ORIGINAL ARTICLE

Phakia and Prior Incisional Surgery Impact MicroPulse Transscleral Laser Therapy for Glaucoma Outcomes: A Retrospective Cohort Study

Skyler G Jones[1], Forrest Clark[2], Marc Toeteberg-Harms[3]

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Abstract

Purpose: To assess (1) safety and efficacy of MicroPulse transscleral laser therapy (TLT) for primary open-angle glaucoma (POAG) and (2) the influence of prior incisional glaucoma surgery, lens status, and visual acuity on TLT outcomes.

Setting: Institutional.

Design: Retrospective cohort study.

Materials and methods: Study population: Included were POAG patients aged 18–85 with TLT between 1st January 2020 and 15th July 2023; excluded were patients with secondary glaucomas, inflammatory disease, or pregnancy.

Intervention: MicroPulse TLT was performed on one or both eyes with an Iridex Cyclo G6 Laser with settings: 31.3% duty cycle, 2,500 mW, 20 second/sweep/hemisphere, four to six sweeps. The revised MP3 probe was used.

Outcome measures: Pre- and postop: intraocular pressure (IOP), best-corrected visual acuity (BCVA), glaucoma meds, subsequent procedures, cystoid macular edema (CME).

Analysis: Kaplan–Meier (KM) survival statistics starting one month postop with dropout parameters: hypotony, subsequent glaucoma procedure, glaucoma medications >baseline, IOP >21 mm Hg, IOP reduction <20%, or loss of LP vision.

Results: Thirty-three eyes were included. Mean KM survival (months) was: all eyes 8.4 ± 1.1; phakia 6.2 ± 0.8; pseudophakia 10.8 ± 2.4; aphakia 9.2 ± 1.8; prior tube shunt 10.2 ± 1.8; no filtration 6.8 ± 0.8. IOP and glaucoma medications remained at or below baseline at all postoperative timepoints. There were no significant changes in BCVA for patients with good baseline vision (>20/40), and no patients developed hypotony, persistent inflammation, or lost LP vision. Factors limiting success were time from the procedure and number of sweeps.

Conclusion: Survival was better in pseudophakic eyes and after tube shunt surgery. Six sweeps resulted in higher success compared to four. There were no significant cases of postop CME. The procedure did not negatively impact vision in eyes with good baseline vision.

Keywords: Glaucoma, Incisional surgery, MicroPulse, MicroPulse transscleral cyclophotocoagulation, Tube shunt surgery.

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Introduction

MicroPulse transscleral laser trabeculoplasty (TLT) is a minimally invasive glaucoma surgery (MIGS) technique primarily employed for cases of refractory glaucoma.[1] Traditional transscleral cyclophotocoagulation (TSCPC) applies a continuous wave diode laser to achieve transscleral coagulation (i.e., cyclodestruction) of the ciliary body to reduce aqueous humor production.[2] MicroPulse TLT, in contrast, utilizes a pulsatile rather than a continuous delivery of the laser energy, which is, in addition, not focused on the pars plicata but rather the pars plana. The resultant "off" or "cooling" period is thought to minimize collateral tissue damage and prevent cyclodestruction[3]; in addition, it has demonstrated a superior safety profile and retreatment rates in comparison to TSCPC.[4] While MicroPulse TLT's exact mechanism of action remains not fully understood, three mechanisms have been postulated: (1) selective achievement of the coagulation threshold for pigmented ciliary body epithelium (decreasing aqueous production); (2) increased uveoscleral outflow; or (3) contraction of the longitudinal fibers of the ciliary body increasing trabecular outflow (similar to pilocarpine).[5–9]

[1,3]Department of Ophthalmology, Medical College of Georgia, Augusta, Georgia, United States

[2]Department of Medicine, Medical College of Georgia, Augusta, Georgia, United States

Corresponding Author: Skyler G Jones, Department of Ophthalmology, Medical College of Georgia, Augusta, Georgia, United States, Phone: +17067212020, e-mail: sjones27@augusta.edu

