Effect of primary selective laser trabeculoplasty on tonographic outflow facility - a randomised clinical trial.

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Title: Effect of primary selective laser trabeculoplasty on tonographic outflow facility - a randomised clinical trial.

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1 Abstract

2 **Purpose:** To investigate the effect of 180° versus 360° primary Selective Laser Trabeculoplasty (SLT) on
3 tonographic outflow facility (TOF) and intraocular pressure (IOP).

4 **Design:** Prospective, single masked randomised clinical trial.

5 **Participants:** Patients with untreated primary open angle glaucoma or ocular hypertension both with IOP
6 >21-35mmHg.

7 **Methods:** Forty patients randomly treated with 180° or 360 ° SLT after baseline TOF (electronic Schiøtz
8 tonography) and IOP measurements were repeated after one month. One eye from each patient was randomly
9 selected for analysis. Eight untreated eyes were included as a control group.

10 **Main Outcome Measures:** TOF and IOP difference. Responders were defined as having at least a 20%
11 reduction in IOP.

12 **Results:** Three patients were excluded due to poor tonography. There were eighteen eyes in 180° group and
13 nineteen eyes in the 360° group. TOF increased significantly (180° p=0.003, 360 ° p=0.005) and IOP
14 decreased significantly (180° & 360° p<0.001) from baseline. There were no significant differences between
15 the two groups as regards the increase in TOF (180° group 37.5%, 360° group 41%, p=0.23) and decrease in
16 IOP (180° group 24%, 360° group 35%, p=0.35). There were similar number of responders in 180° group
17 (72%) as compared to 360° group (89.5%, p=0.23). TOF and IOP did not change significantly from baseline
18 in the control group (TOF-8% increase p=0.48, IOP-4% decrease p=0.33).

19 **Conclusions:** Primary SLT significantly increased the tonographic outflow facility and decreased IOP in
20 patients with primary open angle glaucoma and ocular hypertension but no statistically significant differences
21 were found between the 360° and 180° groups. The level of IOP reduction due to primary SLT treatment
22 could not be explained by the increase in TOF alone.

Intraocular pressure (IOP) reduction remains the only therapeutic means for treating ocular hypertension (OHT) and primary open angle glaucoma (POAG). Argon laser trabeculoplasty (ALT) popularized by Wise & Witter in 1979 became an acceptable form of treatment for open angle glaucoma with its use peaking in the mid 1990s, however, the visible thermal damage, late pressure rise and treatment failure reduced its subsequent use.[1] [2] ALT is usually performed using 50-100 applications of a 50µm spot size, 0.1 second duration and average power setting of between 400 to 1000mW. It is a relatively high energy level treatment causing visible damage to the trabecular meshwork.[3] Selective laser trabeculoplasty (SLT) was developed by Latina in 1995 and FDA approved in 2001.[4, 5] It delivers over 100 times less energy than ALT while providing a similar IOP lowering effect.[6-9] SLT uses a frequency-doubled, Q-switched, neodymium: yttrium aluminium garnet (Nd:YAG) laser and delivers a 400µm diameter treatment spot in three nanoseconds. The power ranges from between 0.4–1.2 mJ with up to 120 applications per eye. This lower energy treatment produces minimal or no visible damage to the trabecular meshwork with a potential for repeat treatment.[3]

A dose response effect of SLT treatment, depending on the degrees of angle treated has been previously suggested but the exact mechanism of action of ALT and SLT remains unclear.[10, 11] Most theories of mechanism of action of laser trabeculoplasty were developed for ALT and little data is available to suggest that SLT has the same mechanism of action, particularly taking into account marked differences between the two laser systems in terms of the energy fluence levels and the physical effects on the trabecular meshwork. Whatever the cellular effect, both ALT and SLT treatments are thought to eventually affect the trabecular outflow pathway.[7]

Previous aqueous dynamics studies on the effect of ALT suggest that it increases the tonographic outflow facility (TOF) without any effect on aqueous production.[12-18] There is however no published report on the

1 effect of SLT on TOF. We performed this prospective randomised clinical trial to study to the effect of SLT
2 on TOF and also to determine whether differences existed between 180° and 360° treatment in newly
3 diagnosed and previously untreated primary open angle glaucoma (POAG) and ocular hypertension (OHT)
4 patients.

5

6 **Methods**

7 Ethics approval for this prospective study was obtained from the St. Thomas's Hospital's local research
8 ethics committee. This research conformed to the recommendations adopted by the Helsinki declaration.
9 Consecutive patients attending the glaucoma clinic for the first time were invited to participate. A patient
10 information leaflet was provided at the initial contact and signed consent obtained before the measurements
11 and treatment.

