Original Article

Effectiveness of Selective Laser Trabeculoplasty and Its Safety on Corneal Endothelium in Patients with Primary Open Angle Glaucoma and Ocular Hypertension

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of selective laser trabeculoplasty (SLT) in patients with primary open-angle glaucoma (POAG) and ocular hypertension (OHT), and to assess its effects and safety on corneal endothelial cell morphology. Patients and Methods: Forty patients with POAG (15 cases, 23 eyes) and OHT (25 cases, 48 eyes) were prospectively evaluated. All cases underwent pachymetry, goniolens examination, Humphrey Visual Field Test, Optical Coherence Tomography, and Corneal Confocal Microscopy measurements. Patients whose intraocular pressure (IOP) was more than 21 mmHg in POAG and OHT, underwent SLT. SLT treatment was applied to the inferior 180° region of the trabecular meshwork. Central corneal thickness (CCT), IOP, and specular microscopy examinations were taken at the visits before and after the first day, first week, first month, third and sixth months of the SLT procedure. Retinal nerve fiber layer (RNFL) thickness measurements and visual field tests were performed before and six month post-SLT. Results of the pre-SLT and post-SLT measurements were compared and a P value of lower than 0.05 was considered statistically significant. Results: The results of IOP measurements at first week, first month, third, and sixth month post-SLT were significantly lower than the results before and post-SLT first day. No significant difference was found between the results of initial and final measurements of CCT and specular microscopic corneal endothelial cell morphology evaluation. There was no statistically significant difference between the results of initial and final measurements for RNFL thickness and the results of the visual field tests. **Conclusion:** SLT is an effective treatment modality for reducing IOP in patients with POAG and OHT and is also a safe procedure in terms of the entirety of corneal endothelial cell morphology.

Background and Aim: The aim of this study was to evaluate the effectiveness

KEYWORDS: Corneal endothelial morphology, ocular hypertension, primary open-angle glaucoma, selective laser trabeculoplasty

INTRODUCTION

Glaucoma is a chronic optic neuropathy characterized by progressive damage to the optic nerve head and nerve fiber layer which results in visual field loss. In studies conducted in past years, the incidence of open-angle glaucoma has been shown to vary between 0.4% and 8.8% and is recognized as the second most common cause of blindness all over the world.^[1]

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POAG is associated with elevated IOP, cupping of the optic nerve head, and loss of the RNFL and visual field. It is the most common type of glaucoma, affecting

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approximately one out of every 100 people over the age of 40; presents insidiously, and progressively and causes anterior optic neuropathy.^[2] One of the features that distinguish it from other types of glaucoma is the clear view of the iridocorneal angle.

OHT is defined as the presence of IOP above 21 mmHg in at least two measurements taken at different times and an open anterior chamber angle on gonioscopic examination, despite the absence of glaucoma-specific optic nerve head changes or visual field loss. People with OHT are suspected to have glaucoma or are considered early-stage POAG cases.^[3] While the incidence of OHT is 10% over the age of 70, the incidence of POAG is 2% in the same age group. Several multicenter studies have been conducted to investigate the rate of conversion of to POAG without any treatment and have shown that the rate of conversion of OHT to POAG is 0.5% – 4% per year.^[4]

High IOP is the most important treatable risk factor for glaucoma, which can be reduced by decreasing the production of aqueous humor and/or increasing its outflow with medical treatment, laser treatment, and different surgical methods. SLT has been shown to reduce IOP effectively in cases with high IOP^[5] and its effectiveness is comparable to the most potent topical drug treatments without serious adverse events.^[6] The success of SLT in terms of reducing IOP brought this modality into an area in which its usage is considered as a first treatment option.^[7]

Although the efficacy of SLT in reducing IOP is well documented, data regarding the safety profile such as alterations in results of visual field and RNFL thicknesses after this therapy is scarce. Moreover, whether this therapy also has an effect on corneal endothelial cell morphology or not, remains unclear. In this study, our aim was to examine the effectiveness of SLT in patients with POAG and OHT and also its effect on the rate of disease progression and on the morphology of the corneal endothelium.