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Conflict of interest: Nil

MicroPulse TLT has been shown to be efficacious for multiple forms of glaucoma (primary and secondary).[10,11] It has also been effective in patients with prior MIGS or incisional glaucoma procedures.[12,13] MicroPulse TLT has demonstrated a good safety

profile in numerous studies, with common adverse effects including inflammation, intraocular pressure (IOP) spikes, and corneal edema, and more rarely hypotony and permanent vision loss.[4]

Our study aims to relate demographic and preoperative data to outcomes for MicroPulse TLT in primary open-angle glaucoma (POAG) patients to better assess and characterize optimal patient candidates for the procedure. The primary hypothesis of our study is that a history of incisional surgery will not significantly impact the outcome relative to no history of incisional surgery, with secondary study groups comparing patient outcomes based on race, history of cataract surgery, stage of glaucoma, and good BCVA at baseline (i.e., BCVA >20/40).

Materials and Methods

Study Design and Setting

This is a monocentric, retrospective chart review. Included were patients with POAG who underwent MicroPulse TLT between 1st January 2020, and 15th July 2023, at the Medical College of Georgia, Augusta University, Augusta, Georgia, USA. The Augusta University Institutional Review Board (IRB) deemed the study exempt from IRB approval. This study complied with the Health Insurance Portability and Accountability Act and adhered to the tenets of the Declaration of Helsinki. Due to a waiver granted by the IRB, informed consent was not required.

Inclusion and Exclusion Criteria

Included were patients diagnosed with POAG and who were between 18 and 85 years old. Excluded were patients with known systemic or ocular inflammatory conditions (e.g., rheumatoid arthritis, uveitis), secondary glaucoma (e.g., neovascular), or pregnancy. The study size was determined by identifying all patients who fit these criteria within the specified timeframe above.

Data Acquisition

Preoperative data were collected from the clinic visit immediately prior to the MicroPulse TLT procedure (range: 1 week to 3.5 months) and up to 1 year postoperatively following the procedure. Data collected included: eye, age, race, glaucoma stage (defined based on ICD-10 staging guidelines),[14,15] number of glaucoma medication classes (counting oral and topical carbonic anhydrase inhibitors separately), best corrected logMAR visual acuity, IOP measured by Goldmann applanation tonometry, history of glaucoma or cataract surgery (and duration from MicroPulse TLT to prior surgery), subsequent glaucoma or cataract surgery (and duration from MicroPulse TLT to subsequent surgery), cystoid macular edema (CME) status, corneal edema (defined as a 1-step clinical grade change from preoperative corneal edema), history of steroid response, duration of topical steroid use, subtenon's steroid status (if applicable), MicroPulse TLT laser settings, MicroPulse TLT surgeon, and type of anesthesia employed for the procedure.

Surgical Parameters

Outcomes were analyzed for two glaucoma surgeons. Both surgeons utilized an Iridex Cyclo G6 Laser with the settings: 31.3% duty cycle, 2,500 mW, 20 second/sweep/hemisphere in accordance with consensus guidelines.[16] However, sweeps per hemisphere were not standardized over this timeframe and ranged from four to six. Monitored anesthesia care was used to perform TLT in all patients except for one procedure, which required general endotracheal anesthesia.

Postoperative Care

Patients standardly received prednisolone acetate 1% eye drops and were instructed to continue all preoperative glaucoma medications until otherwise specified postoperatively. Topical steroids were prescribed differently by the performing surgeon: either at a four times per day frequency for a 1-week duration or in a 4-3-2-1 taper for 1 month (e.g., four times daily for 1 week, then three times daily the next week, etc.). Patients received testing for visual acuity and IOP and slit lamp biomicroscopy at every appointment; of note, OCT was only performed in the postoperative period to assess for CME if the patient had a clinical decline in visual acuity.

Statistical Analysis

Primary aims were analyzed through a Kaplan–Meier (KM) survival model starting 1 month postoperatively. Dropout (nonsurvival) parameters included: hypotony (i.e., IOP of five or less), subsequent glaucoma procedure, glaucoma medications equal to or greater than baseline, IOP equal to or >21 mm Hg, IOP reduction of ≤20%, or loss of light perception vision. Data were gathered initially in Microsoft Excel and then ported to SPSS software (Version 29; IBM Corp., Armonk, NY, USA) for statistical analysis.

