of a topical corticosteroid (Luxazone, Allergan Pharmaceutics, Dublin Ireland) for 4 weeks.

Follow up examinations

All glaucoma medications were discontinued after surgery in both groups.

Follow up examinations were conducted in both groups at 1 day, 1 week and 1, 3, 6 and 12 months. Interim visits were conducted at any time as required. At all scheduled visits, the examinations included best-corrected visual acuity, IOP measurement using Goldmann applanation tonometry, slit lamp biomicroscopy with gonioscopy (gonioscopy was performed at baseline, at month 12 and at discretion of the examiners) and indirect ophthalmoscopy to evaluate cup-to-disk ratio. Visual field examination was routinely repeated at month 12. In both groups, ocular hypotensive medications could be re-introduced at any time if follow up IOP exceeded 21 mmHg or at any IOP if the predefined target pressure was not achieved three times.

Main outcome measures

The primary efficacy end point was the reduction in the mean diurnal IOP (dIOP) in the Hydrus group as compared with the SLT group. Secondary outcome measures included the proportion of patients taking ocular hypotensive medications, medication use throughout the follow-up period and surgical success rate. Surgical success was defined as the maintenance of IOP within the target values without glaucoma medications. Safety end points were intraoperative complications, the observed rate of ocular adverse events, loss of visual acuity and ocular health over the follow-up period.

Statistical analysis

Within group differences were evaluated using a two-sided paired t-test for normally distributed data(determined using the Shapiro-Wilk test). Between groups differences were evaluated using an unpaired two-sided t-test. Statistical analysis was performed using analyse-it statistical software for microsoft excel (version 2.26; analyse-it Software, Leeds, United Kingdom). A P-value less than 0.05 was considered statistically significant.

A priori, a sample size of 23 per group was estimated (β error: 0.8, significance level: 0.05). Data are presented with mean values, standard deviation and confidence intervals where applicable and unless otherwise indicated.

A propensity score (PS) was calculated for each participant using logistic regression, including all relevant baseline variables (age, number of glaucoma medications, IOP, target IOP, visual acuity, mean deviation at visual field analysis and lens status). The region of common support was determined, and the balance of covariates for the two groups of patients within quintiles of the PS was checked. The PS was then included as a continuous variable together with the treatment in two linear regression models predicting IOP and number of glaucoma medications 12 months after the treatments.

RESULTS

Fifty six eyes were included in the study, whilst three patients were not enrolled because of lack of agreement on their target pressure. 25 underwent SLT and 31 were implanted with the Hydrus Microstent. There were no differences between the groups in terms of baseline age, gender, visual

acuity, IOP, mean number of medications, angle width and lens status. Visual field loss severity was greater in the Hydrus group as compared with the SLT group ($P < 0.001$). At baseline, one patient in the Hydrus group had a prior glaucoma laser treatment (SLT), whilst in the SLT group all patients were laser naïve (Table 1).

All patients in the SLT group underwent all follow-up visits. One patient in the Hydrus group was lost to follow-up after the one-month visit because of moving to another city.

Compared with baseline, both the SLT and the Hydrus groups showed a significant decrease in IOP throughout follow-up. Between-group comparison showed no significant difference in either mean IOP drop or percent IOP drop at any follow-up visit.

In the early postoperative follow-up period, there was a greater reduction in IOP in the SLT group (-6.0 ± 3.3 versus -4.3 ± 6.8, $p = 0.26$), but by 12 months, the IOP decrease was the same in the two groups (-7.3 ± 2.5 versus -6.6 ± 5.6, $p = 0.57$). Twenty-two out of 25 patients (88%) in the SLT group and 27 out of 30 (90%) in the Hydrus group had a decrease in IOP greater than 20% at 12 months. (Table 2 and Fig 3)

At 12 months, the patients in the SLT group remained on a mean of 2.0 ± 0.91 medications, whilst the Hydrus patients dropped to a mean of 0.9 ± 1.04 medications. The within-group reduction from baseline was highly significant for the Hydrus group, but significance was not reached for the SLT group. The between-group difference in medication reduction was highly significant in favour of the Hydrus group; the average Hydrus patient used one full medication less than the average SLT patient (-1.4 ± 0.97 vs. -0.5 ± 1.05, difference: 0.9 medications/patient, CL 1.16;1.84, $P = 0.001$) to achieve the targeted IOP. These findings are summarized graphically in Figure 4.