1 **Inclusion/exclusion criterion**

2 Inclusion criteria were previously untreated adult POAG patients (based on characteristic optic disc changes
3 with visual field changes) or high risk OHT patients which required treatment. All patients were required to
4 have an IOP greater than 21mmHg to be eligible. Exclusion criterion were secondary glaucomas
5 (pseudoexfoliation, pigment dispersion, uveitic, traumatic, etc.), primary angle closure, advanced POAG (cup
6 disc ratio ≥ 0.9 and/or visual acuity less than 6/36), very high IOP ($>35\text{mmHg}$), one eyed patients and any
7 previous intraocular surgery.

8 **Sample size calculation**

9 The standard deviation of TOF was derived from a previous study by one of the authors.[19] The study was
10 powered at 80% with an alpha (two sided) of 0.05 to detect a TOF difference of 30% between the two
11 treatment groups. Including a 10% drop out rate the required sample size was 20 patients in each group.

12 **Randomisation**

13 Patients were centrally randomized by a computer (random number method, odd number-180° and even
14 number-360° treatment) to receive 180° or 360° SLT. The numbers were placed in non-transparent brown
15 envelopes and shuffled. One envelope was opened on the day of the treatment for each patient.

16 If only one eye needed treatment then the contra-lateral eye was included in a 'control' group. If however
17 both eyes needed IOP lowering then both eyes were treated by SLT but only one eye was randomly selected
18 for analysis (coin toss).

19

20 **Measurements**

21 All patients underwent a thorough clinical evaluation including ocular and systemic history. Examination
22 included visual acuity, pupils, slit lamp examination, gonioscopy, central corneal thickness (CCT, Pachmate

DGH 55, DGH Technology, Inc. PA, USA), visual fields (VF) (Humphrey automated white on white, 24-2 SITA-standard) and dilated fundoscopy. On the day of treatment all patients had IOP measured by Goldmann applanation tonometry (GAT) and tonography by an electronic Schiøtz tonographer (Model 720, Berkeley Bioengineering Inc, USA) between 9.00 and 11.00am. Three consecutive IOP measurements were recorded by SR and the mean was used as the baseline IOP. Both eye tonography measurements were done by KSL. Both SR and KSL were masked to the treatment and the randomisation.

The facility of outflow was measured from the rate of decay of intraocular pressure in the supine position during application of a recording Schiøtz tonometer over a period of four minutes with various weights depending on the starting IOP. The “R” values of the curve at every 30-second time point was manually entered into the McLaren tonography computer program.[20] This program fits a second-degree polynomial by least squares to the nine data points and determines the best-fit values for time zero and time four minutes by extrapolation. The measurement unit for outflow facility was expressed as $\mu\text{l}/\text{min}/\text{mmHg}$.

Treatment

SLT treatment in all patients was performed by SG. Pilocarpine 2% drops (Minims, Pilocarpine nitrate, Chauvin Pharmaceuticals Ltd, Surrey, UK) were instilled half an hour prior to SLT. SLT treatment was performed using the Ellex Solo machine (Ellex, Adelaide, Australia), spot size of 400 μm , duration three nano seconds. Starting energy level was 0.6 mJ. Energy level was titrated at three o'clock position up to the point where champagne bubbles or minimal blanching was visible. Magna view gonioscopy lens (Ocular instruments, USA) was used to visualize the trabecular meshwork for treatment. Only the inferior half of the angle was treated in patients undergoing 180° treatments. All patients had a standardised postoperative regime of Dexamethasone 0.1% eye drops (Maxidex, Alcon Laboratories, UK) four times a day for five days. Patients were reviewed at one week and one month and in between as necessary. IOP and TOF

measurements were repeated at one month between 9.00 and 11.00am. If needed, additional glaucoma medical treatment was started at one month to achieve the target pressure.

Data collection and Outcome Measure

Data including age, sex, race, IOP, TOF, CCT, VF, treatment details and adverse outcomes were recorded on a datasheet. The primary and secondary outcome measures were TOF and IOP difference respectively. Success (i.e. responders) was defined as at least 20% reduction in IOP from baseline.

Data Analysis

The data was analyzed by statistical software STATA (StatCorp, USA) in a per protocol manner. Non parametric methods of analysis (Wilcoxon signed-rank test and Kruskal Wallis test) were used after distribution analysis for both TOF difference and IOP difference revealed non normal distributions. (Positive skew, $p=0.001$ and $p=0.04$ respectively, Shapiro Wilk Test for normality).