Bias

Attempts to minimize selection bias were made in the following ways: having separate persons collect vs analyze data; having a 1-year overall timeframe for postoperative analysis (to minimize attrition); performing the procedures to be analyzed prior to the conceptualization of the study; having standard IOP and acuity measures (Goldmann applanation and Snellen acuity, respectively); and assessing outcomes based on survivorship dropout (i.e., quantifying survivorship directly to minimize survivorship bias). All patients lost to follow-up were lost at the postoperative day 1 timepoint; these patients did not have their preoperative or operative parameters included and analyzed in the study outcome measures. Any missing data points (e.g., no postoperative week 1 visit) were standardly not included in the KM analysis, which does potentially introduce bias for patients receiving shorter follow-up intervals (i.e., patients with more severe stages of glaucoma were monitored more frequently, increasing their postoperative data points and thereby increasing the number of data points for them to not meet survivorship criteria). This was performed in correspondence with standard practices of glaucoma care and could not be offset given the retrospective nature of the analysis.

Results

Demographics

The study included 36 eyes of 24 patients, of which two patients (three eyes; two with pseudophakia and a history of incisional surgery; one eye with phakia and no prior incisional surgery) were lost to follow-up immediately after the procedure. Basic demographic information for patients who maintained follow-up is listed in Table 1. The mean patient age was 60.2 ± 13.0 years. There were 13 (39.4%) right eyes and 20 (60.6%) left eyes. The ratio of females to males was almost 1:1 [15 (45.5%) females and 19 (55.5%) males]. In descending frequency, patient races were: 16 African American (72.7%), 4 Caucasian (18.1%), 1 Hispanic (4.5%), and 1 Asian (4.5%). The majority of eyes [26 (78.9%)] were severe-stage, and the remaining 7 (21.1%) were moderate-stage POAG.

Fifteen eyes were pseudophakic (45.5%), 15 (45.5%) were phakic, and 3 (9%) were aphakic. Sixteen eyes (48.5%) had no prior incisional

surgery, 14 (42.4%) had prior tube shunt surgery, and 3 (9%) had prior trabeculectomy. The group with prior tube shunt surgery had a higher rate of prior phacoemulsification procedure (10 eyes; 71.4%) compared to the group with no incisional surgery (4 eyes; 25%). Table 2 lists prior surgical information.

Visual Acuity, Intraocular Pressure, and Glaucoma Medication

Overall, IOP and antiglaucoma medications (AGMs) remained at or below baseline at all postoperative time points, and BCVA did not significantly change when comparing 1 year postoperatively with baseline. The exact values are shown in Table 3.

In addition, of the 13 patients with good initial baseline BCVA (>20/40), none had statistically significant changes in BCVA at the 1-year interval, and all retained IOP and AGMs at or below baseline throughout the 1-year follow-up interval. The mean KM survival for this group was 8.0 ± 1.6 months. Table 4 lists outcomes within this subgroup specifically.

Kaplan–Meier Survival Statistics

Mean KM survivals in months were: All eyes 8.4 ± 1.1; Phakia 6.2 ± 0.8; Pseudophakia 10.8 ± 2.4; Aphakia 9.2 ± 1.8; Prior tube shunt 10.2 ± 1.8; No filtration 6.8 ± 0.8. The overall KM survival curve is shown below in Figure 1, with Table 5 illustrating survival sub-data.

A statistically significant difference ($p < 0.05$) was found in KM survival between patients who received a higher number of MicroPulse TLT sweeps at the time of the initial procedure: the mean survival time for patients with four sweeps per hemisphere was

Table 1: Demographic information for patients who maintained follow-up after receiving TLT

	Male	*Female*	*African American*	*Caucasian*	*Hispanic*	*Asian*	*Moderate stage*	*Severe stage*
Eyes	19 (55.5%)	14 (45.5%)	24 (72.7%)	5 (15.2%)	3 (9.1%)	1 (3.0%)	7 (21.2%)	26 (78.9%)
Patients	12 (55.5%)	10 (45.5%)	16 (72.7%)	4 (18.1%)	1 (4.5%)	1 (4.5%)	4 (16.7%)	20 (83.3%)

Table 2: Demographic information by lens status and incisional surgery (listed by eyes)