Figure 5 shows the treatment effect of the Hydrus device. At 12 months, 47% of Hydrus patients were medication free, compared with 4% (one patient) of the SLT group ($P = 0.004$, Fischer's Exact Test). The medication free patients in the Hydrus group had a mean IOP reduction of $23.7\% \pm 15.3$ and a mean drug reduction of 2 ± 0.78. There were no medication-naive patients in the Hydrus group at baseline, and there was one patient in the SLT group, who was intolerant to any topical medical therapy and remained medication free at 12 months. Pre and postoperative IOP in patients who were medication free at 12 months were respectively 21.71 ± 2.55 mmHg and 16.36 ± 2.65 mmHg in the Hydrus group and 23 mmHg and 14 mmHg in the only patient without glaucoma medications at 12 months in the SLT group.

In Figure 6, surgical success is represented in a Kaplan-Meier survival curve.

Because of differential distribution of the visual field mean deviation among the two groups of patients, the common support of the PS ranged from 0.2 to 0.99 and led to the inclusion of 25 (all) patients in the SLT group and 10 patients in the Hydrus group. However, results obtained with the PS adjustment differed only marginally from those obtained through traditional multivariable adjustment. In particular, there were no statistically significant differences in the IOP at 12 months among groups, whereas the number of glaucoma medications was something higher in the SLT group (1.19 glaucoma medications per patient more in SLT group, 95% CI: 0.47−1.90; the same figure was 1.24, 95% CI: 0.63−1.86 with traditional multivariable adjustment).

Safety measures and complications

There were no significant changes in visual acuity (LogMAR scale) from baseline to 12 months in the two groups (SLT baseline: 0.30 ± 0.1, SLT 12 months: 0.33 ± 0.12, $P = 0.34$; Hydrus baseline: 0.25 ± 0.15, Hydrus 12 months: 0.22 ± 0.1, $P = 0.36$.)

No complications were observed In the SLT group.

In the Hydrus group, IOP spikes occurred in two patients (6.45%) on the first post-operative day. Patients were treated with systemic acetazolamide and IOP normalized by the third post-operative day. On the first post-operative day, three patients (9,68%) had a temporary decrease in visual acuity greater than two lines (one patient because of corneal edema secondary to the IOP spike and two patients to hyphema). Visual acuity returned to normal levels at the seventh day post-operative control in all three cases. No peripheral anterior synechiae were observed.

DISCUSSION

Published studies of SLT and MIGS surgery have shown that these treatments are viable methods for reducing IOP. Our study provides further evidence and is the first to compare the IOP-lowering ability and safety profile of these two treatment modalities in stand-alone glaucoma intervention.

The reported efficacy of SLT in lowering IOP ranges from 11% to 40%.7, 20 The variability may be due to differences in treated area, types of glaucoma, severity of glaucoma, and time to follow-up from initiation of therapy. There are a few studies evaluating the efficacy of 360-degrees SLT treatment in uncontrolled POAG.21-23 In a retrospective study with a mean follow up of 16 months, a 16.7% reduction of IOP was observed in a group of 136 POAG patients who were unresponsive to maximum tolerable medical therapy.16 At 12 months post-operatively, the mean reduction of IOP in a similar prospective study was 24.2%.21 Pseudophakic eyes have been reported to have a similar reduction in IOP compared with phakic eyes.24

The 31% IOP decrease after SLT in our study is somewhat higher than most previous reports. However, the number of preoperative medications per patient was lower and our sample included patients who were either non compliant or intolerant to medication. It has been reported previously that SLT may be more efficacious in naive eyes.25

We observed a 20% reduction in medication use along with an IOP reduction in the SLT group. Unfortunately for comparative purposes, most of SLT studies do not report the mean change in medication use. One study did report a 0.1 medication reduction for one year after treatment with 360-degree SLT.22