MATERIALS AND METHODS

Patients

Forty cases diagnosed with POAG and OHT in Selçuk University Faculty of Medicine, Department of Ophthalmology were included in this prospective study. Twenty of the cases were male and 20 were female. The study was approved by the local Ethics Committee of our faculty (decision number: 2012/14). Written informed consent was obtained from all patients.

Patients with IOP above 21 mmHg in at least two separate measurements, typical glaucomatous optic

nerve change (increased C/D ratio, cupping appearance), grade 3 and 4 anterior chamber angle on gonioscopic examination (open-angle), and patients with the criteria for the presence of glaucomatous visual field defects on Humphrey visual filed examination were included in the study with the diagnosis of POAG. For the diagnosis of OHT; the criteria were IOP value above 21 mmHg in at least two random measurements, normal visual field test results, the normal-appearing optic disc in optic disc photographs, absence of bleeding, cupping and RNFL thickness defects. Patients with neovascular glaucoma, congenital glaucoma, narrow-angle or closed-angle glaucoma and patients with corneal clouding that prevents the visualization of the anterior chamber angle, and patients who have previously undergone intraocular surgery other than uncomplicated phacoemulsification surgery and laser trabeculoplasty were excluded from the study.

IOP measurements, Visual field testing, RNFL imaging, and Specular microscopy at baseline and follow-up.

In all patients, IOPs were measured with a Goldmann applanation tonometer. In all patients, IOP values were measured in the morning at baseline before SLT, and on the first day, first week, first, third, and sixth months after the application. All measured IOP values were obtained using the Ehlers CCT- IOP correction chart, and corrected IOP values for CCT were analyzed.[7] The iridocorneal angle was evaluated with a Goldmann triple-mirror goniolens. Corneal thickness were measured with ultrasonic pachymetry (Nidek, Echoscan US-4000, Japan) at the time of admission and at the first week, first month and sixth month follow-up after SLT. RNFL thickness measurement with OCT (Carl Zeiss Meditec AG, Stratus OCT, Germany) and Humphrey 30-2 full threshold visual field test (Carl Zeiss Meditec AG, Humphrey Field). Analyzer 750i, Germany) were performed before the SLT procedure and repeated six months after the therapy.

Specular microscopic measurements of cases were performed with a Confoscan-4 device (Nidek Co., Japan). Specular microscopic assessments including analysis of mean corneal endothelial cell number, polymegethism, and pleomorphism rates were analyzed before and one day, one week, one month, three months, and six months after the SLT therapy.

SLT procedure

SLT procedure was performed with a laser (Lightmed Corp, USA, SeLecTor IEC60825) using Latina goniolens after topical anesthetic drops (proparacaine 0.5%) was instilled, accompanied by premedication with brimonidine drops (0.15%). Starting at the lower part of

the angle at 180° with a power of 0.7 mj, the power was increased by 0.1 mj up to 1.2 mj until bubble formation was observed, and 50-60 laser shots were applied. After the SLT procedure, IOP was measured 2 h later and loteprednol drops QID was given for two days. Adverse events such as anterior chamber inflammation and an increase in IOP after SLT were noted during follow-up visits.

Statistical analysis

For comparing the results of pre-and post-SLT examinations, variance analysis tests in repeated measurements and paired sample t-tests were used. The results were evaluated at the 95% confidence interval and the significance level was taken as 0.05. Analyzes were carried out by using Statistical Package for the Social Sciences (SPSS) for windows version 15.0.

The outcome measure was defined as a reduction of IOP $\geq 20\%$ from baseline in the third month with the pre-SLT IOP lowering medication drops in patients with POAG and without any medication in patients with OHT.

