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Highlights

"...initial results of a study which is, to date, the best designed and possibly the most important clinical trial investigating the use of SLT."



**SLT News from
AAO 2006 Annual
Meeting**

by Michael Belkin

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SLT Gains Global Momentum

A Round Up of Recent Symposia and User Group Meetings

Understanding and acceptance of SLT as a valuable treatment in the fight against glaucoma continues to grow worldwide, as evidenced by the number of countries hosting SLT-specific meetings. In this issue of *Regenerate*, we spotlight a few of those scientific symposia, as well as the first gathering of the new Ellex SLT user group in Russia.



Professor Isabelle Riss performing SLT on patients during the Tabriz SLT symposium.

If you would like to learn about upcoming meetings, log into our exclusive new SLT website, slt-ellex.com. If you are interested in hosting a future symposium, or in forming an SLT user group in your region, Ellex has information, ideas and resources to help you get started. Contact your local representative or Ellex directly at slt@ellex.com.

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"Ask the Experts"

When you incorporate a new procedure into your practice, it can be difficult to find answers to your practical questions, from someone who already has valuable experience.

Mrs. Madhu Nagar, a specialist in glaucoma management, has undertaken several studies investigating the efficacy of SLT as a treatment for glaucoma. She is a leading proponent of SLT, with six years' experience administering the procedure. Mrs. Nagar recently agreed to answer SLT-related questions from other treatment providers via the Ellex SLT website, slt-ellex.com. Those questions, and her answers, appear below.

Q: At what point in the treatment cycle should SLT be introduced?

A. I introduced SLT as adjunctive treatment for patients who were uncontrolled on maximum tolerated medical therapy, had previous failed ALT, were poor/non-compliant patients, or were intolerant to medical treatment.

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Clinical Tips

Enping Chen, MD, Stockholm, Sweden



Dr. Enping Chen is an Associate Professor at Glaucoma Service for St. Erik's Eye Hospital at the Karolinska Institute in Stockholm, Sweden. He performs approximately 12 SLT treatments per week, and has treated over 2,000 SLT patients since 2001. In 2005, Dr. Chen undertook a clinical study to investigate the efficacy of 180-degree treatment versus 90-degree treatment.

Tips for Use of Selective Laser Trabeculoplasty

- It is important to provide patients with educational information on SLT so that they will understand the purpose, the procedure and the risk of complications associated with SLT before undergoing treatment.
- Treatment should be performed just below the level of energy at which champagne bubbles are formed. To do this, determine the level of energy required for bubble formation and then reduce it by 0.1mJ before beginning treatment. For trabecular meshwork without pigmentation, it could be difficult to see the air bubbles. An energy level of 1.2-1.4 mJ is usually enough in this case.
- Adjust the energy level during treatment according to the pigmentation of the trabecular meshwork.
- SLT may be performed with 25 laser effects on 90 degrees of the trabecular meshwork.
- If the target pressure is not achieved, the treatment may be performed in another quadrant after a couple of months.
- Anti-inflammatory agents are not necessary in most cases.
- Preventive hypotensive agents are not necessary in most cases.

SLT for Primary Angle-Closure Glaucoma Study Update

2006 saw the completion of the final patient follow-up in the multi-center, multi-country clinical study on SLT for primary angle-closure glaucoma (PACG).

Involving six centers throughout Southeast Asia, the study was a prospective observational, non-randomised pilot case-series study to determine the efficacy of SLT in achieving a significant reduction of intraocular pressure (IOP) for patients with PACG who have open angle following peripheral iridotomy, but persistent elevation of IOP.

A strict protocol was devised to ensure a homogeneous patient cohort, and required follow-up periods of one day, one week, four weeks, three months and six months. Each study site used either an Ellex Tango™ or Solo™ SLT laser system to perform SLT.

Preliminary data appears promising and was presented at various meetings during 2006, including the APAO Congress in Singapore, Thai Ophthalmology Congress in Bangkok, SEAGIG Meeting in Chennai and the Taiwan Ophthalmology Society Meeting in Taipei.