There are no previous studies reporting the results of the Hydrus Microstent as a stand-alone procedure in phakic and pseudophakic eyes. In this study, we report a decrease in IOP of 6.6 mmHg or 26% reduction in mean IOP and a 61% decrease in mean medication use (2.3 to 0.9). The only published studies on phakic eyes using MIGS have been conducted using a different MIGS device (iStent), where a reduction of 6.4 mm Hg (28.96%) at 12 months13, and of 1.31 medications at 6 months were reported.26 Voskanyan reported a mean decrease of 6.4 mmHg15 and Katz, using two stents, a mean decrease of 6.3 mmHg (31%) with a mean reduction of medications of 1.34.27

Previous SLT studies demonstrated that serious complications are rare;7 although, one study reported post procedure IOP spikes between 5 and 10 mmHg in 3.5% of pseudophakic and 5% of phakic eyes.24

No complications were associated with SLT in our study. There was no evidence of inflammatory reaction 24 hours after treatment and no signs of iritis during subsequent follow-up visits. One day after treatment, eye discomfort was reported by 40% of patients but was mild in all cases.

In a previous investigation on combined MIGS procedures, IOP elevation greater than 10 mmHg was reported in 2% of patients.13 The percentage reported in the present study is possibly higher because of challenges presented by removal of the viscoelastic material in phakic eyes. Some patients in the Hydrus group experienced a temporary reduction of visual acuity due to either transient hyphema or to microcystic corneal edema secondary to the IOP elevation which resolved within a week post-operatively.

This is the first study comparing Hydrus Microstent and SLT in a group of mild to moderate POAG patients. Limitations in the study include the small sample size, the limited follow-up period, the possible improvement in medication compliance after the treatment and the nonrandomized nature of the study. Furthermore, the patients were not masked to the treatment. Nonetheless, this original study provides insight into comparative similarities and differences in IOP-lowering and adverse event rate between these two procedures. Although this study was not randomized, its prospective nature on consecutive patients and the inclusion criteria should provide a real world implication to the results reported.

There were significant preoperative differences between the two groups with the Hydrus device implanted in more severe glaucomatous patients. Nevertheless, the pertinent findings of the present investigation are the following: (i) Hydrus Microstent provided equivalent IOP reduction to SLT at one year of over 7 mmHg; and (ii) patients treated with the Hydrus Microstent used significantly less medication at 12 months to maintain target IOP. From a baseline medication use of over two medications per patient, the average Hydrus patient used one full medication less at 12 months compared with SLT patients. Further, 87% of Hydrus patients experienced a decrease in medication use compared with 44% in the SLT group, and 47% Hydrus patients were medication free at target IOP range at 12 months. Further studies are needed to assess the persistence of these effects beyond one year, and whether a similar IOP reduction profile can be achieved in patients who have had previously failed filtration/tube shunt surgeries or who are unresponsive to SLT.

Competing/conflicts of interest: Iqbal Ike K. Ahmed is a consultant to Hydrus (Ivantis).

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FIGURES

Figure 1. Hydrus Microstent.

