Quality of life in glaucoma patients after selective laser trabeculoplasty

Myrjam De Keyser1, Maya De Belder2, Veva De Groot1,3

1Department of Medicine, University of Antwerp, Universiteitsplein 1, Antwerp B-2610, Belgium
2Department of Experimental Psychology, Ghent University, Henri Dunantlaan 2, Ghent B-9000, Belgium
3Department of Ophthalmology, University Hospital Antwerp, Wilrijkstraat 10, Edegem B-2650, Belgium

Co-first authors: Maya De Belder and Veva De Groot

Correspondence to: Myrjam De Keyser. Den Brem 93, Wilrijk B-2610, Belgium. Myrjam@bijzonder.be

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Abstract

- AIM: To compare quality of life and treatment satisfaction between patients who had selective laser trabeculoplasty (SLT) and those on medication.
- METHODS: A prospective clinical trial on 143 glaucoma patients that received SLT and a control group that continued using anti glaucoma medication was conducted. Tear break-up time (BUT), punctuate keratitis, need for help, use of artificial tears and the treatment satisfaction survey of intraocular pressure (IOP) were measured at baseline, 6 and 12mo.
- RESULTS: SLT was able to reduce the mean number of medications needed from 1.56±0.81 to 0.42±0.66 at six months and to 0.33±0.69 at one year. Punctuate keratitis was observed significantly less often (12.24%) after SLT than before (35.94%; P=0.03). Use of artificial tears and BUT did not change significantly after SLT (P>0.05). At baseline, patients in the SLT group were significantly less convinced of medication effectiveness (P=0.006) and complained more about side effects (P=0.003). After SLT, these patients had significantly more confidence in their therapy (P<0.001), showed less side effects (P=0.006), complained less about changes in appearance of the eyes (P=0.003) and were less inconvenienced by the use of eye drops (P<0.001).
- CONCLUSION: SLT is able to improve treatment-related quality of life in glaucoma patients.
- KEYWORDS: glaucoma; laser treatment; medical treatment; quality of life

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INTRODUCTION

Glaucoma is the second leading cause of blindness in the world[1]. Currently, the only modifiable risk factor for glaucoma is raised intraocular pressure (IOP). Only lowering of the IOP is known to delay glaucoma onset and slow down disease progression[2]. First line therapy of glaucoma consists of ocular hypotensive drugs. As in all chronic diseases, medical adherence is a problem[3-4]. Decades of taking local medications can also reduce quality of life (QoL) of glaucoma patients through local and systemic side effects[5-6]. Local side effects like irritation and a toxic effect on the anterior eye segment have been demonstrated for the preservative of anti-glaucoma medication, most often benzalkonium chloride (BAK)[7], as well as for the active components of glaucoma drops[8]. Long term use of these eye drops is associated with ocular surface disease[7] and induces a range of complaints and signs like burning, stinging, dry eye syndrome, conjunctival hyperemia, foreign body sensation and tearing[8-9]. These symptoms usually become worse in the long term and can result in lower adherence[4,8,10]. Selective laser trabeculoplasty (SLT) has proven to be a valid alternative to medication[11-12]. Using laser instead of medical therapy can get around the problems of compliance[4,9], and can diminish the costs[13] and side effects of anti-glaucoma drugs[14]. We hypothesize that treatment with SLT compared to continuing topical medication for controlled open angle glaucoma patients and patients with ocular hypertension (OHT), will improve patients’ treatment-related QoL.

SUBJECTS AND METHODS

Study Design and Subjects This was a prospective clinical trial including 143 consecutive patients at the Glaucoma Consultation of Jan Palfijn Hospital, Merksem, Belgium. Approval of the Ethics Committee of ZNA was obtained (EC 4313), we followed the guidelines of the Helsinki Declaration. Enrollment occurred from January 2014 to July 2015. Data were recorded at baseline, 1h, 1wk, 1, 3, 6 and 12mo post-SLT (Trial registration: NTR 5417, registered 23 September 2015, retrospectively registered.).
Inclusion criteria concerned primary open angle glaucoma (POAG) or OHT controlled with medical therapy. Patients had to agree to sign an informed consent form. Exclusion criteria were other types of glaucoma than open angle glaucoma, previous trabeculectomy or laser trabeculoplasty treatment. Patients with corneal disease that inhibited good visualization of the trabecular meshwork and those taking systemic steroids were also excluded from the study.