Results

Forty-two consecutive patients between August 2006 and July 2007 were invited to participate in the study, two declined (one was not available for follow up and the other opted for medical treatment). Forty patients were randomized to receive 180° or 360° treatment. All Schiøtz tonography tracings were graded by the examiners before the treatment was unmasked. Poor quality tracings were identified in three participants and they were excluded from the study.

Eighteen patients in the 180° treatment group and nineteen patients in the 360° treatment group were included in the final analysis (Fig.1). Twelve patients (67%) in the 180° group and fifteen (79%) in the 360° group had POAG ($p=0.41$). There were nine (50%) and ten (53%) women in 180° and 360° groups respectively. The majority of patients in both groups were Afro-Caribbean/African in origin, nine (50%) in the 180° group and

seventeen (89.5%) in 360° group ($p=0.01$). There were six Caucasians in 180° and two in 360° group. One patient each in the 180° group was from South East Asia and Latin America. The high number of Afro-Caribbean/African patients in our study generally reflects the local at risk population in this part of London.

The baseline patient and treatment characteristics are shown in Table 1. Patients in the 180° group were significantly younger ($p=0.03$) than the 360° group and had less mean deviation (MD) visual field score ($p=0.02$). The rest of the baseline characteristics including the visual acuity, IOP, cup/disc ratio, CCT, TOF and treatment parameters were comparable. Neither age nor MD were associated with outcome measures and were therefore not regarded as confounders (Spearman's rank correlation age with TOF difference $p=0.07$ and IOP difference $p=0.79$ and MD with TOF difference $p=0.60$ and IOP difference $p=0.82$). The SLT treatment was well tolerated. Two patients, one undergoing 360° SLT (0.95mJ, 110 shots) and one undergoing 180° SLT (1.12 mJ, 56 shots) reported mild pain during the SLT treatment, which resolved within one week. One patient had mild asymptomatic anterior uveitis at one week visit which resolved on its own at the two week review.

1 **Table 1. Baseline characteristics and treatment parameters in the two groups.**

Parameter	180° SLT (n=18)			360° SLT (n=19)			P-value
	Median	IQR	Range	Median	IQR	Range	
	(mean)	(SD)	(min-max)	(mean)	(SD)	(min-max)	
Age	57 (56.4)	50, 64 (11.8)	28-75	67 (65.30)	55, 71 (11.6)	46-88	0.03
VA	0.0 (0.05)	0, 0.17 (0.05)	0.08-0.3	0.18 (0.15)	0, 0.18 (0.20)	0.08-0.60	0.17
CCT	545 (546)	511, 565 (46.7)	465-657	565 (558)	528, 578 (31.50)	508-620	0.30
CD	0.63 (0.6)	0.4, 0.8 (0.23)	0.10-0.85	0.70 (0.66)	0.6, 0.8 (0.17)	0.3-0.85	0.59
VF (MD)	-1.96 (5.4)	-4.41, -0.56 (8.7)	-30-0.69	-4.40 (7.40)	-12.22, -2.99 (6.39)	-25-1.90	0.02
Number of shots	55 (56)	53, 57 (3.3)	52-63	102 (104)	101, 109 (4.75)	97-111	<0.01
Power	1.1 (1.0)	0.9, 1.1 (0.13)	0.80-1.20	1 (1)	0.94, 1.1 (0.12)	0.64-1.20	0.36
Tenergy	57.5 (57.5)	52, 65 (7.56)	44.40-69	108 (105)	98, 113 (12.60)	73.3-126	<0.01

2 n, number of treated eyes in each group; IQR, interquartile range; SD, standard deviation; age, in years; VA, visual acuity (logmar equivalent);
3 CCT, central corneal thickness (microns); CD, cup to disc ratio; VF (MD), visual field (mean deviation in decibels); power of each shot in mJ;
4 tenergy, total energy used in mJ.

5

1 Table 2 describes the effect of SLT on TOF and IOP in the two groups. Overall there was a 37.5%
2 (interquartile range 9.5%, 127.3%) increase in median TOF ($p<0.001$) and 29% (interquartile range 21.2%,
3 41.2%) reduction in median IOP ($p<0.001$).