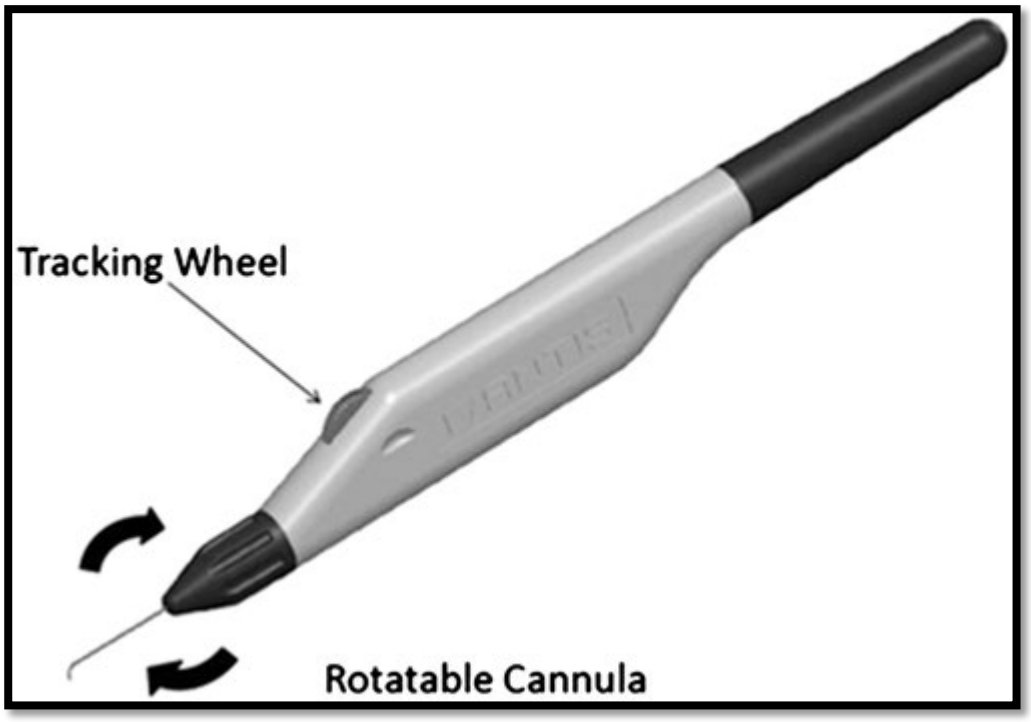

Figure 2. Hydrus delivery system.

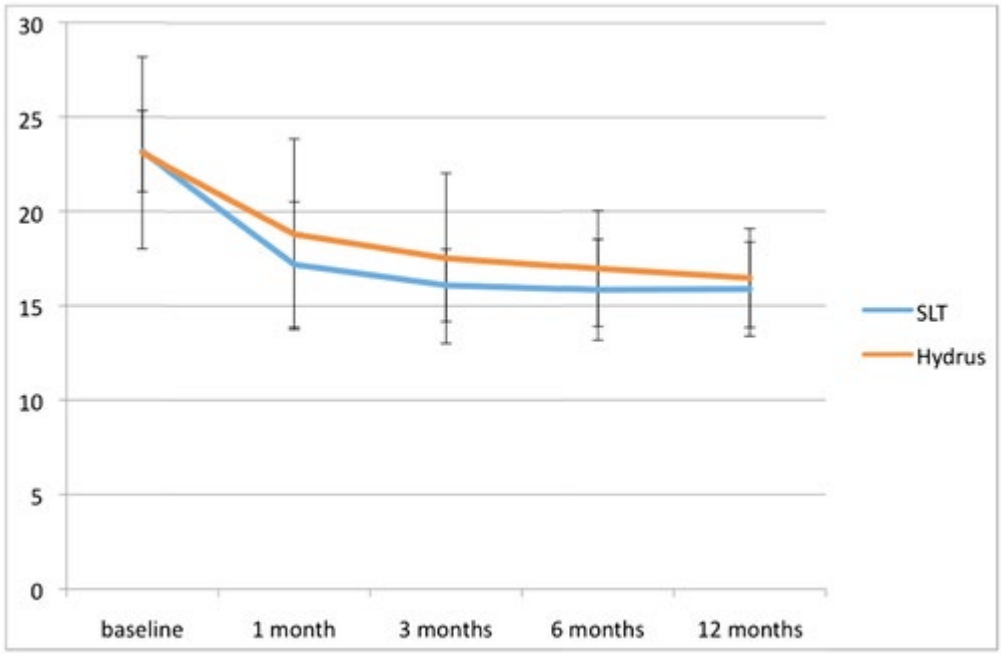

Figure 3. Line graph showing intraocular pressure variations (mmHg, y-axis) from baseline to 12 months in the two groups. Bars represent the standard deviations. SLT, selective laser trabeculoplasty.

