Efficacy of subthreshold trabeculoplasty with micropulse laser in the treatment of primary open angle glaucoma

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Article

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Abstract

Purpose

To report the results of subthreshold micropulse laser trabeculoplasty (MLT) in a consecutive series of patients, affected by primary open angle glaucoma (POAG).

Methods

In this single-center, one-arm, prospective study conducted on sixty-eight patients (112 eyes) affected by POAG, who underwent 360° 577-nm MLT. Follow-up consultations were scheduled at 1, 6, 12, 18 and 24 months. At baseline and at each consultation after MLT, data were collected on IOP, best corrected visual acuity, local and systemic side effects, number of eye-drops in use.

Results

One-hundred and twelve eyes of 68 patients were enrolled. Mean age was 57.68 ± 8.0 years, mean baseline IOP was 18.4 ± 5.2 mmHg with 1.43 ± 0.85 glaucoma medications. Treatment with MLT resulted in significantly lower IOP at both 1 month (18.4 ± 5.2mmHg, $p = 0.045$) and 24 months (18.4 ± 5.2 mmHg; $p = 0.046$) compared to baseline. No statistically significant difference was found between IOP at 1 month and at 12 months and between IOP at 1 month and at 24 months after treatment ($p > 0.05$). A low rate of retreatments was observed, mostly performed after 18 months from baseline. Most of the eyes were free of additional medical therapy at 12 months (88.9%) and 24 months (94.3%). No local or systemic side effects during or after MLT were reported.

Conclusion

This is the first prospective study to report long-term outcomes of MLT in POAG. MLT is safe and effective with an efficacy achieved within the first month and maintained after 2 years of treatment.

Introduction

Glaucoma is a neurodegenerative disease that causes irreversible visual field defects and is one of the leading causes of blindness (1). At the moment, lowering the intraocular pressure (IOP) is the only evidence-based treatment to slow or prevent progression of visual (2).

The first-line treatment of glaucoma is the instillation of eye drops. There are numerous types of chemical substances that are capable to reduce aqueous humour (AH) secretion or help the AH drainage, and thereby lowering IOP. However, all these eye drops have common local side effects, including stinging, redness and itching of the eye surface, changes in eyelid skin color and less frequent but fearsome

systemic side effects, such as depression; low or high blood pressure; fatigue, irregular heart rate, drowsiness and/or blurred vision. Moreover, compliance to these eyedrops in patients is poor (3).

Laser trabeculoplasty, which is a procedure that helps increasing aqueous outflow and decreasing therefore IOP, is comparable to topical treatments when it comes to efficacy and quality of life of patients, but spares them from the side effects of topical treatments (4). This is why a large multicentric randomized controlled trial suggested that selective laser trabeculoplasty (SLT) should be the first-line treatment for open angle glaucoma (5). However, limited effects were reported on open angle glaucoma with a 1-year survival rate of 14.2% (6). Moreover uncommon but serious complications have been descripted after SLT procedure: anterior segment side effects including hyphema, iritis, peripheral anterior synechiae and retinal complication such as cystoid macular edema (7),(8),(9). Evidences based on human eye bank eyes studies demonstrated a damage on trabecular endothelial cells with loss of integrity of cytoplasmic pigment granules (10).

Recently, the micropulse laser technique (MLT) has been developed. It is the newest form of laser trabeculoplasty, with the goal of providing an efficient treatment to lower the IOP without side effects. MLT is a technique that splits laser energy into on-and-off short pulses instead of a continuous long pulse (11). Alike the principle of cut and coagulation technique in surgery, it protects the adjacent tissues from the heat build-up and thermal damage without compromising therapeutic results (11). The effectiveness of MLT requires further validation because of inconsistent results found in the literature, and non-constant irradiation conditions (12), (13),(14),(15),(16). The long-term efficacy and the side effects are also not well established.

The aim of the current study is to report the results of MLT in a series of patients, affected by POAG and undergoing one or more medical treatments to control IOP, consequentially treated in a single center and followed up for two years.

Materials And Methods

Design

An observational study with prospective enrollment, compliant with the tenets of the Declaration of Helsinki.