At the completion of the last follow-up in December 2006, over 50 PACG patients with residual glaucoma and increased IOP glaucoma had been recruited and treated with SLT. Data is currently being analyzed, with a clinical paper anticipated for publication shortly.

If the finalized study results indicate a positive outcome, it may provide insight into what could possibly be a new indication for SLT, as well as another treatment option for PACG patients.

Analyzing SLT results using "SLT Follow Up Results Form"

Javier González Rodríguez, MD, Vigo, Spain

At the recent SOE Congress, I presented a study that showed Selective Laser Trabeculoplasty (SLT) to be an effective and safe method for controlling IOP in patients with primary open angle glaucoma (POAG). The study outlined the results of a two-year prospective, non-randomized study investing SLT on 280 eyes (186 patients).

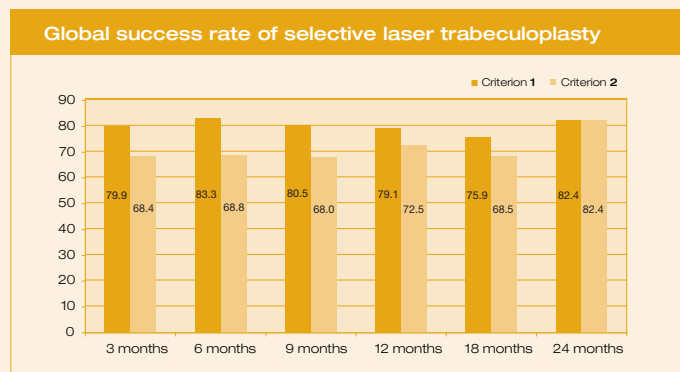
A precise analysis was performed to compare the efficacy of SLT treatment on different subgroups of patients, e.g., patients with ALT or filtering surgery history.

The entire group of patients included primary open angle glaucoma (39.3 percent), pseudoexfoliative glaucoma (23.2 percent), ocular hypertension (15.3 percent) and secondary glaucoma (11.4 percent). In all patients, data and treatment parameters were recorded to perform a retrospective analysis and comparison.

The global success rate was analyzed using two criteria:

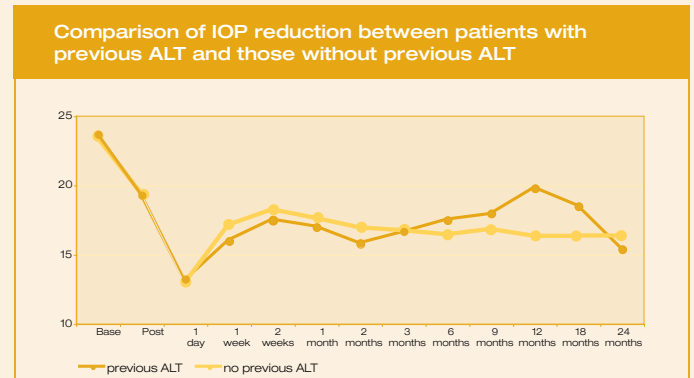
1. IOP reduction superior or equal to 3 mmHg
2. IOP reduction superior or equal to 20 percent

This analysis shows the good global response of patients, with a success rate close to 82 percent at 24 months.



Graph representing percentage success rate of SLT according to IOP reduction superior or equal to 3 mmHg, and IOP reduction superior or equal to 20 percent (Source: Doctor Rodriguez, Spain).

The best results were obtained for the subgroup with ocular hypertension and initial glaucoma, i.e., without glaucoma surgery history and a pressure superior to 21 mmHg without medical treatment. The average pressure reduction on that subgroup ranged from 6.2 mmHg at three months to 5.9 mmHg at 24 months.



Graph comparing IOP reduction over 24 month period in patients who have undergone previous ALT with those patients who have not undergone previous ALT (Source: Doctor Rodriguez, Spain).