Table 1: Demographic characteristics and average ocular parameters of the patients

| | POAG | OHT |
|------------------------------|-------------------|-----------------|
| Number of male patients | 9 | 11 |
| Number of female patients | 6 | 14 |
| Number of the eyes | 23 | 48 |
| Mean age±SD (year) | 67.4±15.87 | 53.62±12.21 |
| Mean IOP±SD (mmHg) | 26.66 ± 4.04 | 30.11±4.32 |
| Mean Initial CCT±SD (µm) | 543.21±21.69 | 545.33±21.49 |
| Mean number of SLT shoots±SD | 56.43±2.14 | 56.77±2.34 |
| Mean energy of SLT±SD (mj) | $0.85 {\pm} 0.18$ | 0.88 ± 0.19 |

POAG: Primary open angle glaucoma, OHT: Ocular hypertension, SD: Standard deviation, IOP: Intraocular pressure, CCT: Central corneal thickness, SLT: Selective laser trabeculoplasty

Table 2: Results of IOP measurements in patients with POAG and OHT (mean mmHg±SD)

| | POAG | OHT |
|----------------------|------------------|------------------|
| Pre-SLT | 26.66±4.04 | 30.11±4.32 |
| Post-SLT first day | 25.92±3.86 | 29.81±4.39 |
| Post-SLT first week | 17.43±3.15 | 19.91 ± 2.58 |
| Post-SLT first month | 17.16 ± 3.06 | 19.88 ± 2.73 |
| Post-SLT third month | 17.18 ± 3.34 | 19.55 ± 3.30 |
| Post-SLT sixth month | 17.20±2.85 | 19.66 ± 2.75 |

Other outcome measures were the preservation of the RNFL thickness and MD, and PSD scores of visual field tests without observing corneal endothelial cell loss.

RESULTS

A total of 71 eyes of 40 patients who were followed up with POAG and OHT who underwent SLT treatment in Selcuk University Faculty of Medicine, Department of Ophthalmology, were included in the study. Fifteen of the patients had POAG (23 eyes) and 25 were suffering from OHT (48 eyes). The mean age of the patients in our study was 57.33 ± 13.99 years (range: 23-81 years). IOP levels of the cases ranged from 22 to 36 mm Hg in the POAG group, with a mean level of 26.66 mmHg \pm 4.04. In the OHT group, IOP values were between 25 and 42 mmHg and the mean level was 30.11 mmHg \pm 4.32. Demographic characteristics and baseline ocular parameters of the patients as also details of SLT therapy are summarized in Table 1.

The cases with POAG were patients who used antiglaucomatous drugs before and had high IOP values



Figure 1: Specular microscopic findings of patient with POAG obtained at baseline and at follow-up visits. (a) pre SLT, (b) post SLT at first week, (c) post SLT at first month, (d) post SLT at third month (e) post SLT at sixth month

| Table 3: Mean results of visual field test in patients with POAG and OHT | | | | |
|--|-------------------|-----------------|----------------|-----------------|
| | POAG | | ОНТ | |
| | MD (dB)±SD | PSD (dB)±SD | MD (dB)±SD | PSD (dB)±SD |
| Pre-SLT | -14.66±6.67 | 6.67±3.64 | -2.37±0.90 | 1.45±0.78 |
| Post-SLT 6th month | -14.58 ± 6.67 | 6.62 ± 3.65 | -2.34 ± 0.87 | $1.39{\pm}0.78$ |

SLT: Selective laser trabeculoplasty, POAG: Primary open angle glaucoma, OHT: Ocular hypertension, MD: Mean deviation, PSD: Pattern standard deviation, SD: Standard deviation, dB: decibel

despite current medical treatment. Seven of the 23 eyes (30%) were using dual drugs, while the rest were using triple drugs.

In both groups, IOP values were measured on the first day, first week, first month, third month, and sixth month after the SLT procedure in the morning. No statistically significant difference was observed between the results of IOPs of pre-SLT and post-SLT one day values in patients with POAG and OHT (P = 0.092 and P = 0.12 respectively, paired sample t-test). However, the decrease in IOP values between pre-SLT and post-SLT at the first week, first month, third month, and sixth month in POAG and OHT groups was statistically significant (P < 0.001, Variance analysis test in repeated measurements). The results of IOP value for pre-and post-SLT measurements are depicted in Table 2.