Patients

Patients were consecutively recruited from those referred between January 2019 and January 2021 at the Eyecare Clinic, Brescia, Italy. All research and measurements adhered to the tenets of the Declaration of Helsinki, the project has been approved by our review board and written informed consent was obtained for each participant. At enrolment, each patient underwent a detailed anamnesis collection including demographic parameters and medical history with special attention to glaucoma medications, prior medical, prior laser or surgical therapies. A full ophthalmic examination including logMAR best-corrected

visual acuity (BCVA) assessment, slit-lamp examination of the anterior segment including indirect gonioscopy of the angle with a Goldmann goniolens, IOP measurement by Goldmann applanation tonometry, fundus examination was performed. After pupil dilation, obtained with 1% tropicamide solution, a detailed examination of the lens and retinal periphery were completed. In particular, the examiner search for pigment deposition on corneal endothelium, peripupillary or mid-peripheral iris defects visualized directly or upon retroillumination, exfoliation material on the anterior lens capsule. Any fundus signs attributable to retinal vascular disorders or ocular ischemic syndrome were excluded. Anterior chamber angle (ACA) was considered open if pigmented trabecular meshwork was clearly visible in all quadrants. Clinical evaluation of pathological aspects of ACA, with special attention to peripheral anterior synechiae or pigmented Schwalbe line, was performed. Baseline examination also included instrumental examinations performed by an experienced examiner (LT). Ultrasound biomicroscopy (UBM) examination (using 50 MHz Aviso S, Quantel Medical, Clermont-Ferrand, France) was performed for qualitative confirmation of open ACA, iris root insertion and ciliary bodies anomalies evaluation (Figure 1). A measurement of thickness of the retina nerve fiber layer (RNFL) using Spectralis (HRA + OCT, software version. 5.3.3.0, Heidelberg Engineering, Germany) was performed. A collection of Mean deviation (MD) values, derived from the most recent visual field examination using the 24-2 Swedish interactive threshold Algorithm (SITA) with a Humphrey Field Analyzer 3 (Carl Zeiss Meditec AG, Jena, Germany) was done. Visual field tests older than 2 months respect to the baseline or performed with another instrument were rejected and a new test was performed at baseline consultation.

Inclusion criteria were:

- Open angle eyes established with gonioscopy or ultrasound biomicroscope (UBM) examination
- Eyes with POAG under treatment with one or more medications
- Patients willing to control IOP without medical therapy, due to side effect of medical therapy

Exclusion criteria were:

- eyes with angle closure glaucoma
- eyes with secondary open angle glaucoma or end-stage glaucoma
- history of prior glaucoma laser or surgical treatment

Technique

All laser MLT procedure were performed by one experienced ophthalmologist to all eyes under topical anesthesia (1-2 drop of Chlorhydrate D'oxybuprocaine, Novesina ® 1.6 mg/0.4 ml, Théa Laboratories, Clermont-Ferrand, France). A Goldmann three-mirror goniolens (Volk Optical Inc., Mentor, OH,USA) was adjusted on the cornea, in order to allow the ophthalmologist to see the trabecular meshwork (TM). A 577 wave-length laser IRIDEX IQ 577® Laser Systems (Iridex Corporation, Mountain View, CA, USA) was used to apply 300 consecutive spots of laser, with a diameter of 300 microns per spot, a power of 1000 mW, in

a time of 300 msec per spot with 15% duty cycle over the full 360° of the TM. No space was left between spots.

Follow-up

After treatment, patients were not prescribed any anti-inflammatory drops post-laser and were instructed to continue the ongoing medical therapy before MLT for one week and to suspend one eye-drop afterwards until the following consultation. Follow-up consultations were scheduled at 1, 6, 12, 18 and 24 months. At baseline and at each consultation, data were collected on IOP (measured by Goldmann applanation tonometry), logMAR BCVA assessment, local and systemic side effects, number of eye-drops in use (for quantifying the number of glaucoma eyedrops, topical fixed combination medications were considered 2 medications and other topical glaucoma medications were assigned 1 medication). At each postoperative consultation, if the IOP was normal (lower than 20 mmHg), the patients still using eye-drops were instructed to stop them. If IOP was not normal a retreatment with MLT was performed prior a written informed consent obtained for each participant.

Outcomes

The primary outcome was to verify the efficacy of MLT in leading the eye to normal IOP values without medical therapy at 12 and 24 months after treatment.