One of the interesting comparisons performed was between subgroups with and without ALT history. This analysis shows the similar efficacy of SLT treatment in both groups, as well as the interest of SLT for patients who have had failed ALT.



Doctor Javier González Rodríguez

Editor's Note: This study was statistically analyzed using the "SLT Follow Up Results Form," developed by Doctor Javier Gonzalez Rodriguez, which uses patient data and treatment parameter information to automatically generate graphs and statistical analysis of the clinical results. This form, which can be used in routine practice or for tracking results of clinical studies, is now available for download at slt-ellex.com.

Tabriz SLT Symposium

Nearly 40 people attended a November 27 SLT symposium organized by Ellex and Teb Tasvir in Tabriz, Iran. The meeting proved so popular, in fact, that several last minute, unregistered attendees had to be turned away due to space constraints. Teb Tasvir CEO Saeed Yasdani hosted the meeting, which started with a presentation by Christine Warren, Ellex. Ms. Warren introduced Ellex and discussed the company's commitment to making SLT more widely available for treating the growing number of glaucoma patients worldwide.

Next, Dr. Behzad Fallahi of the Nikoukari Eye Hospital in Tabriz gave a thorough overview of the SLT technique, including its advantages over ALT. This provided an introduction to guest speaker Professor Isabelle Riss, head of anterior segment department in Bordeaux University Hospital, France. In her presentation, she discussed the importance of early diagnosis of glaucoma to enable early treatment given that a safe and effective treatment option with no side effects is now available – even of younger people who are potentially at risk of developing the disease.

Then, Professor Riss, a glaucoma specialist and accomplished cataract and glaucoma surgeon, performed SLT on four patients, so that the audience could observe the quick and easy procedure.

“SLT enables early treatment of patients at risk of developing glaucoma...”

First-person experience and expert advice from Professor Riss' presentation included:

SLT enables early treatment of patients at risk of developing glaucoma because there are no local or systemic side effects and no damage to the trabecular meshwork (TM). This means we should ask to see all the family members of our glaucoma patients, evaluate the risk of them developing glaucoma (taking into consideration age, sex, myopia, diabetes, etc.) and treat early with SLT.

SLT should be tried before surgery – the pressure usually increases after a failed trabeculectomy due to collapse of the TM and of Schlemm's canal. The higher the pressure before SLT treatment, the better the results.

If the TM has been hidden for some time, its capacity to function will have been reduced and it may not respond as well as a functional TM. If glaucoma is long-standing, especially if patients have been on beta blockers for a long time, the TM will likewise be less functional as there has been less aqueous humour to evacuate (the production by the ciliary body has been slowed) and SLT may not be able to stimulate the TM to function correctly again.

It is advisable when possible to use prostaglandin analogues to treat IOP in glaucoma patients since they do not block aqueous production and the function of the TM is maintained.

Presence of a large quantity of visible pigment may cause pressure spikes: use lower energy, fewer spots (90° treatment) and observe results for a couple of weeks before retreating.

First Russian SLT User Group Forms, Meets

In early December 2006, the first-ever Russian Ellex SLT user group meeting provided an opportunity for Russian SLT users to come together in Moscow to share their experiences.

The event, which took place at the conclusion of the Russian SLT Symposium, served to officially launch the Ellex SLT website. Members were introduced to slt-ellex.com with a short presentation on the site's navigation and content, along with plans to open a Russian SLT forum and to publish some of the clinical papers presented during the day's SLT symposium.

The next meeting topic was how to position SLT in daily practice in Russia, with attendees sharing their methods to introduce this new treatment to their patients. While standard Russian practice is for patients to make the final decision between laser treatment

and alternative therapies, all attendees strongly agreed that the clinician's role is to lead the decision-making process based on their deep understanding of all treatment options.

A critical point outlined by Mrs. Madhu Nagar from the UK's Clayton Eye Center was the importance of patient selection.

