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ORIGINAL RESEARCH

Selective Laser Trabeculoplasty and Outcomes of Subsequent Phacoemulsification Combined with Kahook Dual Blade Goniotomy

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ABSTRACT

Introduction: To investigate the relationship between intraocular pressure (IOP)-lowering success of selective laser trabeculoplasty (SLT) and combined phacoemulsification/Kahook Dual Blade (phaco/KDB) goniotomy in eyes with mild to severe open angle glaucoma (OAG).
Methods: Eyes undergoing combined phaco/KDB goniotomy and that had previously undergone SLT were analyzed. Data collected included demographics, glaucoma type and severity, IOP, and topical IOP-lowering medications before and after both procedures. Eyes were divided into two groups based on success of SLT, defined as IOP reduction of at least 20% maintained on at least two consecutive follow-up visits without any subsequent medication additions or interventions. Phaco/KDB goniotomy success was defined as IOP reduction of at least 20% and/or reduction in the number of IOP-lowering medications of at least one up to 12 months of follow-up.
Results: Overall, SLT was successful in 20 of 43 eyes (46.5%), of which 63.6% (7/11) had successful phaco/KDB goniotomy at 12 months follow-up. Among eyes with unsuccessful SLT, 60.0% (9/15) had successful phaco/KDB at 12 months follow-up. Phaco/KDB success rate was similar in patients regardless of their previous response to SLT at all postoperative time points up to 12 months follow-up ($p = 0.87$).
Conclusions: The presence or lack of IOP-lowering response to SLT did not influence the success rate of subsequent phaco/KDB goniotomy in eyes with mild to severe OAG. Patients who did not respond to SLT still benefited from phaco/KDB goniotomy at a later date.

Keywords: Goniotomy; Intraocular pressure; Lasers; Phacoemulsification

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Key Summary Points

Why carry out this study?

Despite overcoming the primary site of outflow obstruction with trabecular bypass procedures, such as KDB goniotomy, it is still common to see patients who do not respond with IOP reduction after removal of the trabecular meshwork tissue. This variable response suggests a significant role of the distal outflow system and prompts the question of whether the presence or lack of IOP-lowering response of SLT may influence the outcomes of subsequent goniotomy.

Our study sought to investigate the possible role of SLT as a clinical predictor of the IOP-lowering success of subsequent combined phaco/KDB goniotomy.

What was learned from the study?

We found no predictive relationship between a patient's response to SLT and the success of subsequent phaco/KDB goniotomy.

Patients with a history of failed SLT still benefit from a subsequent phaco/KDB goniotomy to further lower IOP or medication burden.

INTRODUCTION

Elevated intraocular pressure (IOP) has been shown to be a major risk factor for the development and progression of open angle glaucoma (OAG) [1–3]. Subsequently, reduction of IOP is the primary target of all currently available therapeutic methods in the treatment of glaucoma [4]. However, despite the development of multiple therapeutic options including medical, laser, and surgical treatments, reducing IOP in glaucomatous eyes continues to present a challenge.

The juxtacanalicular meshwork layer of the trabecular meshwork (TM) is thought to be the site of greatest resistance to aqueous outflow and the largest contributor to IOP elevation in patients with OAG making it an attractive target for therapeutic intervention [5, 6]. Selective laser trabeculoplasty (SLT) is a laser treatment that is thought to act on the TM to increase aqueous outflow through the conventional outflow pathway [7–9]. The treatment uses a 532 nm Nd:YAG photodisruptive laser to target the pigmented cells of the TM [9]. Although the mechanism by which SLT increases trabecular outflow facility and lowers IOP remains incompletely characterized, various mechanisms have been proposed spanning biological, mechanical, and structural theories [10, 11]. Regardless of the underlying mechanism(s), multiple studies have demonstrated the safety and efficacy of SLT for the sustainable reduction of IOP in patients with glaucoma [10, 12–23].