Randomization of patient allocation was performed with a computer-generated allocation schedule using a blocked allocation sequence of 6 possibilities per block. Patients were consecutively introduced into the study; only after introduction of the personal patient data, the allocated group became clear to patient and observer. Patients were assigned to a group to be treated with SLT or to the control group that continued on topical glaucoma medication. However, we did allow patients who refused SLT, to enter into the control group, which partially biased randomization. No further masking was executed. In the SLT group, both eyes received SLT; the right eye was treated first. Only one eye of each patient was used for this analysis, this was chosen by a blocked randomization schedule.

The study was not designed to create additional IOP lowering effect, because IOP was already controlled with medication before treatment with SLT. The main goal of this study involved changes of ocular surface, quality of life parameters and treatment satisfaction.

**Baseline Examinations** At baseline a full ophthalmological examination of each study participant was conducted, including a medical history review, best corrected visual acuity measurement, IOP measurement using Goldmann applanation tonometry (mean of two measurements was taken), slit lamp examination of the anterior segment [conjunctival injection, tear break-up time (BUT), cornea, iris, lens appearance, gonioscopy], central corneal thickness (CCT) measurement (iPac Pachymeter, Reichert, Depew, USA), dilated fundus examination, visual field examination by computerized perimetry (program 24-2, Humphrey Field Analyzer 745i, Zeiss, Jena, Germany), optical coherence tomography (OCT) of the optic nerve head and recording of glaucoma medications and use of artificial tears. Need for help was defined as the complete dependency upon others to instill the glaucoma eye drops. All OCT scans were performed with the spectral-domain OCT RTVue (Optovue, Fremont, USA). We used focal loss of volume (FLV) as determinant for the OCT.

IOP before treatment was calculated as the mean of three measurements taken on 3 different visits, each 4 to 6mo apart, before starting anti glaucoma medication. IOP at baseline was calculated as the mean of the Goldmann measurements made on different time points on the three last visits before laser treatment.

For determination of BUT, a drop of 0.2% fluorescein solution was applied to the inferior fornix, and the participant was asked to close his/her eyes. Using the blue light of the slit lamp, the time in seconds between eyelid opening and the appearance of initial defects in the tear film was measured. The same examiner performed all examinations.

**Laser Technique** A frequency doubled, Q-switched Nd:YAG laser was used, emitting a wavelength of 532 nm, coupled to a slit lamp delivery system (Selecta Duet laser, Lumenis, Dreieich, Germany). We used single pulses with pulse duration of 3ns and spot size of 400 µm. The laser energy was initially set at 0.9 mJ and a single laser pulse was delivered at the 12 o’clock position. If a cavitation bubble appeared, the laser energy was reduced by 0.1 mJ increments until minimal bubble formation was observed. Treatment was then continued at this energy level. If no cavitation bubble was observed, the pulse energy was increased by steps of 0.1 mJ until bubble formation. Immediately before the laser procedure a drop of pilocarpine 1% and apraclonidine 0.5% were instilled into the treated eye. After the laser treatment, no anti-inflammatory drops were administered.

**Postoperative Management** Patients were examined 1h, 1wk, 1, 3, 6, 12 and 18mo after SLT. They received a clinical examination as part of their routine glaucoma care at 6 and 12mo, comparable to the examination at baseline. After SLT, anti-glaucoma drops were continued until IOP was more than 2 mm Hg below target pressure, at which point they were stopped one by one. A fixed combination of drugs was considered as a combination of two medications; the first step entailed a switch to a single medication. The second drug was stopped if possible, after respecting a minimal wash out period of three months. The number of applications daily was not changed during the study; a medication was continued at the normal frequency or stopped.

**Quality of Life** We used the Treatment Satisfaction Survey for Intraocular Pressure (TSS-IOP) to assess patients’ satisfaction with their anti-glaucoma treatment. The TSS-IOP questionnaire is a patient reported outcome measure designed to assess patients’ perception of the treatment used to lower their IOP. The validation study was presented by Atkinson et al in 2003, a clinical application of the test was published in 2006. We translated the questions in Flemish, the patients’ language. A non-exclusive right to use the TSS-IOP was granted to our study group by Pfizer in December 2013 for the duration of the trial protocol.