“When a new treatment is used, and when the clinician is still in the learning curve process, it is important to select patients with a good prognosis,” she said. “One should not start SLT on patients with advanced glaucoma on maximum tolerated medical treatment and previous failed ALT or trabeculectomy.”

Members agreed that the user group has helped them to better understand each other and will enable better organization of similar events in the future. At the conclusion of the meeting, members discussed next steps for the user group.

Russian SLT Symposium

A Russian SLT symposium took place on December 1, 2006 in the Mandryka 2nd Central Military Clinical Hospital of Moscow. The symposium, which was co-chaired by A.I. Yeremenko, G.F. Kachalina, M.E. Konovalov and V.V. Novoderejkin, featured the presentation of both local and international clinical studies.



Delegates during the Russian SLT symposium, December 2006.

Madhu Nagar from the U.K.'s Clayton Eye Center presented the first paper titled "Selective Laser Trabeculoplasty (SLT) in Clinical Practice," based on two of her clinical studies: a prospective non-randomized cases series analysis and a randomized prospective study comparing 90/180/360 degrees SLT to Latanoprost.

Combined results of these studies outlined three important points:

1. 360-degree SLT efficiency is similar to standard medication therapy, with 80 percent of the eyes achieving an IOP reduction of 20 percent or more.
2. Long-term follow up is always necessary to control pressure after treatment.
3. SLT retreatment is effective with an average of 26.4 percent IOP decrease for enhancement treatment (36 eyes analyzed) and an average of 23.7 percent IOP decrease for retreatment (25 eyes analyzed).

During the symposium, Russian experts presented two additional papers. In the first, N.I. Kurisheva presents a retrospective analysis of 100 patients with glaucoma and myopia who were treated by SLT. In the second, T.B. Jafarly from Doctor Visus Clinic in Moscow outlined a three-year retrospective analysis of SLT in cases of pseudoexfoliation glaucoma. Following the presentations, attendees took part in a variety of practical discussions regarding SLT.

With more than 120 participants, the Russian SLT symposium was a great success. Attendees and other parties who are interested in continuing the discussion and sharing of information can easily do so – just visit the Bulletin Board at slt-ellex.com.

Slovak SLT Symposium a Great Success

The recent Slovak SLT symposium provided a welcome opportunity for participants to share different clinical experiences with SLT and to take part in a variety of interesting clinical discussions. Held on October 20th, 2006 in Ruzomberok Slovakia, it was attended by over 114 doctors from throughout Slovakia and Czech Republic.

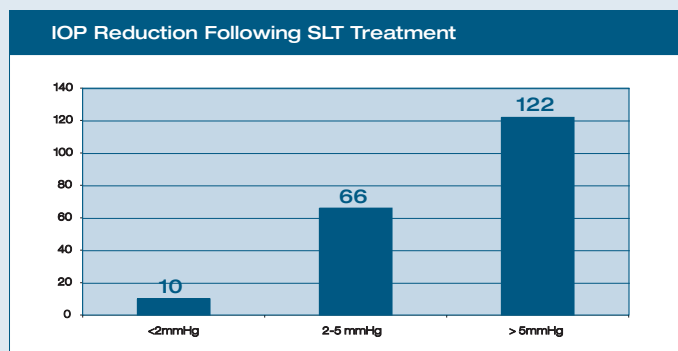
Professor Combor, the director of Military Hospital in Ruzomberok, and Professor Izak, the moderator and head of the Slovak Ophthalmic Society, opened the symposium by describing the challenges of glaucoma management.

In the first presentation, "Glaucoma Pathogenesis as a Key for Successful Treatment," Professor Potocky addressed the various forms of glaucoma. Dr. Hazuchová then delivered a detailed paper on the evolution of laser treatments in the management of glaucoma, the differences between those treatments and the effects of the non-thermal SLT laser. Dr. Vyborny outlined the important criteria to be checked during glaucoma treatment.