Goniotomy with the Kahook Dual Blade (KDB) (New World Medical, Rancho Cucamonga, CA) is one surgical treatment option that, like SLT, reduces IOP by increasing aqueous outflow facility through the conventional pathway. However, unlike SLT, KDB accomplishes this through removal of the diseased TM [5, 6]. KDB goniotomy uses a single-use dual-bladed device designed to make parallel incisions in the TM and completely excise a full strip of the TM en bloc allowing the aqueous to drain directly to distal outflow pathways [24]. This procedure has been shown to be effective in OAG as a standalone therapy or when combined with phacoemulsification [25–28].

Despite overcoming the primary site of regulatory outflow obstruction with trabecular bypass procedures, such as KDB, it is still common to see patients who do not respond with IOP reduction after removal of the TM tissue [29]. Additionally, steroid-related IOP elevations, which are thought to be mediated by changes in the TM, often occur in eyes after anterior chamber angle-based surgeries [30–32]. These observations provide evidence suggestive of a significant contribution of the distal outflow system to overall flow resistance, and recent work has indeed demonstrated that distal channels could contract and thus have the potential to regulate flow resistance [33].

The variable response of patients to KDB goniotomy and other TM microinvasive bypass procedures has made patient selection for surgery a challenge, as there currently does not exist a reliable method for predicting outcomes of these surgeries or of evaluating the function of the distal outflow pathway. The advancement of various imaging techniques using optical coherence tomography and fluorescein angiography may soon provide a practical way of assessing the patency and function of the distal outflow pathway [34, 35]. In the meantime, it is logical to conclude that if SLT works well there is probably good flow in the canal and distal channels, while if it does not work well there may be more downstream resistance. In this context, response to SLT may serve as a clinical predictor of success of KDB and other trabecular bypass procedures that rely on an intact distal outflow system for their IOP-lowering success [36]. A reliable, relatively inexpensive, and minimally invasive clinical predictor for the success of combined phaco/KDB goniotomy and other trabecular bypass procedures would have tremendous clinical and therapeutic value.

In order to evaluate the possible role of SLT as a clinical predictor of IOP-lowering success of subsequent combined phaco/KDB goniotomy, we present a case series of eyes that underwent SLT followed by phaco/KDB goniotomy to investigate outcomes.

METHODS

Approval for this retrospective review was obtained from the University of Colorado Multiple Institutional Review Board and a waiver of consent was granted (COMIRB# 16-1345). The research adhered to the Helsinki Declaration of 1964, and its later amendments, and was compliant with the Health Insurance Portability and Accountability Act. An electronic medical chart review was performed on a consecutive series of eyes with mild to severe OAG, as defined by ICD-10 classification, from June 1, 2016 to January 31, 2020 at the University of Colorado Department of Ophthalmology [37]. The analysis included eyes of patients over 18 years old that underwent SLT and required combined phaco/KDB goniotomy at a later date as a result of visually significant cataract and a need for better IOP control and/or a reduction in topical glaucoma treatment. Eyes were excluded if they had previously undergone any glaucoma procedures/surgeries other than SLT prior to the phaco/KDB goniotomy, had unavailable or insufficient pre or post SLT IOP documentation to adequately evaluate response to SLT, had any IOP-lowering medication addition from when the decision was made to pursue SLT through 6 month post SLT follow-up, or had any IOP reduction of at least 20% at either 2 or 6 month follow-up, but not both. Eyes were divided into two groups, identified as either SLT responders or SLT nonresponders, based on the success of SLT at two consecutive visits at about 2 months (range 0.5–4 months) and 6 months (range 2.5–9 months) follow-up. Data collected included demographic information, glaucoma type and severity, best corrected visual acuity (BCVA), IOP, number of IOP-lowering medications, time between procedures, adverse events, and additional IOP-lowering interventions.

SLT was performed according to the methods described by Latina et al. [10]. Prior to SLT, topical anesthetic and alpha agonist were instilled. Beginning with energy set at 0.8 mJ, treatment spots were applied overlapping the TM. Power was subsequently titrated until few fine champagne bubbles were observed and approximately 100 contiguous nonoverlapping treatment spots were applied to 360° of the TM. Patients were reexamined at approximately 2 and 6 months after the SLT procedure.