4 **Table 2- Baseline and one month Tonographic outflow (TOF, $\mu\text{l}/\text{min}/\text{mm}$) and Intraocular pressure**
5 **(IOP, mmHg) and differences between the 180° and 360° treatment groups.**

Parameter	180° SLT (n=18)			360° SLT (n=19)			P-value
	Median	IQR	Range	Median	IQR	Range	
	(mean)	(SD)	(min-max)	(mean)	(SD)	(min-max)	
Pre-SLT TOF	0.08 (0.08)	0.06, 0.09 (0.04)	0.01-0.16	0.08 (0.11)	0.07, 0.11 (0.07)	0.05-0.31	0.35
Increase in TOF from baseline	0.03 [#] (0.04)	0, 0.06 (0.05)	0.04-0.13	0.04 [#] (0.06)	0.02, 0.0 (0.09)	0.08-0.33	0.23
Pre-SLT IOP	24.4 (26)	23, 29.3 (4.1)	21.3-35	26 (25.54)	24.3, 26.7 (2.1)	22-30	0.76
Decrease in IOP	6.1* (6.9)	4.2, 8.3 (4.1)	2.66-19.33	9* (8.2)	5.7, 11 (3.52)	1.33-13.83	0.35

6
7 n, number of treated eyes in each group; SLT, selective laser trabeculoplasty; IQR, interquartile range; SD, standard deviation.
8 [#]Change in TOF from baseline (180°, $p=0.003$; 360°, $p=0.005$).
9 *Change in IOP from baseline $p<0.001$.

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Although there was a significant increase in TOF from baseline in both groups (180° p=0.003, 360° p=0.005) the differences between the two groups were not statistically significant (180° group 37.5% and 360° group 41%; p=0.23).

Similarly the decrease in IOP in the 360° (35%) group as compared to the 180° group (24%) did not reach statistical significance (p=0.35).

Control group

Eight eyes of eight patients (average age- sixty-six years, six males, three white, three Afro-Caribbean, av. CD ratio-0.48, av.VF MD score=-2.52, av. CCT=543µm) out of the forty patients in this trial did not require treatment and were included as a no treatment ‘control’ group. There was no significant change in TOF (median baseline: 0.12 µl/min/mmHg, one month; 0.129 µl/min/mmHg, 8% increase, p=0.48) or IOP (median baseline: 19.7 mmHg, one month: 19.0 mmHg, 4% decrease, p=0.33) from baseline to one month in these eyes.

Responders versus non-responders

The overall success rate of SLT in reducing the IOP by at least 20% was 81%. SLT was successful in 89.5% of patients in 360° treatment group as compared to 72% of patients in 180° treatment group (p=0.232). There were no differences in baseline IOP between the responders and non-responders in the two groups (360° group p=0.462, 180° group p=0.62).

Discussion

This is the first study which investigates the effect of SLT on outflow facility in previously untreated patients. Overall, we found a significant increase in TOF and a corresponding decrease in IOP with a success

rate of 81% one month after SLT. Although there was a tendency for the 360° treated arm to respond more than the 180° treatment arm both in terms of TOF increase and IOP reduction, these differences did not reach statistical significance.

We used the classic electronic Schiøtz tonometer to measure trabecular outflow facility as described in a recent paper by the author and rejection rate of 7.5% (three out of forty) subjects due to ‘poor’ tonography is comparable to that study by the same operator in a different population.[19]

The overall IOP reduction of 29% in this study is comparable to other studies of both SLT and ALT.[10-18]. In our study this was associated with a 37.5% increase in tonographic outflow facility. Most studies on the effect of ALT on outflow facility were done in patients who were already on medical treatment making a direct comparison difficult.[12-17] The only study of the effect of ALT on outflow facility in medically untreated eyes with POAG was performed over fifteen years ago by Bergeå et al.[18] A comparable level of IOP reduction was found in those with POAG but this reduction was associated with a much higher TOF increase (65%). Although Bergeå’s study used the same measurement technique, the results are limited by the relatively small number of POAG patients. These patients also had much higher pre laser IOP than our patients.[18]

Similarly, Brubaker and Liesegang’s study found a higher increase in TOF (64%) after ALT treatment but similar IOP reduction (29%) in medically treated patients (n=17) using the same tonographic technique.[16] The authors did not find any effect on aqueous production. In another study of ALT treatment reported by Thomas et al there was a 29% average reduction in IOP and 64% increase in outflow in patients with different types of glaucoma who were on maximal tolerated medical treatment.[14] Although these two study patients were already on medical treatment they had a similar pre laser IOP as our previously untreated patients.

1 Our results differ significantly from these ALT studies, in that although a comparable level of IOP reduction
2 was achieved, the TOF increase following SLT was only about half of that observed with ALT.[14, 15, 16,
3 18] This is a curious finding which could indicate a difference in mechanism of action of SLT as compared to
4 ALT. This could also be due to differences in study populations including the different racial distribution.
5 Our study had a proportion of African/Afro-Caribbean patients who are also known to have lower CCT.
6 Although CCT is known to affect Goldmann applanation tonometry readings its exact effects on Schiøtz
7 indentation tonographic outflow facility are not well understood.

