Adjunctive micropulse laser trabeculoplasty: analysis of treatment efficacy based on disease stage

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ABSTRACT

Objectives: To determine (a) the efficacy and safety of micropulse laser trabeculoplasty (MLT) as an adjunctive therapy in patients with medically uncontrolled mild, moderate, and severe primary open angle glaucoma (POAG) and (b) the influence of ocular and systemic characteristics on MLT outcomes.

Methods: One hundred and twenty consecutive patients who received MLT between April 2015 and November 2017 were reviewed in this retrospective study. One eye was randomly selected per patient. Variables collected included: age, sex, race, cup-to-disc ratio (C/D), complications, additional glaucoma treatments, and intraocular pressure (IOP). Success was defined as ≥10% reduction of IOP or final pressure of ≤18 mmHg, whichever was lower, at one year. Failure was defined as not meeting IOP goals or requiring additional laser or surgical glaucoma treatments. Statistical analyses included Chi-square, one-way ANOVA, and Univariate and multivariate binary logistic regression.

Results: Average IOP reduction for all patients at one-year post-MLT (n=55, 46%) was 11.15%, while reduction in those with mild moderate and severe glaucoma was 9.53%, 15.93%, and 7.63% respectively ($p<0.05$). At one year, MLT was successful in forty (43.0%) patients. Four cases (3.3%) had transient IOP spikes between 5 and 10 mmHg while two (1.7%) reported pain. Variables found to be significantly correlated with failure were higher pre-op: IOP (OR=0.866), number of medications (OR=0.077), and C/D ratio (OR=0.086).

Conclusion: Our study found adjunctive MLT to be an efficacious and safe treatment in patients with POAG who were not adequately controlled. Patients with mild to moderate glaucoma responded better to MLT than those with severe glaucoma. Systemic patient characteristics did not appear to affect outcomes.

Key words: Intraocular pressure (IOP), Micropulse laser trabeculoplasty (MLT), Primary open angle glaucoma (POAG).

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Introduction

Micropulse laser trabeculoplasty (MLT) using a diode laser is a recent addition to the treatment of glaucoma.[1] MLT breaks up the laser energy into shorter (milliseconds) repetitive pulses followed by an intermittent rest period.

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Breaking up the laser energy into short segments reduces build-up of thermal energy and allows for return of the cells to baseline temperature and prevents cell death. There appears to be no visible cellular molecular changes while still inducing beneficial remodeling of the trabecular meshwork.[1,2]
Although the exact mechanism of MLT in lowering intraocular pressure (IOP) is unclear, it has been shown to be an efficacious and safe treatment in small studies consisting of homogenous patients and shorter follow-up.[1,3-9] Increased energy and larger spot size have been shown to influence IOP reduction, while number of spots, presence of peripheral anterior synechiae (PAS), age, and sex did not appear to affect MLT outcomes.[7] The effect of the stage of glaucoma damage (mild, moderate, or severe) and other ocular and systemic characteristics on the outcome of MLT has not been fully investigated.

Therefore, the primary aim of our study was to determine the efficacy and safety of MLT in patients with mild, moderate, or severe primary open angle glaucoma (POAG). The secondary aim was to determine any correlations between ocular patient characteristics (visual field defect (VFD), spherical equivalence (SE), best corrected visual acuity (BCVA), central corneal thickness (CCT), cup-to-disc (C/D) ratio, phakic status, pre-operative IOP, pre-operative number of medication, and any prior glaucoma treatment) or systemic patient characteristics (age, sex, race, family history of glaucoma, body mass index (BMI), hypertension (HTN), and diabetes mellitus (DM)) on MLT outcomes. It is also hypothesized that MLT results will be at least similar to the published IOP outcomes of adjunct selective laser trabeculoplasty (SLT) and demonstrate less post-operative complications.

METHODS

Study Design

This retrospective chart review study was approved by the Institutional Review Board of the University Of Texas Southwestern Medical Center (UTSW). A list of consecutive patients who received MLT between April 2015 and November 2017 was obtained from the laser log book maintained at UTSW. We adhered to the tenets of the United States Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Helsinki Declaration. All patients provided written informed consent prior to surgery.