The phaco/KDB goniotomy began with standard cataract removal with phacoemulsification through a clear corneal incision with implantation of an intraocular lens (IOL) within the capsular bag. KDB goniotomy was performed according to the KDB's instructions for use [38]. Briefly, after IOL insertion, an ophthalmic viscoelastic was used to flatten the iris and deepen the anterior chamber. The patient's head was tilted, and the microscope adjusted to allow visualization of the nasal angle by a Swan-

Jacob gonioprism. The KDB was inserted into the anterior chamber and the tip used to make an initial incision into the TM. A circumferential strip of nasal TM spanning approximately 90–120° was then excised and the remnant removed with microforceps. The ophthalmic viscoelastic was subsequently removed from the anterior chamber. All wounds were hydrated, and the eye was brought up to IOP in the mid-20s using balanced salt solution to minimize blood reflux. Postoperatively a topical fluoroquinolone antibiotic was prescribed four times daily for 1 week. Prednisolone acetate 1.0% and ketorolac 0.5% four times daily were given for 1 week and then tapered over 1 month.

In accordance with the World Glaucoma Association's guidelines, BCVA, IOP, glaucoma medication use, and complications were recorded for each patient at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months post phaco/KDB goniotomy. To evaluate the safety of the procedure, the need for additional surgery and postoperative complications were noted. SLT responders were defined as eyes that achieved an IOP reduction of at least 20% maintained at both 2 and 6 months follow-up without any subsequent medication additions or further IOP-lowering interventions, reductions in topical medications were allowed. SLT nonresponders were defined as eyes that failed to achieve an IOP reduction of at least 20% at both 2 and 6 months follow-up. Phaco/KDB goniotomy success was defined as IOP reduction of at least 20% and/or reduction in at least one glaucoma medication.

For the statistical analysis BCVA was assessed via Snellen chart both pre and postoperatively. The main outcome measures were the IOP and number of IOP-lowering medications. Percentage changes in IOP were calculated (preoperative IOP minus IOP at follow-up, divided by preoperative IOP). Follow-up comparisons of eye characteristics were performed using logistic regressions with general estimating equations (GENMOD; SAS, Inc., Cary, North Carolina, USA) to account for the intrasubject correlation for patients who had both eyes included in the analyses. IOP and topical medication burdens were compared to the preoperative time point for patients who had data at each particular follow-up time point. A linear model with generalized estimating equation using an exchangeable correlation structure was used to compare the mean IOP and number of medications preoperatively and postoperatively by SLT group. Means are reported with standard errors and p values less than 0.05 were considered statistically significant. Statistical analysis was performed using SAS version 9.4 software (Cary, North Carolina, USA).

RESULTS

A total of 141 eyes with OAG that had previously undergone SLT followed by combined phaco/KDB goniotomy at a later date were identified for the analysis. Eyes were excluded if they had previously undergone any glaucoma procedures/surgeries other than SLT prior to the phaco/KDB goniotomy ($n = 18$), had unavailable or insufficient pre or post SLT IOP documentation to adequately evaluate response to SLT ($n = 50$), had any IOP-lowering medication addition from when the decision was made to pursue SLT through 6 month post SLT follow-up ($n = 6$), or had any IOP reduction of at least 20% at either 2 or 6 month follow-up, but not both ($n = 24$).

Data from 43 eyes of 33 patients were included in this analysis and divided into two groups based on the success of SLT, identified as either SLT responders or SLT nonresponders. Twenty of 43 eyes (46.5%) were identified as SLT responders and 23 of 43 eyes (53.5%) were identified as SLT nonresponders. Baseline demographic data and glaucoma status for each group are presented in Table 1. Overall, a greater percentage of women (72.1%) than men was included in the analysis; however, the gender distribution was not significantly different between the SLT responders and nonresponders ($p = 0.60$). Patients in both groups had similar mean ages and a majority had primary OAG (72.1%).