8 If we assume that the increase in TOF is likely to be from the direct cellular effect of SLT on the trabecular
9 meshwork, leading to an increase in trabecular outflow, then according to Goldmann's equation (see
10 Appendix 1), a 29% reduction in intraocular pressure (P_i) should correspond to 100% increase in TOF (C).
11 As we found an increase of only 37.5%, this raises the possibility that other aspects of aqueous dynamics
12 parameters, such as aqueous production (F), uveoscleral outflow (U) or episcleral venous pressure (P_v) may
13 be affected by SLT. Previous aqueous dynamic studies of ALT have demonstrated that aqueous humour
14 production rates were not affected by ALT.[16, 17] Whether SLT treatment can cause a decrease in aqueous
15 production or a significant increase in uveoscleral outflow needs further investigation.

16

17 The overall responder rate of 81% in our study is similar to that of other studies of primary SLT.[8, 10, 21]
18 There was a trend favouring 360° SLT treatment in terms of more responders, which is consistent with
19 previous reports.[10, 11] Nagar et al. found progressively greater success rates with 90°, 180° and 360°
20 treatments (34%, 65%, 82% respectively).[10] One eighty degree and 360° treatments were significantly
21 more successful than 90° treatment but the differences between the 180° and 360° groups did not reach
22 statistical significance. Prasad et al also found a greater IOP reduction with 360° treatment as compared to
23 180° treatment in patients who had primary SLT but again the difference between the two groups was not
24 statistically significant.[11] It is likely that a smaller treatment effect exists when increasing SLT treatment

1 from 180° to 360° therefore in order to detect this difference a much larger study population than that of the
2 present study will be required (i.e. introducing the possibility of a type II error in the present study).

3
4 To our knowledge, this is the first study which systematically investigates the effect of SLT on outflow
5 facility as a step towards understanding its mechanism of action. Prior ocular hypotensive treatment can
6 affect the aqueous dynamics and for this reason we restricted eligibility to previously untreated patients. In
7 doing so, this study is the largest to investigate the effect of laser trabeculoplasty on TOF in previously
8 untreated primary open angle glaucoma. Although we did not have active controls in this study, the results
9 from our 'passive' control group suggest that all the changes seen in this study are due to treatment effect
10 rather than by chance. The slight caveat from this study is the over representation of the Afro-
11 Caribbean/African population, which may mean that the findings are not applicable to other population
12 groups.

13
14 In conclusion, both 180° and 360° SLT treatments increase tonographic outflow facility and reduce
15 intraocular pressure but no significant differences between the two groups were evident. Furthermore, the
16 extent of IOP reduction cannot be explained by TOF increase alone, raising the possibility that SLT may
17 affect other aqueous dynamics parameters.

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1 **Appendix 1**

2

3 Goldmann's equation. The aqueous production (flow) rate is equal to the sum of trabecular outflow and
4 uveoscleral outflow:

5
$$F_f = (P_i - P_e)C + F_u$$

6 Where, F_f is aqueous humour flow measured by fluorophotometry, P_i is pressure in the anterior chamber, P_e
7 is the episcleral venous pressure, C is trabecular outflow facility measured by tonography and F_u is
8 uveoscleral outflow. In this study, P_i and C were measured at baseline and at one month, while SLT
9 treatment is assumed to have no effect on F_f , F_u and P_e . Therefore, a 30% drop in P_i should correspond to
10 100% increase in C .

11

1 Legends for figure.

2

3 **Figure 1 – Study flow chart.** A top down flow chart outlines the study process, showing the number of
4 patients (n) with primary open angle glaucoma (POAG) or ocular hypertension (OHT) in each step from
5 participation in the study until last visit one month following selective laser trabeculoplasty (SLT).

6

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8 authors/licence-forms/).”

9

10 **Competing Interest**

11

12 The SLT machine was provided by Ellex (NSW, Australia) on loan for the duration of the study. The
13 sponsor or funding organisation had no role in the design or conduct of this research. Dr Lim and Dr Goyal
14 have received travel grants from Ellex,

Figure 1. Patient Flow Chart

Figure legends

Figure 1 - Study flow chart. A top down flow chart outlines the study process, showing the number of patients (n) with primary open angle glaucoma (POAG) or ocular hypertension (OHT) in each step from participation in the study until last visit one month following selective laser trabeculoplasty (SLT).