Lens status	*No incisional surgery*	*Prior tube*	*Prior trab*	*Total*
Phakia (subtotal%)	9 (56.25%)	4 (29.6%)	2 (66.7%)	15 (45.5%)
Pseudophakia (subtotal%)	4 (25%)	10 (71.4%)	1 (33.3%)	15 (45.5%)
Aphakia (subtotal%)	3 (18.75%)	0	0	3 (9.0%)
Total	16 (48.5%)	14 (42.4%)	3 (9.0%)	33 (100%)

Table 3: Average postoperative BCVA, IOP, and AGMs with respect to baseline values—all patients

	Baseline	*POD1*	*POW1*	*POM1*	*POM3*	*POM6*	*POM12*
BCVA (logMAR)	0.9 ± 1.0	0.9 ± 1.0 ($p > 0.05$)	0.8 ± 1.1 ($p > 0.05$)	0.9 ± 1.0 ($p > 0.05$)	1.2 ± 1.1 ($p = 0.02$)	1.1 ± 1.2 ($p = 0.02$)	1.1 ± 1.1 ($p > 0.05$)
IOP (mm Hg)	21.7 ± 6.3	21.7 ± 6.3 ($p < 0.001$)	14.1 ± 4.0 ($p < 0.001$)	15.0 ± 5.1 ($p < 0.001$)	16.3 ± 6.8 ($p < 0.001$)	16.9 ± 6.6 ($p < 0.001$)	19.6 ± 7.5 ($p < 0.001$)
AGMs	3.8 ± 1.2	3.8 ± 1.2 ($p > 0.05$)	3.1 ± 1.4 ($p = 0.03$)	3.7 ± 0.8 ($p = 0.01$)	3.5 ± 1.2 ($p > 0.05$)	3.6 ± 0.9 ($p > 0.05$)	3.9 ± 0.6 ($p > 0.05$)

*Note: confidence intervals encompass the 95% range. *p*-values specify if there is a statistically significant difference from baseline

Table 4: Post-operative BCVA, IOP, and AGMs with respect to baseline values—BCVA > 20/40 patients

	Baseline	*POD1*	*POW1*	*POM1*	*POM3*	*POM6*	*POM12*
BCVA (logMAR)	0.1 ± 1.3	0.3 ± 0.1 ($p > 0.05$)	0.0 ± 0.0 ($p > 0.05$)	0.1 ± 0.1 ($p > 0.05$)	0.2 ± 0.4 ($p = 0.05$)	0.1 ± 0.2 ($p = 0.05$)	0.2 ± 0.3 ($p > 0.05$)
IOP (mm Hg)	20.1 ± 6.9	19.3 ± 9.1 ($p < 0.05$)	14.6 ± 2.9 ($p < 0.001$)	14.2 ± 4.8 ($p < 0.001$)	14.2 ± 8.2 ($p < 0.001$)	18.5 ± 8.8 ($p < 0.05$)	22.8 ± 7.0 ($p < 0.05$)
AGMs	4.1 ± 0.7	4.6 ± 0.5 ($p > 0.05$)	3.7 ± 0.5 ($p = 0.05$)	3.9 ± 0.6 ($p = 0.05$)	4.1 ± 0.3 ($p > 0.05$)	3.9 ± 0.7 ($p > 0.05$)	4.2 ± 0.4 ($p > 0.05$)

*Note: confidence intervals encompass the 95% range. *p*-values specify if there is a statistically significant difference from baseline