As expected, there was a statistically significant lowering of IOP after phaco/KDB goniotomy at nearly all postoperative time points at and after month 1 when compared to preoperative IOP baseline. There was no statistically

Table 1 Characteristics of study population, June 2016–January 2020

	Responded to SLT	Did not respond to SLT	*p* value
Number of eyes	20	23	–
Gender			
Female	15 (75.0%)	16 (69.6%)	0.60
Male	5 (25.0%)	7 (30.4%)	
Age (years)			
Mean (SD)	69.7 (9.6)	68.1 (7.4)	0.41
Glaucoma severity			
Mild	9 (45.0%)	6 (26.1%)	
Moderate	5 (25.0%)	13 (56.5%)	
Severe	6 (30.0%)	3 (13.0%)	
Indeterminate	0	1 (4.4%)	
Glaucoma type (grouped)			
POAG	15 (75.0%)	16 (69.6%)	
PXG/PXF	2 (10.0%)	1 (4.4%)	
LTG/NTG	1 (5.0%)	4 (17.4%)	
PDG	2 (10.0%)	2 (8.7%)	
Number of months between SLT and phaco/KDB			
Mean (SD)	28.6 (21.4)	51.8 (44.6)	0.16

SLT selective laser trabeculoplasty, *Phaco/KDB* phacoemulsification/Kahook Dual Blade, *SD* standard deviation, *POAG* primary open angle glaucoma, *PXG* pseudoexfoliation glaucoma, *PXF* pseudoexfoliation syndrome, *LTG* low tension glaucoma, *NTG* normal tension glaucoma, *PDG* pigment dispersion glaucoma

significant difference in IOP reduction between the SLT responders and nonresponders at any postoperative time point up to 12 months follow-up (Table 2). Similarly, there was no statistically significant difference in medication reduction between the SLT responders and nonresponders at any postoperative time point after undergoing phaco/KDB goniotomy up to 12 months follow-up (Table 3). Among the 11 SLT responder eyes and 15 SLT nonresponder eyes with 12 months follow-up data, 63.6% and 60.0% of eyes, respectively, had successful phaco/KDB goniotomy. There was no statistically significant relationship between SLT and phaco/KDB goniotomy success observed in our study ($p = 0.87$) (Table 4).

The time interval between final SLT and subsequent phaco/KDB goniotomy varied greatly between patients. Interestingly, patients who responded to SLT had on average a shorter interval period between SLT and subsequent phaco/KDB goniotomy at 28.6 (SD 21.4) months versus 51.8 (SD 44.6) months for SLT nonresponders, but this difference was not significant ($p = 0.16$) (Table 1).

All procedures were well tolerated. Following SLT, two eyes (SLT nonresponders group) experienced elevated IOP requiring phaco/KDB goniotomy 1 month after the procedure. Following phaco/KDB goniotomy, three eyes experienced hyphema, and six eyes experienced transient IOP spikes that resolved with

Table 2 IOP at baseline and follow-up times post phaco/KDB for patient eyes

Phaco/KDB	Preop	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 16	Month 20	Month 24
Responded to SLT										
Number of eyes	20	20	19	18	15	17	11	7	7	5
IOP, mean (SE)	17.5 (1.0)	16.5 (1.9)	18.1 (1.9)	13.8 (0.6)	13.5 (1.0)	15.0 (0.9)	14.8 (1.3)	13.8 (1.4)	13.8 (1.7)	12.8 (1.4)
p value (vs. preop)	–	0.64	0.66	< 0.0001	0.0006	0.03	0.04	0.04	0.07	0.003
Did not respond										
Number of eyes	23	23	23	23	22	15	15	8	7	7
IOP, mean (SE)	17.9 (1.0)	14.9 (0.9)	18.8 (1.7)	14.2 (0.7)	14.2 (0.9)	14.3 (1.0)	14.6 (1.0)	14.8 (0.7)	14.4 (0.9)	14.0 (0.6)
p value (vs. preop)	–	0.0004	0.60	< 0.0001	0.004	0.0002	0.007	0.01	0.004	0.0007
p value	0.79	0.42	0.77	0.67	0.57	0.77	0.98	0.47	0.77	0.42

Phaco/KDB phacoemulsification/Kahook Dual Blade, *SLT* selective laser trabeculoplasty, *IOP* intraocular pressure, *SE* standard error, *Preop* preoperative

conservative treatment. Both groups of SLT responders and SLT nonresponders showed improvement in BCVA at 12 months follow-up; however, the difference between groups was not significant ($p = 0.21$) (Table 5).