With SLT treatment, 12 (48%) of 25 eyes with POAG showed a decrease in the IOP of more than 30% at the first-week follow-up, and this decrease was observed to be maintained for six months. In the remaining 13 eyes (52%), a decrease in the IOP of 20% to 30% was observed in the same follow-up period, which lasted for six months. Considering the OHT group, 23 (48%) of 48 eyes showed more than a 30% decrease in IOP in the first week of follow-up, and it was observed that this decrease was maintained for six months. In the remaining 25 eyes (52%), a decrease in the IOP of between 20% and 30% was observed in the same follow-up period, which lasted for six months.

When the visual field results were analyzed, the initial MD values for the POAG case group were -14.66 ± 6.67 and -14.58 ± 6.67 dB before and after SLT, respectively, and there was no statistically significant difference

Table 4: Results of RNFL analysis obtained with OCT at pre-SLT and post-SLT 6th month in patients with POAG and OHT

| | Results of RNFL analysis (mean µm±SD) | |
|--------------------|---------------------------------------|------------|
| | POAG | OHT |
| Pre-SLT | (50.2±5.1) | (89.4±8.3) |
| Post-SLT 6th month | (51.1±5.4) | (90.5±9.1) |
| | | |

POAG :Primary open angle gloucoma, OHT: Ocular hypertension, RNFL: Retinal nerve fiber layer, SLT: Selective laser trabeculoplasty, OCT: optical coherence tomography, SD :standard deviation between these two values (P = 0.60, paired sample t-test). Again for the same group, the PSD values obtained before and sixth month post-SLT were 6.67 ± 3.64 and 6.62 ± 3.65 , respectively, and there was no statistically significant difference between them (P = 0.35, paired sample t-test). Similarly, the MD values for the OHT case group were -2.37 \pm 0.90 and -2.34 \pm 0.87 dB before and sixth month post-SLT, respectively and the difference between these values was not statistically significant (P = 0.41, paired sample t-test). In the same group, the PSD values obtained before and sixth post-SLT were 1.45 ± 0.78 and 1.39 ± 0.78 , respectively, and again; no statistically significant difference was found between these two values (P = 0.29, paired sample t-test). The mean results of the visual field tests obtained before and after SLT in patients with POAG and OHT are shown in Table 3.

In the POAG and OHT groups, the RNFL values obtained by OCT before SLT were 50.2 ± 5.1 and $89.4 \pm 8.3 \mu m$, respectively. In sixth month post SLT, the values were 51.1 ± 5.46 and $90.5 \pm 9.1 \mu m$, respectively, and no significant difference was found between the groups between the two periods (P = 0.22 and P = 0.35, paired sample t-test, respectively). The results of RNFL analysis obtained with OCT at pre-SLT and sixth post-SLT in patients with POAG and OHT are shown in Table 4.

The mean of the CCT measurements taken before and at first week, first and sixth month post-SLT were 540.2 ± 27.7 , 539.3 ± 27 , 540.1 ± 27.2 , and 538.9 ± 26.9 , respectively and no statistical significant difference was found between these results (P = 0.36, Variance analysis test in repeated measurements).

There was again no statistically significant difference between the results of corneal endothelial cell counts, polymegathism, and pleomorphism rates before and sixth month post SLT (P = 0.126, P = 0.159, P = 0.32respectively; Variance analysis test in repeated measurements, Figure 1). The results of corneal endothelial cell number and morphology analysis of all cases at pre- and post-SLT periods are shown in Table 5.