Next, Professor Melamed from the Sam Rothberg Glaucoma Center at Tel Aviv University Medical School addressed delegates with a presentation titled, "SLT as a Primary Method in POAG Treatment." This topic generated several interesting questions from the audience, including:

When can we consider a patient a good candidate to be retreated?

Melamed: Patients can be retreated when pressure starts increasing again. We know that good responders to first treatment will be good responders to retreatment. I have some patients who are good responders but who need to be retreated every year to keep their pressure stabilized.



Graph representing reduction in IOP measurement following SLT treatment over 21-month period. (Source: Doctor Cuvala from UVN Ruomberok)

To conclude the symposium, different papers were presented on Slovakian and Czech clinical experiences with SLT by Vyborny MD, Sebesta MD, Ferkova MD and Cuvala MD. Dr. Cuvala from ÚVN Ruomberok also presented a paper on a 21-month retrospective analysis of 119 patients (198 eyes) treated by SLT. This study showed a pressure reduction superior to 5 mmHg for 62 percent of the eyes.

SLT at the 2006 American Academy of Ophthalmology

Michael Belkin, MA, MD, Professor of Ophthalmology at Tel-Aviv University



The use of Selective Laser Trabeculoplasty (SLT) for the treatment of primary open angle glaucoma (POAG) figured highly in the meeting of the American Academy of Ophthalmology (AAO) which took place in Las Vegas, Nevada in November 2006. In addition to six practical courses on laser use in glaucoma, some devoted solely to SLT, there were five presentations that provided solid evidence that:

- SLT is effective as a primary therapy as compared to conventional drug therapy
- SLT is effective when repeated
- SLT enhancements are effective
- SLT reduces diurnal IOP fluctuations
- SLT is more effective in people before cataract surgery

Katz and the SLT/MED Study Group

The most significant presentation was by Jay Katz and the SLT/MED Study Group detailing the initial results of a study which is, to date, the best designed, and possibly the most important, clinical trial investigating the use of SLT. The study evaluated SLT as the primary therapy for open angle glaucoma (OAG) in a prospective, multi-center (17 sites) randomized double-arm trial.

The 47 patients (94 eyes) were randomized to receive either SLT (100 applications over 360 degrees) or medical therapy in both eyes. Failure was defined as IOP exceeding 2 mmHg above the target or when the next step in the treatment paradigm was taken – in the SLT arm, SLT was repeated; in the medicine arm, the medical regime was changed. After a follow-up of at least eight months, the mean IOP reduction in the 36 medically treated eyes was 7.6 mmHg, with 6.7 mmHg reduction in the 58 eyes treated with SLT. The numbers of treatment changes were 1.1 for the SLT group and 1.3 for the medical group, indicating that the target IOP range was reached in the majority of eyes for both groups.

The authors concluded, “SLT is an effective first-line therapy in the treatment of OAG. Efficacy with IOP reduction in the SLT group was comparable to the medical arm. There will be less concern with side effects and compliance in the laser treated patients.”

Bournias and Lai

In another study, Bournias and Lai investigated the effectiveness of repeating 360 degree SLT treatment on 52 eyes of the same number of patients whose original SLT was effective for at least one year. The average reduction in IOP of the original treatment was 4.1 mm Hg, and that of the repeat treatment was 3.6 mm Hg. Among the authors’ conclusions was that “SLT may be successfully repeated in eyes with OAG previously treated with SLT.”

Nagar et al.

Nagar et al. presented the results of two studies at the AAO. In the first, they investigated the IOP control efficacy of SLT enhancement (treating previously untreated angle area) and repeatability (retreating previously treated area) by retrospective analysis of 27 eyes that underwent SLT enhancement and 15 eyes treated with repeat SLT.

The enhancement success rate was 70.37 percent, 55.55 percent, and 25.93 percent after one, two and three years respectively. With repeat treatment, the success rate was 70.37 percent at one year and 53.33 percent after two years. Average duration of significant IOP lowering after enhancement was 18.26 months, and after repeat treatment, 17.47 months. Nagar et al. concluded, “Enhancement and retreatment with SLT is effective in reducing IOP.”