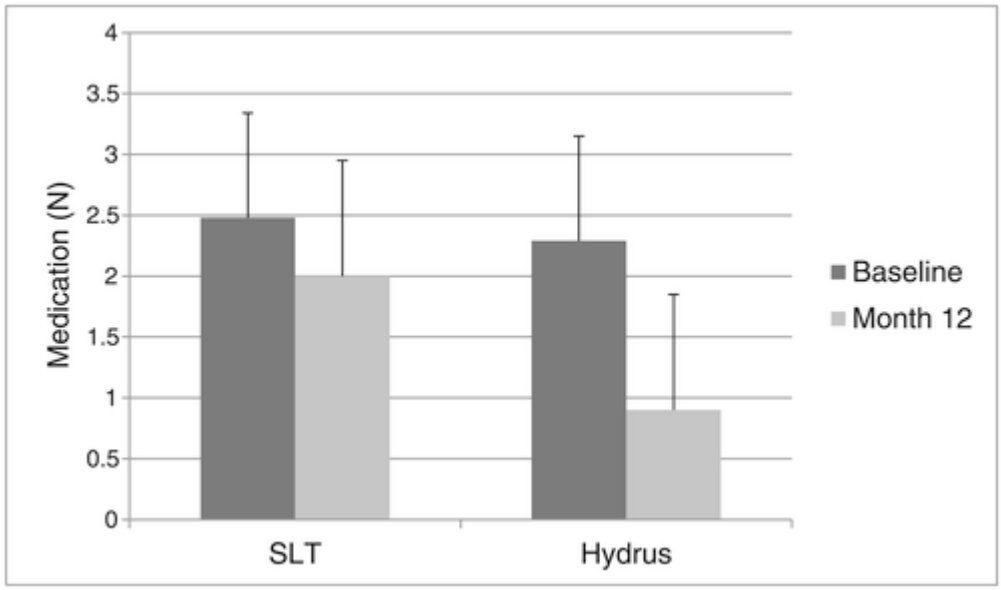

Figure 4. Change in medications: SLT and Hydrus groups. SLT, selective laser trabeculoplasty.

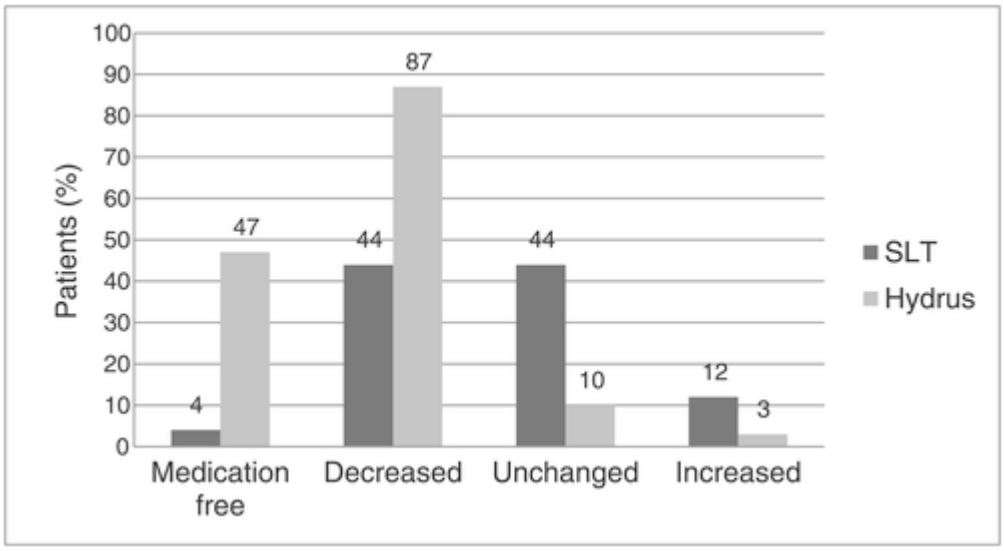

Figure 5. Medication status at Month 12 versus Baseline in the two groups. SLT, selective laser trabeculoplasty.