Mild (1 + cell) anterior chamber inflammation was observed in half of the cases in the second hour and

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| Table 5: Results of corneal endothelial cell number and morphology analysis of all cases at pre- and post-SLT periods | | | |
|---|---|----------------------------|---------------------------|
| | Mean corneal endothelial cell number±SD | Mean polymegethism rate±SD | Mean pleomorphism rate±SD |
| Pre-SLT | 2313.06±279.48 | 48.20±7.74 | 39.17±7.16 |
| Post-SLT first week | 2271±273.84 | 49.44±10.04 | 39.08±7.56 |
| Post-SLT first month | 2282.86±266.5 | 50.60±10.09 | 38.09±7.22 |
| Post-SLT third month | 2313.86±255.18 | 48.87±7.64 | 39.01±7.23 |
| Post-SLT sixth month | 2308.06±265.46 | 48.30±7.47 | 39.35±7.03 |
| | | | |

SLT: Selective laser trabeculoplasty, SD: standard deviation

there was no evidence of inflammation in any of the patients at first week post-SLT. In one patient with unilateral POAG, IOP decreased in first week post-SLT; however, 3+ cell reaction, posterior synechiae, and corneal clouding were detected in the chamber. Topical prednisolone, cyclopentolate HCl, and tropicamide drops were given to the patient, whose specular microscopic endothelial analysis showed dark spots and patch-like spots on the corneal endothelial layer in both eyes, and it was observed that the findings regressed in two weeks. No increase in the IOP of 5 mmHg or higher was observed in the second-hour measurements after SLT in any of the cases.

DISCUSSION

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In recent years, reducing IOP by facilitating the outflow of aqueous fluid has become increasingly important in the treatment of glaucoma. The mechanism by which SLT lowers IOP is still unclear. Stein and Challa stated that mechanical effect, biochemical effect, and cellular effect play a role in the decrease of IOP after SLT.[8] SLT activates proliferation and remodeling in trabecular and endothelial cells. It stimulates macrophages and phagocytosis by causing the release of cytokines such as IL-1a, IL-1b, and TNF- α with damage to the pigmented trabecular meshwork cells. Increasing the migration and phagocytosis functions of macrophages removes debris from the trabecular meshwork and biologically stimulates the formation of healthy trabecular tissue which results in outflow increase and eventually reduced IOP.^[8]

The first description of the reducing effect of SLT on IOP was reported by Latina et al.^[9] In this study IOP reduction of \geq 3 mmHg was reported in 70% of the eyes of patients who received and did not receive Argon Laser Trabeculoplasty (ALT) treatment before.^[9] After this report, several studies were published about the clinical efficacy of SLT, and pooled results suggest that average IOP reduction following SLT is 21.8-29.4% at six months with a gradual decrease in this lowering effect with time reaching 7.7-27.8% at two years.^[10] Besides, the effect of SLT on the reduction of IOP is more pronounced in patients with POAG showing resistance to medical therapy.^[11] In our study, we interestingly demonstrated the continuous effect of SLT in terms of lowering IOP for six months and the patients with POAG in our study group were the ones showing resistance to medical therapy. Success rates also vary as time goes on; and >20% reduction of IOP from baseline occurs in 66.7-75% of eyes at six months and in 11.1-31% at five years.^[10] We evaluated the effectiveness of SLT in a short time follow-up of six months and observed a more than 20% decrease in IOP in all eyes starting from the

first week of the therapy that lasted during the follow-up period. Mansouri et al.,[12] who evaluated the lowering efficacy of SLT in a short-term follow-up period of six months like us, reported a percentage reduction in IOP of 18.5 at six months which is lower than our result. This may be secondary to the baseline IOP levels of our patients which were higher than the ones of their study and this was also suggested as an explanation for their finding of the relatively modest IOP-lowering effect of SLT compared to other studies in the literature. Wong et al.,[13] evaluated the efficacy and safety of SLT and compared it with pattern scanning laser trabeculoplasty and reported SLT as a safe procedure without observing any detectable difference in visual field tests and average RNFL thickness. The absence of significant difference between the results of RNFL measurements and Humphrey visual field tests at baseline and follow-up visits lasting for six months is also prominent in our study showing the effectiveness and continuity of SLT treatment.

Nagar and colleagues showed that 90° SLT results were less successful than 180° or 360° SLT results, but they reported no significant difference between 180° and 360° SLT results.^[14] It is generally believed that there is a dose-response relationship between the extent of SLT application and the reduction of IOP. In this study, we applied SLT 180° to the cases. In this way, it was aimed to minimize the existing side effects with the lowest angle at which sufficient benefit can be achieved with SLT and the corresponding shot number.