Nagar et al. also reported the result of their second study, an investigation of SLT in reducing diurnal fluctuations of IOP in POAG eyes as compared with Latanoprost. The fluctuations were reduced by SLT from 6.90 ± 2.73 mm Hg to 3.20 ± 1.32 mm Hg, and by Latanoprost from 6.40 ± 1.26 mm Hg to 1.70 ± 0.95 mm Hg. The authors concluded “SLT and Latanoprost significantly reduced IOP and IOP fluctuations.”

Riansuwan et al.

In the final presentation, Riansuwan et al. investigated retrospectively the IOP lowering effects of SLT in eyes with aphakia and pseudophakia, as well as phakic eyes. They reported that the decrease in mean IOP was 18 percent for aphakia, 25 percent for pseudophakia, and 29 percent for eyes that did not undergo cataract removal. The authors’ conclusion: “In this series, after SLT, phakic eyes have significantly greater reduction in IOP compared with pseudophakic and aphakic eyes.”

The Mechanisms of Action of Selective Laser Trabeculoplasty

In late September, a new study investigating the mechanism of action of Selective Laser Trabeculoplasty (SLT) commenced at the Department of Ophthalmology of St. Thomas' Hospital in London. The study's primary investigator, Dr. Sheng Lim, spoke with *Regenerate* and described the interesting work being undertaken for the study.

It is true that numerous clinical studies have shown that SLT can provide significant IOP reduction in patients with open-angle glaucoma, and studies using animals and human cadaver eyes had confirmed the non-thermal property of SLT. However, the mechanism by which laser treatments to the human angle result in IOP lowering is still not clearly established. For this reason, we decided to run this prospective study at St. Thomas' Hospital to determine the effect of SLT on the trabecular outflow facility in human eyes. The other aim of the study is to establish whether baseline outflow facility is a determining factor in the response to SLT therapy.

Patients diagnosed with ocular hypertension (OHT) or primary open angle glaucoma (POAG) were selected for the study, with intraocular pressure (IOP) and outflow facility measured on three occasions: the day prior to the SLT treatment (baseline), at one month and at three months.

Each patient is randomized (using a random number generated by Excel program) to treatment of one eye with the Ellex Solo SLT laser system in one of two treatment groups: Group I receive 360-degree treatment in the eye, while Group II receive 180-degree treatment in the eye. Thus, 20 patients will be allocated to each group for a total of 40 patients. The energy level is varied according to each patient's response to the SLT treatment. Sub-threshold energy levels (between 0.6 to 1.2 mJ/shots) are used in all treatments.

The study will analyze two parameters:

1. The IOP is measured with a Goldmann applanation tonometer, using a topical anesthetic and fluorescein as the disclosing agent.

2. The tonographic outflow facility is measured by the rate of decay of IOP in the supine position during application of an electronic Schiotz tonography probe over a period of four minutes.

The initial and final values of the tonometer scale reading are used to determine the value for the facility of outflow using the 1955 scale approved by the Committee on Standardization of Tonometers.

St Thomas' Hospital is one of the UK's pioneering research centers. This study is important, as it will improve our understanding of the mechanism of action of selective laser trabeculoplasty to the trabecular outflow facility, and as such may help us to better understand why some patients respond better to SLT treatment.

We have treated 27 patients to date and will be completing the study in March 2007. We hope to present the results of this six-month study during the forthcoming World Glaucoma Congress in Singapore.



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Value-Added SLT Program and slt-ellex.com launched

The Ellex Value-Added SLT Program was launched in late 2005 to further the role of SLT in glaucoma management. The program consists of a comprehensive set of resources designed to accomplish two goals: first, to equip physicians with tools to better educate their patients about SLT; and second, to facilitate information sharing with their peers.