TSS-IOP contains four questions about perceived effectiveness of treatment (Questions 1-2, 16-17) in which patients are asked how satisfied they are about their treatment and how convinced they are that the treatment will maintain eye pressure within the normal range. The questions concerning unintended treatment effects (Questions 3-5) inquire about burning or stinging of
the eyes, feelings of grittiness or sandiness or the presence of crusts around the eyes. Three questions examine whether the treatment induces redness of the eye or other changes in appearance (Questions 7-9, 18). Convenience of use of the medication (Questions 10-12) inquires about the number of times per day a treatment has to be applied, at which time and if this can be easily remembered. Ease of administration of the drops (Questions 13-15) concerns the difficulty of getting the drops into the eye and whether only one or more drops have been applied.

All of these questions are assessed by 5- to 7-level answers ranging from e.g. "very sure" to "very unsure". Higher scores are indicative of greater satisfaction. The questionnaire was filled out at baseline, after 6 and 12 mo. Patients were given time to do so in the waiting room, so as not to feel pressured by the physician to answer the questions in a certain direction. Individual scores were computed by adding the scale values of the answers within an item, and transforming the resulting value into a score between 0 and 10.

### Results

#### Population

Demographic and baseline characteristics are shown in Table 1. No significant differences were present between the SLT and the control group for most baseline characteristics. At baseline, more patients were taking prostaglandin analogues in the SLT compared to the control group. Studies by Lai et al.\(^1\) and Singh et al.\(^2\) however showed that pre-laser glaucoma medication, more specifically prostaglandins, does not influence the outcome of SLT.

#### Laser Technique

All patients received a 360° treatment of the trabecular meshwork. We used a mean number of 102.03±8.39 non-overlapping spots with a mean energy of 1.10±0.30 mJ. The same experienced surgeon (De Keyser M) applied all treatments.

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**Table 1 Baseline characteristics of the population**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>SLT group (n=64)</th>
<th>Control group (n=61)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (a)</td>
<td>68.59±12.84</td>
<td>72.07±11.79</td>
<td>0.17</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>33 (51.56)/31 (48.44)</td>
<td>30 (49.18)/31 (50.82)</td>
<td>0.47</td>
</tr>
<tr>
<td>Risk factors (^1)</td>
<td>1.52±0.96</td>
<td>1.64±1.32</td>
<td>0.13</td>
</tr>
<tr>
<td>Glaucoma parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IOP before medication (mm Hg)</td>
<td>23.21±5.28</td>
<td>22.92±4.50</td>
<td>0.98</td>
</tr>
<tr>
<td>IOP at baseline with medication (mm Hg)</td>
<td>13.66±3.35</td>
<td>12.47±3.31</td>
<td>0.07</td>
</tr>
<tr>
<td>POAG/OHT</td>
<td>52 (81.25)/12 (18.75)</td>
<td>42 (68.85)/19 (31.15)</td>
<td>0.11</td>
</tr>
<tr>
<td>BCVA</td>
<td>0.85±0.22</td>
<td>0.81±0.22</td>
<td>0.28</td>
</tr>
<tr>
<td>CCT (µm)</td>
<td>545.66±44.25</td>
<td>552.20±40.46</td>
<td>0.24</td>
</tr>
<tr>
<td>Cup disc ratio</td>
<td>0.83±0.82</td>
<td>0.76±0.62</td>
<td>0.57</td>
</tr>
<tr>
<td>Visual field MD</td>
<td>5.07±6.04</td>
<td>5.23±6.59</td>
<td>1.0</td>
</tr>
<tr>
<td>Visual field PSD</td>
<td>4.43±3.31</td>
<td>4.59±3.72</td>
<td>0.84</td>
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<td>OCT FLV</td>
<td>4.34±4.52</td>
<td>4.88±4.67</td>
<td>0.52</td>
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<tr>
<td>Medication at start</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total number</td>
<td>1.56±0.81</td>
<td>1.39±0.67</td>
<td>0.57</td>
</tr>
<tr>
<td>Prostaglandin analogs</td>
<td>59 (92.19)</td>
<td>48 (78.69)</td>
<td>0.03</td>
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<tr>
<td>Betablocker</td>
<td>26 (40.63)</td>
<td>29 (47.54)</td>
<td>0.44</td>
</tr>
<tr>
<td>Carboanhydrase inhibitor</td>
<td>10 (15.63)</td>
<td>6 (9.84)</td>
<td>0.34</td>
</tr>
<tr>
<td>Alphamimetics</td>
<td>5 (7.81)</td>
<td>2 (3.28)</td>
<td>0.27</td>
</tr>
</tbody>
</table>