The secondary outcomes were:

1. Verify the IOP change in time after treatment, by reporting the IOP values at 1, 6, 12, 18 and 24 months
2. Verify the rate of retreatments at 1, 6, 12, 18 and 24 months
3. Verify the change in medical therapy at 1, 6, 12, 18 and 24 months, compared to the preoperative therapy.
4. Verify the change in side effects. The side effects that were looked for were:

    a. local (stinging, redness, itching; changes in eyelid skin color, blurred vision, IOP spikes, hypotony, bleeding, choroidal detachment);

    b. neurological (depression; loss of memory, drowsiness);

    c. cardiovascular (low or high blood pressure; fatigue, irregular heart rate).

Statistics

Study parameters were described by means of descriptive statistics: absolute and relative frequencies for qualitative parameters (gender, eye, lens status) and mean value, standard deviation for quantitative parameters (age, number of ocular hypotensive medications, MD, RNFL thickness).

Mean IOP changes were compared with baseline and during follow-up by analysis of variance as a mix effect with repeated measures model (ANOVA). It was analyzed the statistical significance in IOP values comparing:

the preoperative value and the 1-month value, the preoperative value and the 24-month value, the 1-month value and the 12-month value, the 1-month value and the 24-month value. BCVA mean changes, mean number of glaucoma medications were compared using paired samples t-test. Statistical analyses were performed by using SAS software version 9.4 (SAS Institute, Cary, NC, USA). Data were assumed significant if $p < 0.05$.

Results

One hundred and twelve eyes of 68 patients gave their consent and were enrolled in the study. Demographic and all preoperative data are summarized in Table 1. The mean age at the time of MLT was 57.68 ± 8.0 years, the mean IOP before MLT was 18.4 ± 5.2 mmHg. Baseline and 1-month visits counted for 112 patients, respectively at 6, 12, 18 and 24 months from baseline we examined 104, 90, 102 and 106 patients. Table 2 shows mean intra-ocular pressure (IOP), mean best corrected visual acuity (BCVA), number of glaucoma medications used and number of retreatments in our study cohort of patients during follow up examinations (1, 6, 12, 18 and 24 months).

Mean IOP significantly decreased with time from 18.4 ± 5.2 mmHg to 15.8 ± 3.1 mmHg after 24 months, a slight non-significant increase to 16.1 ± 3.2 mmHg was shown at 12 post-operative months, the lowest mean IOP value registered during follow up was 14.9 ± 4.0 mmHg and it was reached at 6 post-operative months (Fig. 2). The number of medications used between baseline and 24 weeks after treatment (1.43 ± 0.85 vs. 0.06 ± 0.23; $p < 0.0005$) was significantly reduced (Fig. 3). BCVA remained stable during follow up ($p < 0.005$). A statistically significant difference between both the mean pre-operative IOP and IOP at 1 month after treatment (18.4 ± 5.2 vs. 16.0 ± 4.3 mmHg; $p = 0.045$) and the mean pre-operative IOP and IOP at 24 months after treatment (18.4 ± 5.2 vs. 15.8 ± 3.1 mmHg; $p = 0.046$) were observed. A low rate of retreatment was performed during the following consultations: at 6 post-operative months 4 retreatments (3.9%), at 12 post-operative month 2 retreatments (2.2%), at 18 post-operative months 8 retreatments (7.8%) were done (Fig. 3). Follow up measurements demonstrated that initial IOP reduction, achieved after 1 month from baseline treatment, has been preserved for a long time. No statistically significant difference was found between IOP at 1 month and at 12 months after treatment (16.0 ± 4.3 vs. 16.1 ± 3.2 mmHg; $p = 0.378$). Similarly, no statistically significant difference was found between IOP at 1 month and at 24 months after treatment (16.0 ± 4.3 vs. 15.8 ± 3.1 mmHg; $p = 0.295$).

Most of the eyes (88.9%) were without ocular hypotensive medications 12 months after the treatment with MLT. For the remainder of eyes (11.1%) only 1 type of hypotensive medication was used. The hypotensive effect was stable after 24 months from baseline: one hundred of eyes (94.3%) were without topical medications, 5.7% of eyes were treated with only one type of hypotensive medication. Mean reduction of number of eye drops used during follow up was significant.

MLT induced no side effects and, more specifically, no significant local, neurological, and cardiovascular side effects.