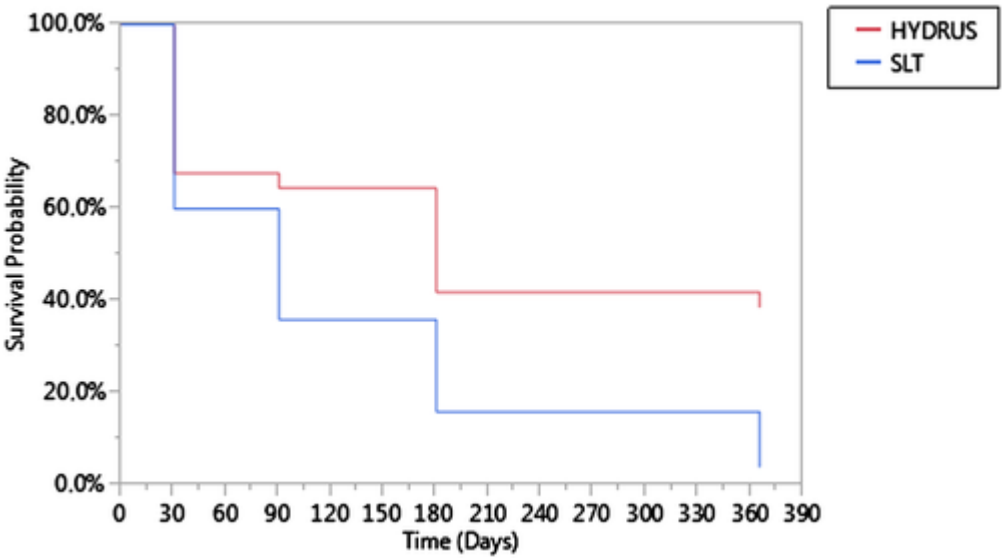

Figure 6. Kaplan-Meier survival curve for surgical success (proportion of patients medication free within target intraocular pressure).

TABLES

Table 1. Baseline data in the two groups

	SLT *n* = 25 mean ± SD (CI)	**Hydrus *n* = 31 mean ± SD (CI)**	**Statistical significance**
Age (years)	69.0 ± 11.28 (64.6;73.5)	70.8 ± 11.83 (66.6;75)	0.56
Male (%)	9/25 (36%)	18/31 (58%)	0.10
Female (%)	16/25 (64%)	13/31 (42%)	–
IOP (mmHg)	23.18 ± 2.15 (22.3;24)	23.09 ± 5.08 (21.3;24.9)	0.93
Mean number of medications (*n*)	2.48 ± 0.92 (2.1;2.8)	2.29 ± 0.83 (2;2.6)	0.42
Visual acuity (logMAR)	0.30 ± 0.1 (0.26;0.34)	0.25 ± 0.15 (0.21;0.29)	0.14
Visual field MD (dB)	−3.04 ± 0.65 (−2.8;−3.3)	−8.43 ± 6.84 (−6;−10.89)	$P < 0.001$
Angle width (Shaffer grade)			
III	6 (24%)	10 (32%)	0.52
IV	19 (76%)	21 (68%)	–
Lens Status			
Phakic	17 (68%)	20 (65%)	0.79
Pseudophakic	8 (32%)	11 (35%)	–
Previous glaucoma procedures	–	1 SLT	0.36

- CI, confidence intervals; IOP, intraocular pressure; MD, mean deviation; SD, standard deviation; SLT, selective laser trabeculoplasty; –, inconclusive results

Table 2. Intraocular pressure variations throughout the follow-up in the two groups

	Baseline	Month 1	Month 3	Month 6	Month 12
SLT mean ± SD (CI)					
Patients (*n*)	25	25	25	25	25
IOP mmHg	23.2 ± 2.15 (22.3;24)	17.2 ± 3.33 (15.9;18.5)	16.1 ± 1.93 (15.3;16.9)	15.8 ± 2.67 (14.8;16.9)	15.9 ± 2.49 (14.9;16.9)
IOP mean change from baseline (mmHg)	–	−6.0 ± 3.29	−7.1 ± 2.27	−7.3 ± 3.10	−7.3 ± 2.53
% IOP change from baseline	–	−26 ± 14	−30 ± 9	−31 ± 12	−31 ± 10
P-value (follow-up *vs.* baseline)	–	<0.001	<0.001	<0.001	<0.001
Hydrus mean ± SD (CI)					
Patients (*n*)	31	31	30	30	30
IOP mmHg	23.1 ± 5.08 (21.3;24.9)	18.8 ± 5.06 (17.1;20.7)	17.5 ± 4.52 (15.9;19.2)	17.0 ± 3.06 (15.8;18)	16.5 ± 2.6 (15.5;17.4)
IOP mean change from baseline (mmHg)	–	−4.3 ± 6.79	−5.5 ± 6.54	−6.7 ± 5.61	−6.6 ± 5.62
% IOP change from baseline	–	−16 ± 24	−21 ± 25	−27 ± 21	−26 ± 18

	Baseline	Month 1	Month 3	Month 6	Month 12
P-value (follow-up *vs.* baseline)	–	<0.001	<0.001	<0.001	<0.001
P-value (SLT *vs.* Hydrus)	–	0.26	0.27	0.59	0.57

- CI, confidence intervals; IOP, intraocular pressure; SD, standard deviation; SLT, selective laser trabeculoplasty; –, inconclusive results