The Ellex SLT website, slt-ellex.com, was recently launched as the primary access point for Ellex SLT users to exchange information about the procedure. Exclusive to Ellex SLT users, the site is also designed to help users incorporate SLT into their practices. It provides a forum to network with peers, direct questions to Ellex clinical advisory network experts, and download a bibliography or a spreadsheet to help track patient results.

Users can easily navigate the site to access a comprehensive database of clinical tools, including patient education materials. The site is continually updated to feature highlights from user group meetings, symposia and congress events.

We encourage you to review the Ellex SLT website and provide feedback on how we can help you learn more about SLT and better educate your patients. If you have comments, questions or ideas, please contact us via slt@ellex.com or by phone at +61 8 8104 5214.



Events

Symposia

IGS SLT Symposium

6th International Glaucoma Symposium
SLT: Today and Tomorrow
Athens, March 28-31 2007, 2:45-4:15pm
Register online via www.ellex.com/events

Korean SLT Symposium

SLT - A New Paradigm in Glaucoma
Therapy
Seoul, April 14

WGC SLT Symposium

World Glaucoma Congress
Singapore, July 18-21

Congresses

Middle Eastern African Congress of Ophthalmology (MEACO)

Dubai, March 29-April 1

American Society of Cataract and Refractive Surgeons (ASCRS)

San Diego, April 27-May 1

European Society of Cataract and Refractive Surgeons (ESCRS)

Stockholm, September 8-12

American Academy of Ophthalmology (AAO)

New Orleans, November 10-13

IGS symposium SLT: Today and Tomorrow

Prominent glaucoma specialists Ivan Goldberg and Shlomo Melamed will lead a panel of international speakers to provide insight on SLT;

- Review of SLT Literature: Where We Are Today, Michael Belkin (Israel)
- SLT Repeat Treatment Results, Enping Chen (Sweden)
- SLT for Secondary Glaucomas, Miroslav Vukosavljevic (Serbia)
- SLT for PACG: Results of a Multi-Center Study, Prin RojanaPongpun (Thailand)
- The Future for SLT, Ivan Goldberg (Australia)

Register to receive this newsletter

Welcome to the Ellex SLT newsletter, **Regenerate** - a customer-focused initiative dedicated to sharing information on SLT.

Through **Regenerate**, Ellex will provide insights on SLT covering literature reviews and clinical study updates, drawing on the expertise of experienced SLT users and the Ellex clinical advisory network.

Regenerate will be published quarterly, and can be received via email.

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Ask the Experts, continued

Gradually, over time, SLT proved to be a safe and an effective treatment modality, and I now offer SLT as a first-line treatment option.

Q: What types of glaucoma can be treated with SLT?

A: Open angle glaucoma, i.e., primary open angle glaucoma, pigmentary glaucoma, pseudoexfoliative glaucoma and ocular hypertension all respond well to SLT. I have successfully treated traumatic glaucoma - angle recession glaucoma in two patients, glaucoma secondary to complicated cataract surgery in seven, and juvenile glaucoma.

Q: What adverse effects do patients experience?

A: Adverse effects are transient and minimal. The most common adverse effects are mild discomfort during treatment, blurred vision for 10-15 minutes, sore eyes for 2-3 days and post-SLT IOP spike. Occasionally, patients may experience a headache after treatment and photophobia for a day or two.

Q: Schedule of post-treatment follow-up - ideal follow-up periods?

A: I review my patients one week, one month and three months post-SLT, and then every six months thereafter.

Q: How long after treatment is the optimum pressure reduction reached?

A: IOP reduction following SLT is observed on day one, but 8-10 percent of patients are "slow/late responders" where response may be seen between 4-12 weeks time.

Q: When can you start taking patients off medicine post-SLT?

A: I prefer to do this prior to SLT, rather than post SLT, because the higher the baseline IOP, the greater the IOP reduction.

To find other answers from the "Ask the Experts" section, or to submit questions for review by the Ellex clinical advisory network, please visit slt-ellex.com.



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