Selection of Patients

Charts of all consecutive patients who underwent MLT were reviewed. Patients were included if they were diagnosed with POAG and were on antiglaucoma medications. POAG was defined as an ocular condition with an open iridocorneal angle on gonioscopy, characteristic glaucomatous optic nerve changes such as cupping, notching, corresponding VFDs consistent with glaucoma with or without elevated IOP. Those who had received SLT or argon laser trabeculoplasty (ALT) more than one year prior to MLT were included.
Patients were excluded if they were <18 years old, had angle closure glaucoma, secondary glaucoma, only one functional eye, no light perception vision, corneal, retinal or any other media opacities, any intraocular surgery three months prior to MLT, less than three months of post-MLT follow-up and those who were unable to keep post-op appointments or who left the area.

Measurements

Age, race, gender, family history of glaucoma, BMI, HTN, DM, BCVA, SE, CCT (Corneo-Gage Plus Sonogage Pachymeter Sonogage, Cleveland, OH, USA), pre-operative BCVA in LogMAR units, C/D ratio, phakic status, VFD (Humphrey Field Analyzer 3, Humphrey Instruments, CA, USA), pre-operative number of antiglaucoma medications, prior ALT or SLT, prior glaucoma surgeries, number of

MLT spots, pre-operative IOP, complications, post-operative IOP at one hour, one week, one month, three months, six months, and one year were recorded.
Pre-operative IOP was the average pressure of the last three visits prior to MLT and was measured by Goldman applanation tonometer (Haag-Streit, Inc. Koeniz, Switzerland). Combination anti glaucoma drops were counted as two medications. Complications recorded included IOP spikes between 5 and 10 mmHg, IOP spikes ≥10 mmHg, peripheral anterior synechiae (PAS), pain, and any other serious complications. VFDs were classified as mild (mean deviation (MD) 0 to -6 dB), moderate (MD -6.01 dB to -12.0 dB), and severe (MD > -12 dB) based on a modified Hodapp-Parish-Anderson grading scale.[10]

Intervention
A single session of MLT was performed by KSK using an Iridex IQ All-Yellow 577 diode laser system (Iridex Corporation, Mountain View, CA, USA) with a spot size of 300 μm, power of 1000 or 1400 mW, a duration of 300 milliseconds, over 360° of the pigmented trabecular meshwork and a duty cycle of 15%. A duty cycle is the percentage of time that the laser stays active during treatment duration. An average (range) of 140 (50-218) confluent spots were administered using a MLT goniolens (Ocular Instruments, Bellevue. Washington, USA.)

One hour prior to surgery, two drops of proparacaine 0.5% (Bausch & Lomb, Rochester, NY, USA) and one drop of apraclonidine 1% (Alcon Laboratories, Fort Worth, TX, USA) each five minute apart were instilled followed by one drop of the latter post-operatively. At one-hour post-MLT, patients were reexamined and had their IOPs checked. They were instructed to continue their usual glaucoma regimen and return in one week. No anti-inflammatory medications were necessary.

Definition of Success and Failure
Success with MLT was defined as reduction of pre-treatment IOP by ≥ 10% or to ≤18 mmHg, whichever was lower, without additional antiglaucoma intervention at one year follow up. We selected IOP of ≤18 mmHg based on the criteria used by the Advanced Glaucoma Intervention Study (AGIS) .[11] Failure was defined as no further reduction of IOP or when patients required additional glaucoma treatments. Upon meeting the failure criteria, further data collection for the patient was ended. Final date of examination, BCVA, IOP, and additional treatment were also recorded.

Statistical Analysis
Patients who received MLT in both eyes, only one eye was randomly selected for analysis. Chi square goodness of fit and one-way ANOVA tests were used to determine any characteristic differences between patient groups. Paired t-tests were performed to compare IOP at various time points for all groups. Univariate and multivariate binary logistic regression analyses were performed to analyze differences between success and failure groups at one year. Odds ratios (ORs) were also generated from binary logistic regression analyses. A p-value <0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics package (IBM SPSS, New York, NY, USA).