DISCUSSION

This retrospective analysis evaluated the relationship between a patient's IOP-lowering response to SLT and subsequent success of combined phaco/KDB goniotomy in eyes with mild to severe OAG. The analysis of our data shows that there is no statistically significant difference in IOP-lowering effect or medication reduction after phaco/KDB goniotomy between eyes that previously responded successfully to SLT and those that did not. Both groups showed statistically significant post phaco/KDB goniotomy reductions in mean IOP and number of IOP-lowering medications at various time points throughout the follow-up period compared to baseline, which is consistent with previous studies of KDB goniotomy and combined phaco/KDB goniotomy in eyes with similar baseline IOP [27, 28, 39, 40].

Although SLT and KDB goniotomy act via different mechanisms, both lower IOP by increasing aqueous outflow through the conventional TM outflow pathway. The existence of a common effector pathway shared by SLT and KDB goniotomy raises the possibility that the success of one might influence the subsequent success of the other. For example, an initial failure of SLT may indicate outflow impairment in distal channels that could portend the failure of trabecular bypass procedures, such as KDB goniotomy, which do not address distal outflow resistance. Alternatively, if early SLT acts to maximize flow through distal outflow pathways and limits or slows the autoregulatory action of distal channels that can lead to increased outflow resistance over time, then we might see an improved IOP-lowering response to subsequent trabecular bypass procedures.

Table 3 Number of glaucoma medications at baseline and follow-up times post phaco/KDB for patients

Phaco/KDB	Preop	Week 1	Month 1	Month 3	Month 6	Month 12	Month 16	Month 20	Month 24
Responded to SLT									
Number of eyes	20	19	18	15	17	11	7	7	5
Number of meds, mean (SE)	2.1 (0.3)	1.9 (0.3)	1.5 (0.3)	1.9 (0.3)	1.9 (0.3)	2.1 (0.2)	1.9 (0.3)	2.1 (0.3)	2.4 (0.5)
p value (vs. preop)	–	0.69	0.03	0.59	0.67	0.87	0.53	0.90	0.54
Did not respond									
Number of eyes	23	23	23	22	15	15	8	7	7
Meds, mean (SE)	2.1 (0.2)	2.1 (0.2)	1.8 (0.2)	1.6 (0.2)	1.6 (0.2)	1.8 (0.3)	2.1 (0.3)	2.0 (0.4)	2.1 (0.3)
p value (vs. preop)	–	0.84	0.17	0.04	0.01	0.30	0.88	0.49	0.91
p value	0.91	0.69	0.38	0.35	0.28	0.35	0.59	0.70	0.60

Phaco/KDB phacoemulsification/Kahook Dual Blade, *SLT* selective laser trabeculoplasty, *SE* standard error, *Preop* preoperative

Table 4 Success rates at follow-up times post phaco/KDB for patient eyes

Phaco/KDB	Month 1	Month 3	Month 6	Month 12	Month 16	Month 20	Month 24
Responded to SLT							
Number of eyes	18	15	17	11	7	7	5
Success[a] (%)	61.1	60.0	47.1	63.6	71.4	57.1	40.0
Did not respond to SLT							
Number of eyes	23	22	15	15	8	7	7
Success[a] (%)	69.6	81.8	66.7	60.0	62.5	28.6	71.4
p value	0.60	0.18	0.34	0.87	0.67	0.32	0.40

Phaco/KDB phacoemulsification/Kahook Dual Blade, *SLT* selective laser trabeculoplasty

[a]Success of phaco/KDB surgery defined as having a reduction in IOP of at least 20% from baseline and/or a reduction in the number of IOP-lowering medications of at least one

Given the inherent risks and expenses associated with incisional glaucoma surgeries, there would be substantial benefit for surgical planning purposes if SLT were shown to be a safe and minimally invasive predictor of clinical outcome after KDB [41, 42].