Discussion

POAG is the most common cause of open angle glaucoma and prescribing topical hypotensive medications is the most common first approach when POAG has been diagnosed. Local and systemic side effects of glaucoma medications, a low adherence to medical therapy, the cost of glaucoma medications for a long-term medical management or a desire to be free of a daily eye drops instillation, have led to the development of new laser trabeculoplasty techniques. Laser trabeculoplasty has gained a growing role as a primary treatment in open angle glaucoma or as an adjuvant to medical or surgical therapies for glaucoma. MLT is the most recent laser trabeculoplasty technique developed to preserve the effectiveness of SLT minimizing side effects, the rationale resides in the lowest level of laser energy sufficient to stimulate similar biological and therapeutic effects. Several investigators have experimented MLT effects with various laser types, 810 nm diode laser system, 577 nm and 532 nm laser systems, and different protocols of laser settings have been proposed in primary or secondary open angle glaucoma patients. During MLT treatment, no visible changes of trabecular meshwork are detectable, different laser types or settings may reach different IOP-lowering effects and a lack of consensus about the best protocol of MLT prevented its widespread use among clinicians. To our knowledge, this is the first prospective study to report long-term outcomes of MLT in primary open angle glaucoma patients. In this study, we evaluated the effectiveness of 360° MLT treatment using a 577-nm wavelength laser with a diameter of 300 microns per spot, a power of 1000 mW, in a time of 300 msec per spot with 15% duty cycle. MLT has demonstrated to be effective in leading 88.9% of eyes to a normal value of IOP without medical therapy at 12 months and 94.3% at 24 months. Mean IOP reduced since the first month after treatment with a statistically significant difference when compared to the preoperative value, the hypotensive effect was unchanged and sustained over a long term of 24-months. In fact, the difference in IOP value was not statistically significant when comparing the value at 1 month and at 24 months. These results need to be judged in the context of our sample's study that presented a young mean age at the time of treatment and a low mean preoperative number of glaucoma medications for patient. Probably, the responsiveness and plasticity of trabecular meshwork in such a type of POAG population may lead to a favorable remodeling of involved structures with greater outflow potential. The rate of retreatment was low and concentrated around the 18 months follow-up, meaning that the effect of treatment lasts at least 12 months. MLT induced no side effects and, more specifically, no significant local, neurological, and cardiovascular side effects. MLT demonstrated to be repeatable without any clinically evident side effects preserving a residual efficacy after the initial treatment. The absence of a coagulative damage with MLT may lead the clinician to be more confident prescribing retreatments compared to SLT. Several studies have been conducted in order to test MLT for open angle glaucoma showing conflicting results. In an interventional study done by Abouhussein et al., using 577 nm diode laser with 300 microns MLT significantly decreased IOP by a mean of 21.6% in 30 eyes affected by POAG after a follow-up of 6 months; this was the longest follow-up published until then in the literature (17). Babalola et al. used a

180-degree MLT with the same low power of 1000 mW that we have used, and spot sizes of 75, 125 and 200 microns in 30 eyes (18). They have shown statistically significant immediate decrease in IOP of 17.2% sustained over weeks to months. Hong et al. evaluated MLT in 72 patients affected by POAG, with only one eye treated with MLT (12). Statistically significant difference was found after a follow-up with IOP of 1 day, 1, 2, 4, 12 and 24 weeks after treatment. A statistically significant difference was also found for the number of medications used between before and 24 weeks after treatment (1.7 vs. 1.5; $p = 0.031$). Our study demonstrated that hypotensive effect of MLT may be observed since the first month and may be sustained over a much longer period with a low rate of retreatments; this is the longest follow up among similar studies conducted on patients affected by POAG. Unfortunately, different outcome measure have been used to define success rate preventing to compare them correctly. On the other hand, Rantala et al. also evaluated MLT in 29 patients (40 eyes) with open angle glaucoma with a follow-up of 6 months (15). Overall success rate – defined as > 20% or > 3mmHg decrease in IOP, no further need for surgery and number of glaucoma medication same or less than pre-operatively – was only 2.5% or 7.5% depending on the definition of success used, a relatively low success rate compared to other studies. No peri and post-operative complications were seen. The authors suggested therefore that MLT is safe but ineffective for open angle glaucoma (15). These conflicting results are due to the heterogeneity regarding the definition of success of the procedure.