IOP: Intraocular pressure; BCVA: Best corrected visual acuity; POAG: Primary open angle glaucoma; OHT: Ocular hypertension; CCT: Central corneal thickness; MD: Mean deviation; PSD: Pattern standard deviation; OCT: Optical coherence tomography; FLV: Focal loss of volume in %. \(^1\)Risk factors: myopia, hypertension, diabetes, migraine, vascular problems, family history of glaucoma.

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(Supplementary text continues...
Evolution of Intraocular Pressure and Medication

Totally 72 patients were appointed to the SLT group, 64 of them completed a minimum six months of follow up, 49 were followed for one year. The control group contained 71 patients; 61 patients completed the minimal six months follow up schedule, 30 of them also completed the one-year follow up. No severe complications were recorded; data collection was stopped for practical reasons, resulting in limited follow up time.

IOP did not change significantly in both SLT and control groups, as was expected in this population of patients controlled under medication (Table 2). In the SLT group, the mean number of medication needed lowered from 1.56 at baseline to 0.42 at six months and 0.33 after 12mo. The difference compared to the control group was significant at 6 (P<0.001) and 12mo (P=0.001).

In the control group at baseline, 42 patients (68.85%) were taking one anti glaucoma medication; 15 patients (24.59%) were on two medications, 3 (4.92%) took three different medications and one (1.64%) took four medications. In the SLT group the number of patients on respectively one, two, three and four medications at baseline was 39 (60.94%), 16 (25.00%), 7 (10.94%) and 2 (3.13%). After one year, 38 (77.55%) of the patients in the SLT group no longer needed any medication to maintain their IOP. Seven patients (14.29%) were using one drop, 3 (6.12%) still needed two different drops and one patient (2.04%) needed three medications.

“Need for help” to instill the eye drops was comparable between the SLT and the control group at baseline, but patients in the SLT group needed significantly less help 6 (P=0.002) and 12mo (P=0.01) after SLT (Table 2).

Anterior Segment Condition

Mean BUT was below normal but comparable for SLT and control group (6.23s vs 6.13s) at all time points, as shown in Table 3. At baseline, 35.94% and 31.15% of patients showed punctuate keratitis in the SLT and control group respectively. Six months after SLT, there was a trend towards less punctuate keratitis (14.06%) (P=0.14) in the SLT group; after 12mo, the difference in punctuate keratitis (12.24%) compared to the control group became significant (P=0.03). Totally 35.94% of the patients in the SLT group and 24.59% of the control group at baseline used artificial tears. The use of artificial tears did not change significantly in both groups during follow up (Table 3).

Quality of Life/Treatment Satisfaction Survey for Intraocular Pressure Questionnaire

At baseline, there was a significant difference between the SLT and the control group for all items except ease of administration. Patients that were in some way bothered by their therapy, seemed to be motivated easier to have an SLT performed. Therefore, we further analyzed the evolution of each item within the groups (Tables 4, 5).

All items of the questionnaire (perceived effectiveness of the treatment, side effects, eye appearance changes, convenience of use of therapy, ease of administration of eye drops) remained the same in the control group that continued using the same medication. However, all of the examined items improved significantly one year after use of SLT (P<0.001).
Quality of life after selective laser trabeculoplasty

DISCUSSION

The medical treatment of glaucoma has a number of side effects, is expensive and often inconvenient to instill. It is therefore not surprising that glaucoma frequently has a large impact on a patients’ QoL.[4,6] The burden of this treatment, including cost,[13] inconvenience,[7-8] tolerability[9] and QoL[4] are factors that the doctor and patient should discuss because they can lead to poor or noncompliance, followed by progression of disease[10].