SLT-induced inflammation which evolves secondary to biological changes including the release of pro-inflammatory cytokines is transient and self-limiting. Up to 83% of eyes demonstrating some degree of inflammation is described in the literature. Concordant with the results of the literature, transient mild inflammation early after the therapy was observed in half of our patients which resolved one week later in all cases.

Latina *et al.*^[9] found an IOP elevation of 5 mmHg at the 2^{nd} h in 25% of eyes that underwent SLT. They showed that the pressure was lowered in 24 h with drug therapy that temporarily lowers IOP. It has also been observed that this elevation is not permanent and does not recur with the discontinuation of the drug. Similarly, Lai *et al.*^[15] found a temporary IOP elevation of 5 mmHg or more at the second hour in 10.3% of patients who underwent 360° SLT treatment. However, in our study, no increase in the IOP of 5 mmHg or higher was observed in the second-hour measurements in any of the cases which may be secondary to the application of SLT only on the 180° lower half.

There are also studies on the effects of various laser applications on the corneal endothelium. In one study, it was shown that corneal endothelial cells decreased depending on the laser power after argon laser photocoagulation of the retina, while in another study it was reported that the number of corneal endothelial cells did not change with argon laser iridotomy.[16,17] The etiology of corneal endothelial damage is thought to develop with laser blasts thrown at the Sampaolesi line, but it was stated that edema should start from the corneal periphery as a result of such damage, and central corneal edema developing after SLT could not be associated with direct laser effect. Paiva and Fonseca stated that SLT may increase vasoactive and chemotactic cytokines which may cause the destruction of collagen by fibroblasts and reported the increase of aqueous matrix metalloproteinases type 2 and free radicals resulting in inefficient corneal reepithelization and endothelial cell damage; respectively.[18] They suggested low-power laser therapy as an alternative approach in order to obviate the potential side effects of the SLT procedure. Again, corneal epithelial toxicities of alcohol and other disinfectants remaining in the SLT lens used in the etiology of corneal edema developing after SLT, the role of previous iritis or HSV keratitis, and the effects of brinzolamide used after SLT on the endothelium were discussed, but no definite opinion could be reached. Finally, it has been shared that topical steroid drugs may be beneficial to prevent the occurrence of this complication.^[19] Ong et al.^[20] reported 2 cases with pigment changes in the corneal endothelium and endothelial deposits on biomicroscopic examination after SLT. These deposits disappeared completely at the end of the first month and were emphasized that this may develop in patients undergoing repeated SLT and that the deposits may possibly lead to endothelial toxicity.

In this study, corneal endothelial cell count, endothelial pleomorphism and polymegethism rates, and CCT findings of POAG and OHT cases were evaluated before and after SLT, and no statistically significant difference was found during six-month follow-up. Without mentioning the effect of SLT on corneal cell morphology, Wong et al.[13] also reported no change in corneal endothelial cell count, at the baseline and 12-month-follow which was concordant with the results of our study. Although a short follow-up period of six months was used, observing in change on corneal cell morphology in terms of pleomorphism and polymegethism rates during follow-up can be underlined as an unusual point of our study. Other factors were tried to be kept constant in order to evaluate the effect of SLT on the corneal endothelium, and no change was made in drug treatments after SLT for six months. Taken together, in light of these findings, it can be concluded that SLT applied once has no side effects on the corneal endothelium. Prospective controlled studies are needed to evaluate the results of multiple applications.

The weakness of this study is the small number of patients who underwent SLT, the short follow-up period, and the fact that it was applied only at a 180° angle. We also could not evaluate the density of aqueous flare and cells after SLT application with a flare meter.

In conclusion, SLT treatment may control IOP strongly while protecting nerve fibers and the visual field at the same time, both in patients with POAG and OHT. It can be used safely without severe side effects and without any change in corneal cell morphology.

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Conflicts of interest

There are no conflicts of interest.

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