Hirabayashi et al. compared the effectiveness of MLT compared to selective laser trabeculoplasty (SLT) in 100 eyes (50 treated with SLT vs. 50 treated with MLT) (14). POAG was the most representative diagnosis, respectively 82% and 94% of patients in the MLT and SLT groups. Similar success rates were shown for MLT and SLT (44% vs 40%, $p = 0.983$). Older age and greater baseline IOP predicted success for SLT while MLT was equally effective regardless of these two factors. IOP spike post procedure was experienced by 10% of SLT patients vs. 0% in MLT patients. MLT was therefore demonstrated as a safer alternative to SLT (14). The results we observed in a study group characterized by a younger mean age, a low mean number of medications before treatment are in contrast with Hirabayashi and colleagues.

Study Limitations

This study also had several other limitations. It has no control group that compared results of MLT with other laser trabeculoplasty techniques. The limited number of patients recruited is due to the strict inclusion criteria, but actually it is the largest prospective series of MLT tested on patients affected by POAG. Several patients didn’t attend some of follow up consultations, so different number of data were available for statistics. Moreover, study outcomes were limited to IOP and number of glaucoma medications, MD and RNFL thickness was not determined at the end or during follow up. It Unfortunately trabecular meshwork pigmentation wasn’t graded at baseline consultation to correlate it to the hypotensive effect of the treatment.

Conclusion

This is the first study to report long-term outcomes after MLT for primary open angle glaucoma. MLT seems to be safe and effective for lowering IOP. This effect was seen after one month of the procedure and was maintained until 24 months after treatment. Further prospective randomized comparative studies are needed to support our findings.

Declarations

Disclosure of funding

Drs Parolini, Sahyoun, Carbognin, Tozzi, Gius, Greggio, Frisina certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or nonfinancial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials. All research and measurements adhered to the tenets of the Declaration of Helsinki and written informed consent was obtained for each participant. No funding was received for this research.

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Author contributions:

Dr Parolini - conceptualization, writing of the manuscript, supervision, formal analysis

Dr Jean-Yves Sahyoun - review and editing

Dr Carbognin, Tozzi, Gius, Greggio - collection and analysis of the data, writing of the manuscript

Dr Frisina - conceptualization, writing of the manuscript, supervision

All authors have read and agreed to the published version of the manuscript.

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Tables

Table 1. Baseline demographic, clinical and instrumental parameters in the study group

Number of patients (eyes)	68 (112)
Age in years, mean ± SD	57.68 ± 8.0
Study eye, Right (%) / Left (%)	58 (52) / 54 (48)
Gender, Male (%) / Female (%)	24 (35.3) / 44 (64.7)
Lens status, fachic (%) / pseudophakic (%)	85 (75.9) / 27 (24.1)
BCVA in logMAR, mean ± SD	0.16 ± 0.33
IOP in mmHg, mean ± SD	18.4 ± 5.2
RNFL thickness in micron, mean ± SD	78.69 ± 16.04
MD in visual field examination in dB, mean ± SD	-7.29 ± 6.31

SD, standard deviation; BCVA, best-corrected visual acuity; logMAR, logarithm of the minimum angle of resolution; IOP, intraocular pressure; RNFL, Retinal nerve fiber layer; MD, mean deviation.

Table 2. Preoperative and postoperative functional parameters (intraocular pressure and visual acuity, medical therapy (number of medications), and retreatments

Timing of follow-up	**baseline**	**1 month**	**6 months**	**12 months**	**18 months**	**24 months**
Patients, n. (eyes n.)	68 (112)	68 (112)	61(104)	54 (90)	64 (102)	66 (106)
IOP in mmHg, mean ± SD	18.4 ± 5.2	16.0 ± 4.3	14.9 ± 4.0	16.1 ± 3.2	15.1 ± 2.3	15.8 ± 3.1
BCVA in logMAR, mean ± SD	0.16 ± 0.33	0.13 ± 0.29	0.16 ± 0.34	0.17 ± 0.26	0.19 ± 0.25	0.18 ± 0.35
Eyes using 1 medication, n (%)	52 (46.43)	42 (37.5)	28 (26.92)	10 (11.11)	8 (7.84)	6 (5.67)
Eyes using 2 medications, n (%)	38 (33.93)	16 (14.29)	8 (7.69)	-	2 (1.96)	-
Eyes using 3 medications, n (%)	8 (7.14)	-	-	-	-	-
Eyes using 4 medications, n (%)	2 (1.79)	-	-	-	-	-
MLT retreatments, n (%)	-	-	4 (3.85)	2 (2.22)	8 (7.84)	-