As in any chronic disease, noncompliance with drug therapy of glaucoma medication poses a therapeutic problem.[5] The addition of a second or third medication or therapeutic is correlated with a significant decrease in adherence.[3] Using eye drops more times a day, leads to a higher trend to disregard the treatment.[17] With effective laser trabeculoplasty, eliminating or reducing the need for glaucoma medications[13] may minimize the impact of compliance.

Lowering of Medication Compared to the control group on medication, SLT lowered the number of anti-glaucoma medications significantly (P<0.001) and when still medication was needed after laser treatment, SLT simplified the treatment schedules. Similar findings have been reported by several studies.[12,21-24]

In our study, use of SLT produced a mean drop of 1.23 medications. This is in agreement with the study from Lai et al[9] who reported a mean of 0.99-1.08 less medications needed after SLT. A mean of 0.7 less medications was reported by Bovell et al[25], five years after using SLT. Francis et al[26] recorded a very large mean drop of medication of 2.0 drops per person after six months. However, they started with an average of 2.79 medications taken at baseline, while we started with a mean of 1.56 medications per patient. Francis et al[26] showed that 63% of their patients were able to discontinue all eye drops. In our study, 77.55% of the patients that were treated with SLT no longer needed medication after one year of follow up. The patients remaining on medication had a simplified treatment schedule. The QoL study of Day et al[17] demonstrated that glaucoma patients are more satisfied about their treatment when they only need to instill one medication instead of using several. This was in part due to the decreased ocular irritation associated with dosing less medication and partly related to greater convenience of use from instilling fewer dosages per day.[8,17]

A very large cohort study by Nordstrom et al[5] demonstrated that physicians traditionally overestimate the adherence of their patients to their local glaucoma treatment since nearly half of the patients discontinued the initially prescribed drop therapy completely within six months. Using SLT can make us at least sure of actually treating the patient.

Need for Help Part of patients’ QoL is also their independence. In a large cross sectional study on QoL in glaucoma patients, Odberg et al[5] found that 11% of glaucoma patients were dependent upon help from relatives or others to instill their medication. In this context, Sleath et al[27] showed that unmarried patients had significantly more problems than married patients in managing their glaucoma and confessed more often to be less than 100% adherent. We recorded 12 patients in the SLT group (20%) and 18 in the control group (30%) at baseline that needed help from others to instill their drops. This changed little in the control group, but the amount lowered significantly in the SLT group at 6 and at 12mo to 10% and 12% (P=0.01), suggesting enhanced independence.

Anterior Segment Condition As reported in several studies, ocular surface disease and reduced BUT are very common in glaucoma patients.[7-8,14,28]. The severity of the reported symptoms is positively correlated to the number of IOP lowering medications used.[9,14,28]. Leung et al[28] recorded a reduced BUT in 78% of glaucoma patients on local medication. In our study, BUT was reduced in 72.80% of patients, we found no difference in BUT between the SLT and the control group at any time point.

At baseline, punctuate keratits was recorded in 31.15% to 35.94% of the patients. There was a trend towards less punctuate keratitis in the SLT group (14.06%) after six months, which became statistically significant after 12mo (12.24%; P=0.03). The incidence of punctuate keratitis at baseline was higher in our groups than in a report by Pisella et al[9], which showed a prevalence of 19% of superficial punctuate keratitis among patients using glaucoma medication. Leung et al[28] recorded 22% of their patients showing corneal and conjunctival lissamine green staining. Our progressive decrease may be explained by additional decrease of medication, or by the fact that epithelial recovery takes some time. A large segment of our glaucoma patients were taking artificial tears at baseline: 35.94% in the SLT group and 24.59% in the control group. At the six months follow up this number was significantly lower in the SLT group (31.25%) while it was raised in the control group (34.43%). Being part of a study possibly drew attention to side effects (scratching, redness, sandy feeling), leading to more artificial tears use in the control group after 6 and 12mo.

In a study of Costa et al[29], more glaucoma patients (53%) used artificial tears compared to their age-matched controls (18%) without glaucoma therapy. Pisella et al[8] registered use of artificial tears in 19% of their glaucoma patients. Our findings seem to lie in between those of Costa et al[29], and the ones from Pisella et al[8], confirming more need for artificial tears in patients on anti glaucoma treatment.