Table 5: Number of eyes at risk for major KM postoperative timepoints

	Time (months)					
	0	3	5	8	10	13
Number at risk	33	30	27	17	16	9

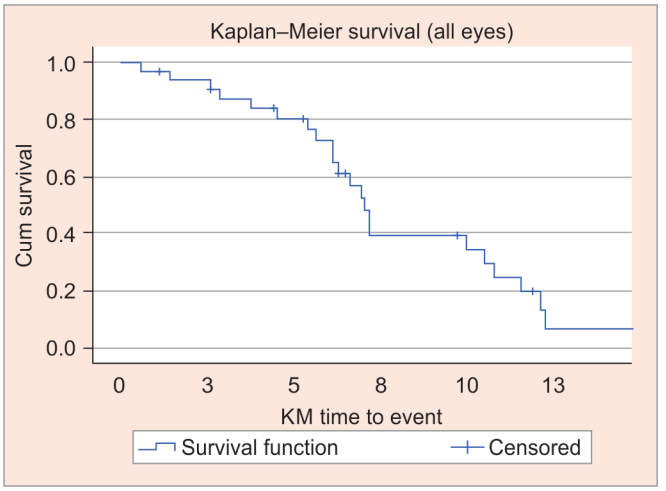

Fig. 1: Graph of KM survival curve

5.5 ± 0.7, five sweeps was 7.1 ± 1.2, and six sweeps was 10.0 ± 0.0. Caucasian patients had the highest mean survival time at 9.1 ± 3.7, followed by African Americans at 7.6 ± 0.8, and then Hispanics at 6.4 ± 0.5. While the included Asian patient eye had a mean KM survival time of 10.8 ± 0.0, this was not statistically significantly different from other racial groups.

Complication Rates

Overall, two (6.1%) eyes developed postoperative CME, which required long-term topical steroids (3 months) followed by sub-tenons Kenalog injections. Both of these eyes were pseudophakic; one had prior tube shunt surgery, and the other had no prior incisional surgery. The vision for these eyes decreased from 20/200 to CF and 20/400 to CF, respectively. No eyes developed persistent postoperative anterior chamber inflammation, new or worsening corneal edema, hypotony, retinal detachment, or loss of light perception vision.

Discussion

Patients overall and with initial BCVA >20/40 receiving TLT maintained IOP lower than baseline and AGMs at or lower than baseline throughout the 12-month follow-up period. Overall visual acuity outcomes were no different at 12 months than baseline for either group. A total of two eyes (6.1%) developed CME requiring treatment. No eyes developed persistent inflammation or corneal edema or severe complications (e.g., hypotony, loss of LP vision). There was no significant difference in mean survival time between the >20/40 group and the group of all eyes.

Regarding KM survival, in descending order, survival was highest in patients with: pseudophakia, prior tube shunt surgery, higher sweeps at initial procedure date, and Caucasian race. In ascending order, survival was lowest in patients with: phakia, no incisional surgery, lower sweeps, and African American race. The strongest overall predictor of survival was time from the initial procedure.

The primary limitations of the study were its retrospective nature (e.g., inability to fully randomize treatment groups) and limited sample size (33 total eyes) based on the volume of our institution. Based on sample size, certain confounders (e.g., the tube shunt surgery group having higher rates of pseudophakia, different postoperative topical steroid tapers between surgeons) could not be statistically offset or controlled for.

The study demonstrates that TLT has a favorable efficacy and safety profile. Patients overall maintained IOP and AGMs at or lower than baseline throughout all follow-up intervals, and overall, patients and patients with baseline BCVA >20/40 had no significant change in BCVA at 12-month follow-up. Significant complications other than CME (6.1%) were not observed. The groups with the highest KM survival rate were pseudophakic patients (10.8 ± 2.4) and patients with tube shunt surgery (10.2 ± 1.8). Caucasian patients and patients with a higher number of MicroPulse TLT sweeps at the time of the initial procedure also had better survival.

As there was a significant demographic overlap between patients with tube shunts and pseudophakic patients, more research and a larger sample size are required to examine if differences in MicroPulse TLT outcomes are driven by pseudophakia or by a history of prior incisional surgery.

Clinical Significance and Generalizability

The study suggests that for POAG patients undergoing MicroPulse TLT, pseudophakia and prior incisional surgery may be predictive factors for sustained pressure reduction. TLT thereby might be a safer and more efficacious option than previously thought for refractory glaucoma in these patients. Further research is needed to assess optimal candidacy for TLT. The authors believe the findings above to be generalizable for open-angle glaucoma (OAG) patients based on the broad selection criteria utilized, though they do believe that variations in intraoperative technique (e.g., sweeps utilized) may impact results.

Orcid

Skyler G Jones https://orcid.org/0000-0003-4463-338X
Forrest Clark https://orcid.org/0009-0006-7102-2807
Marc Toeteberg-Harms https://orcid.org/0000-0002-2134-1336

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