IOP, intraocular pressure; SD, standard deviation; BCVA, best corrected visual acuity; logMAR, logarithm of the minimum angle of resolution ; MLT, Micropulse laser trabeculoplasty

Figures

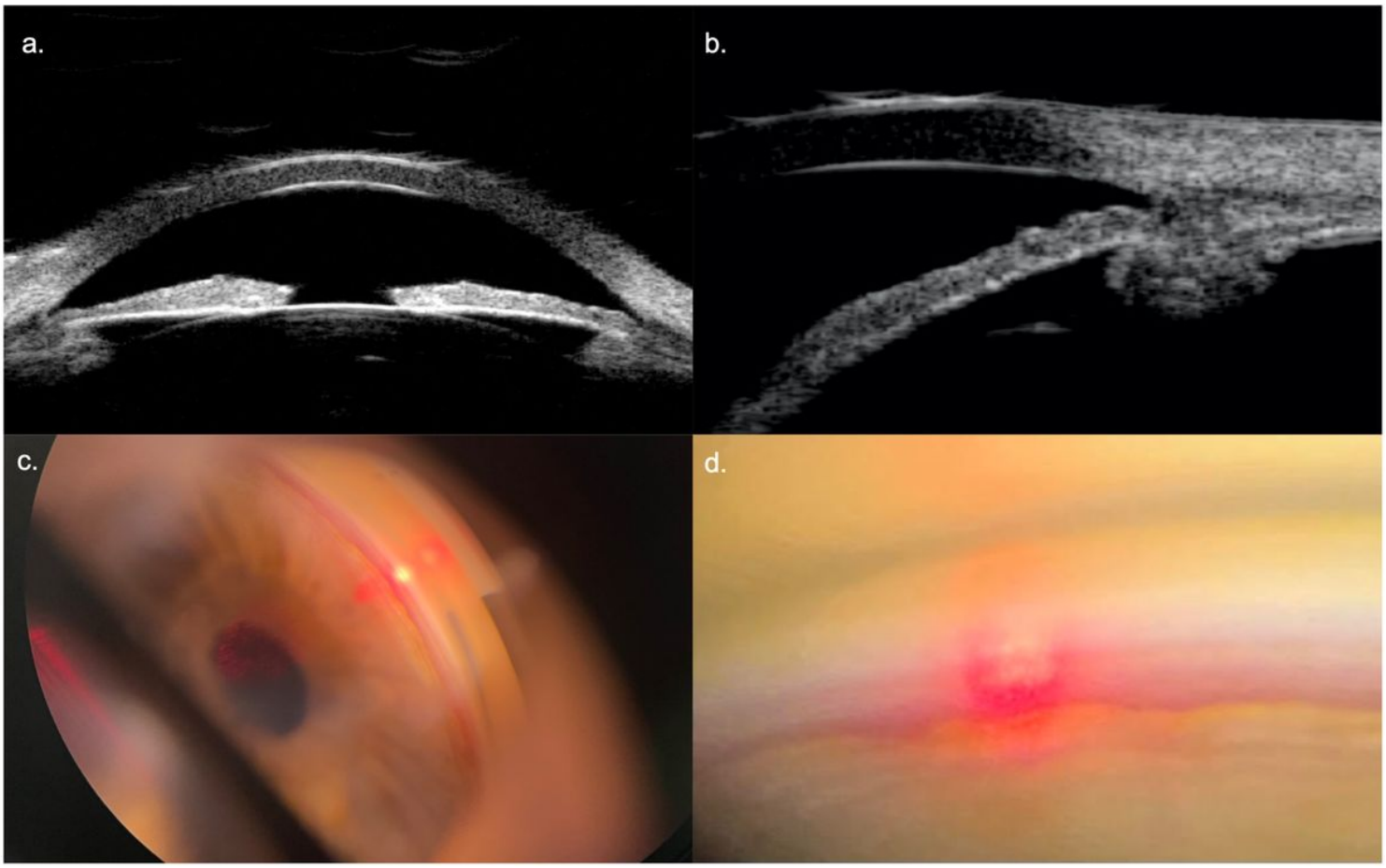

Figure 1

Ultrasound biomicroscopy (UBM) image of the central anterior chamber (a). Standard axial image of one quadrant under standard lighting conditions illustrates an open anterior chamber angle (ACA). The arrow points to the location