Quality of Life

Perceived effectiveness Satisfaction or dissatisfaction with medication predicts patients’ continuance of their treatment, the correct use of medication and compliance with the medication
regimens[18]. In our study, patients that agreed to have an SLT done were less sure of the effectiveness of the medication they were taking (P=0.006); complained more about its side effects (P=0.003) and were bothered more by the inconvenience of using eye drops (P=0.01). They had difficulties putting in the drops and using only one drop at a time, but this did not differ from the control group (P=0.67). After the laser treatment, all these parameters scored significantly better in the SLT group. Patients believed more in the effectiveness of treatment, had less burning and stinging of the eyes, the eye appearance improved and remaining medication was easier to remember and to apply.

Similar findings were reported by a treatment related study by Odberg et al[5], who took patients on glaucoma medication and examined their QoL. Half of their patients treated with laser or surgery evaluated their situation as improved after these operations. Possible explanations were the relief by doctor and patient related to a lowering of the IOP or to a lesser need of medication. Odberg et al[5] stated that it is likely that a satisfactory regulation of the IOP without use of topical therapy will give patients a better QoL.

Nordmann et al[6], who did a large cross-sectional survey studying the link between patient-reported side effects of anti-glaucoma medication and vision-related QoL, reported that poor subjective treatment satisfaction was related to poor vision related QoL, which in turn could be connected to less compliance. Since compliance is of major importance to get the full potential protective effect against visual field defect, tolerance of and satisfaction with treatment are a critical issue[17].

Side effects Pisella et al[9] questioned a group of 4107 patients on anti glaucoma medication; 61% of patients reported some kind of irritation. The prevalence of signs and symptoms was dose-dependent and increased with the number of preserved eyedrops usedby the patient. Odberg et al[5] noted complaints about side effects in 47% of their glaucoma patients; most common were itching (24%) and pain (10%). Nordmann et al[6] reported 62.4% of their glaucoma patients complained of at least one local side effect. Presence of local side effects correlated to poor treatment satisfaction and additional visits to the ophthalmologist.

In a study of Schwartz et al[30] hyperemia was noted by the physician in 19.5%-31.5% of the patients on prostaglandin analogues for glaucoma; it was a common reason for medication change and responsible for additional therapeutic costs. In our study the questionnaire recorded a significant improvement in side effects and complaints about eye appearance after SLT.

Ease and convenience of use Multiple medications and multiple daily administrations can be an inconvenience and, for a subset of patients with dexterity problems, present significant difficulties to its use. The costs and side effects (discoloration of eye lids) associated with wastage of product by missing the eye can be a substantial concern for patients[17]. Use of SLT minimized the inconveniences associated with the administration of medications (P<0.001).

Limitations of This Study Patients who had been allocated to the SLT treatment by the randomization program, but refused this, were allowed to serve as control patients. This interfered with proper randomization. However, in our opinion this does not deter from the fact that all complaints improved after SLT. Secondly, the TSS-IOP questions were translated taking into account translation, back-translation and cultural adaptation. No further specific methodology was used. TSS-IOP includes questions referring to the use of medication and ease of administration of eye drops. This is less applicable after SLT since this simplifies treatment schedules. However, problems with use and administration of medication can result in loss of compliance, so it should be taken into account when deciding to use SLT or not. Using a vision specific QoL questionnaire would have been another option, but vision does generally not change in glaucoma patients within the restrictions of a one to two year study period[31].

Clinicians tend to over-estimate compliance[3,32] and underestimate the impact on QoL of glaucoma medication[5,7]. SLT can significantly lower the burden of treatment for glaucoma patients with respect to QoL, as well as convenience and tolerability of the treatment.

In conclusion, SLT significantly lowers the amount of anti glaucoma medication needed and improves treatment-related QoL. Patients show less dependence upon help of others to instill drops, have less punctuate keratitis and less subjective side effects. They are convinced of the effectiveness of their treatment and have fewer problems applying any remaining drops. Maybe SLT should become first-line treatment instead of medication in the therapy of glaucoma.

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Conflicts of Interest: De Keyser M, None; De Belder M, None; De Groot V, None.

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