Interestingly, eyes that did not respond to SLT showed slightly higher rates of subsequent success of phaco/KDB goniotomy surgery (although not statistically significant) between 1 and 6 months follow-up, supporting the potential benefit of KDB goniotomy in patients with a history of failed SLT. These findings are in accordance with results of the only previously published study on this subject by King et al. [7]. In their investigation, however, the cohort of eyes included for analysis was smaller ($n = 30$) and only patients who had 2 months of follow-up after SLT were included. We chose to include patients with IOP-lowering response at

Table 5 Hyphema, IOP spike*, secondary surgeries, and BCVA after phaco/KDB

	Responded to SLT No./total (%)	Did not respond to SLT No./total (%)	*p* value
Hyphema	2/20 (10.0%)	1/23 (4.4%)	0.48
IOP spike day 1	1/20 (5.0%)	0/23 (0%)	0.28
IOP spike week 1	2/19 (10.5%)	3/23 (13.0%)	0.80
IOP spike month 1	0	0	NC
Secondary glaucoma surgeries	6/20 (30.0%)	4/23 (17.4%)	0.35
	Mean (SD)	Mean (SD)	
Difference in BCVA (logMAR) from baseline to 12 months FU	0.04 (0.17)	0.12 (0.18)	0.21

*Defined as IOP > 30 and/or IOP > 10 change from baseline

IOP intraocular pressure, *BCVA* best corrected visual acuity, *Phaco/KDB* phacoemulsification/Kahook Dual Blade, *SLT* selective laser trabeculoplasty, *NC* not calculable, *SD* standard deviation, *logMAR* logarithm of the minimum angle of resolution, *FU* follow-up

two consecutive visits up to 6 months post SLT treatment to ensure that it was successful for a longer period of follow-up and to account for any medication adherence improvement in the immediate short-term period after SLT.

The lack of observed association between SLT response and KDB goniotomy outcomes is likely multifactorial. There is some evidence that SLT may act to improve distal outflow in addition to outflow through the TM, confounding the site of effect and limiting the utility of SLT as a predictor of TM bypass procedures. Studies have shown that SLT treatment acts to increase permeability not only of the TM but also of the slightly more distal Schlemm's canal endothelial cells through recruitment of macrophages and upregulation in the expression of numerous cytokine genes [43–46]. It seems plausible that SLT may also act to increase permeability and decrease outflow resistance of even more distal channels in a similar fashion given that endothelial cells have been demonstrated to line the walls of the distal outflow system [33]. In accordance with this idea, new theories of TM outflow hypothesize that aqueous outflow is highly dependent on collector channels and distal outflow pathways [47]. Our study was not poised to answer these questions. The time interval between final SLT and subsequent phaco/KDB goniotomy varied greatly between patients. Patients who responded to SLT had on average a shorter interval period between SLT and subsequent phaco/KDB goniotomy than SLT nonresponders, but this difference was not statistically significant ($p = 0.16$). Additional studies that directly observe the effect of SLT on the distal pathway and the cellular components responsible for its outflow resistance will better determine the efficacy of SLT as a clinical predictor for phaco/KDB goniotomy outcomes.

The limitations of this study include established issues related to retrospective studies. Given the small sample size and high number of excluded patients there is potential for bias and unknown confounders to influence the interpretation of results. The patients were a heterogeneous sample with multiple forms of glaucoma at different severity levels. Different medication regimens with variable sites of action were being used that could possibly confound the study focus on IOP-lowering mechanisms and sites of action. For example, it is known that patients with pseudoexfoliative glaucoma have a greater response to phacoemulsification than those with primary OAG [48].

CONCLUSIONS

The present study assessed the association between SLT IOP-lowering response and phaco/KDB goniotomy outcomes. The success of SLT treatment was not a good clinical predictor of subsequent phaco/KDB goniotomy efficacy in eyes with mild to severe OAG. Patients with a history of failed SLT still benefit from a subsequent phaco/KDB goniotomy to further lower IOP or medication burden.

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Compliance with Ethics Guidelines. Approval for this retrospective review was obtained from the University of Colorado Multiple Institutional Review Board and a waiver of consent was granted (COMIRB# 16-1345). The research adhered to the Helsinki Declaration of 1964, and its later amendments, and was compliant with the Health Insurance Portability and Accountability Act.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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