of the scleral spur (b). Gonioscopic view of ACA structures and spot laser during MLT treatment, all patients received 360 degrees of confluent laser treatment to the pigmented trabecular meshwork (c). A detailed image of the spot laser applied to pigmented trabecular meshwork; there were no visible changes on target tissue during treatment (d).

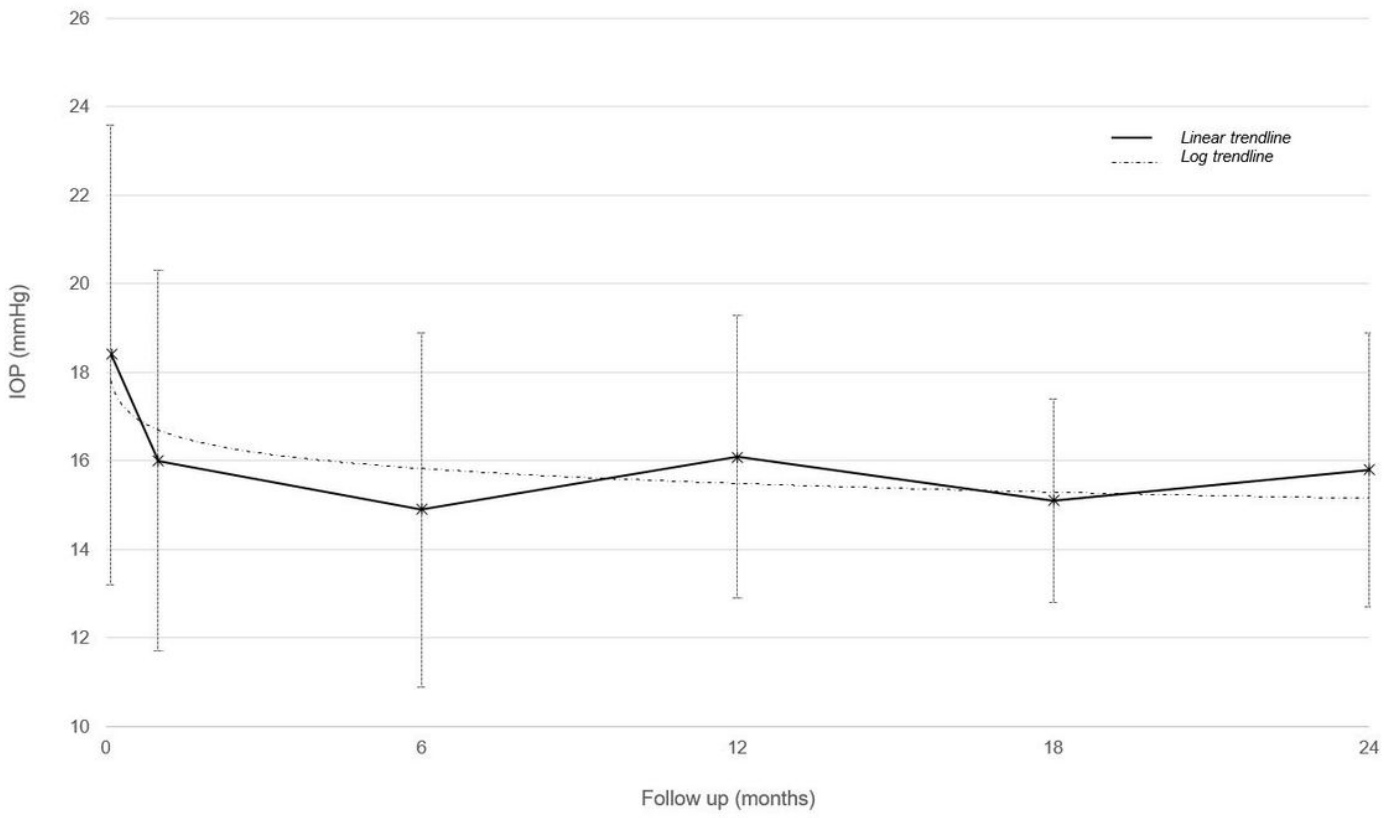

Figure 2

Intraocular pressure (IOP) changes during follow-up (months)

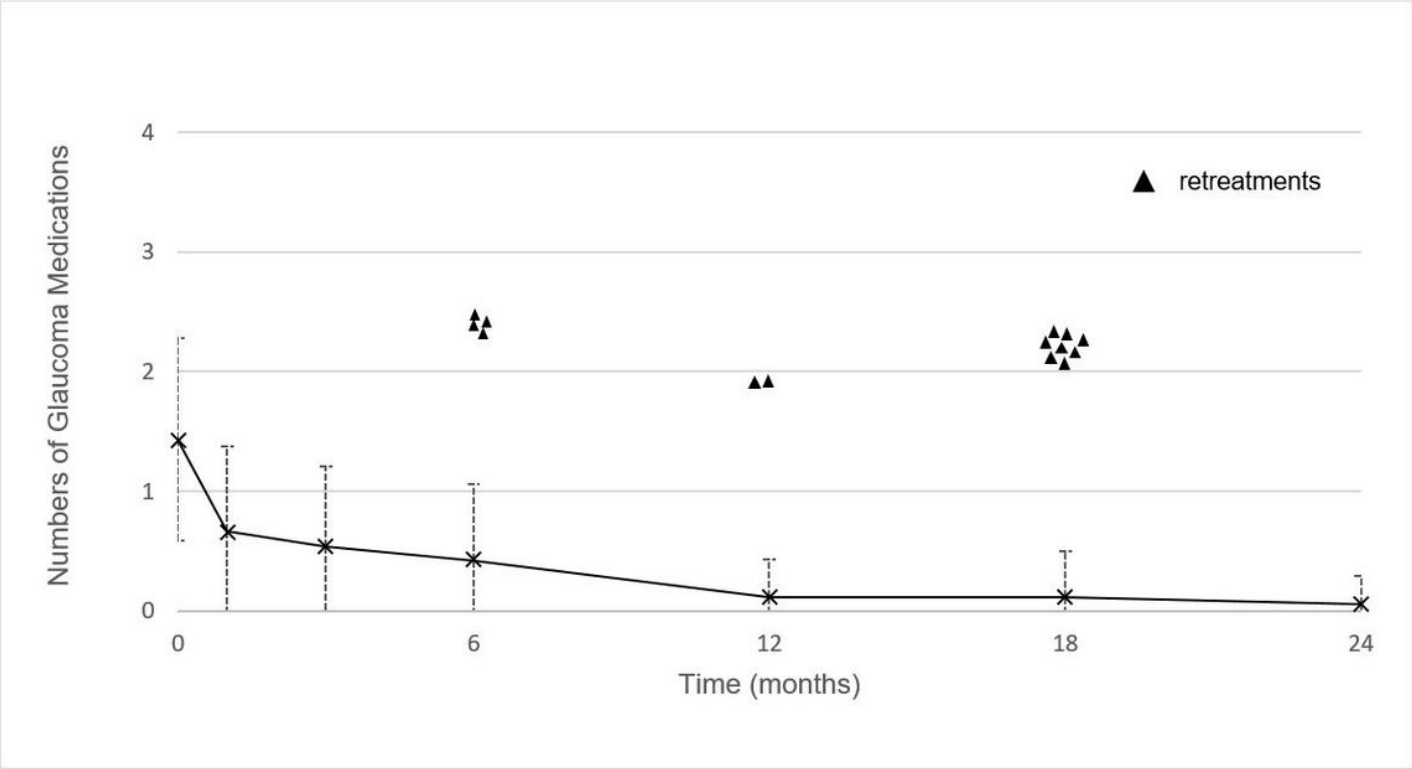

Figure 3

Mean number of glaucoma medications at follow-up intervals up to 2 years. A reduction of number of medications used was detectable within the first post-operative month and progressively decreased over 24 months. Black arrowheads represent the number of retreatments performed during follow up, the rate of retreatment was low and concentrated around the 18 months of follow-up. Error bars represent standard error of the mean