RESULTS

Demographics
The charts of 186 patients identified from the laser room log book were reviewed. Sixty-six (35.4%) patients were excluded based on the selection criteria. Demographics for the remaining 120 (64.5%) patients included in the study broken down into patients with mild, moderate, and severe glaucoma are shown in ***(Table I).*** Overall, the population was 53.3% female, 42.5% white, and had a mean age of 69 years. Patients with severe glaucoma were found to be younger and more likely to be black while those

with mild glaucoma were found to have lower C/D ratios and less pre-op medications. In addition, patients with moderate glaucoma had more prior cataract and glaucoma filtering surgeries. Other variables were not different between groups.

Table I. Baseline demographics and pre-operative descriptive statistics.

Variable (%) ± SD	Mild (n=23)	Moderate (n=53)	Severe (n=39)	Total (n=120)	P-Value
Sex (F)	48.00	55.00	56.00	53.30	0.797
Age (yrs.)	68.78 ± 9.23	72.43 ± 8.66	64.36 ± 10.56	69.3 ± 9.99	<0.001
Race					
White	30.400	54.700	30.800	42.500	0.038
Black	56.500	22.600	48.700	38.300	0.003
Hispanic	4.300	13.200	12.800	10.800	0.529
Asian	4.300	5.700	5.100	5.000	0.951
East Indian	4.300	3.800	2.600	3.300	0.910
Body mass index (kg/m^2)	31.95 ± 9.85	28.18 ± 6.83	30.64 ± 7.62	29.9 ± 7.8	0.112
Hypertension	82.6	62.26	74.36	71.70	0.163
Diabetes mellitus	34.80	28.30	33.30	31.70	0.808
Family history of glaucoma	47.80	39.60	48.70	44.20	0.994
Right eye selected	56.50	50.90	56.40	54.20	0.840
Visual Field Defect					
Mild	100.00	0.00	0.00	19.20	<.001
Moderate	0.00	94.30	0.00	41.70	<.001
Severe	0.00	0.00	97.40	31.70	<.001
Spherical Equivalence	-.37 ± 2.47	-.90 ± 1.94	-1.61 ± 1.86	-1.04 ± 2.74	.241
Myopia	57.20	69.60	62.60	63.40	0.681
Hyperopia	0.00	3.80	12.81	7.73	0.225
BCVA LogMAR (Median)	0	0.2	0.2	0.1	0.313
CCT (μm)	542.43 ± 37.45	538.82 ± 40.39	532.06 ± 42.56	537.28 ± 40.14	0.637
Cup-to-disc ratio	0.582 ± .19	0.775 ± .16	0.828 ± .17	0.755 ± .19	<.001
Phakic	95.70	64.20	82.10	75.83	0.007
Pre-op IOP (mmHg)	17.913 ± 3.20	18.516 ± 4.33	19.015 ± 5.07	18.663 ± 4.42	0.633
Pre-op Number of Medications	2.09 ± 1.0	2.34 ± 1.11	3.23 ± 1.01	2.58 ± 1.12	0.002
No Prior Operative Treatment	82.60	67.90	61.50	68.30	0.222
Prior ALT/SLT	17.40	28.30	20.50	23.30	0.509
Prior Laser Peripheral Iridotomy	0.00	0.00	2.56	0.83	0.336
Prior Filtering Device	0.00	5.70	2.31	10.80	0.005
Complications *	0.00	3.80	7.70	5.00	0.344
Requiring Additional Medications	21.70	20.80	15.40	20.00	0.761
Requiring Additional Surgery	8.70	17.00	20.50	15.80	0.477
Successful treatment	52.38	44.73	35.48	43.01	0.573
IOP reduction at one year	9.53	15.93	7.63	11.16	.332

*Complications were four cases of transient IOP rise ≥5mmHg and two cases of self-reported pain

Legend
Table I. Baseline demographics and pre-operative descriptive statistics
BCVA: Best corrected visual acuity
LogMAR: Logarithmic of the minimum angle of resolution
CCT: central corneal thickness
IOP: Intraocular pressure
ALT: Argon laser trabeculoplasty

SLT: Selective laser trabeculoplasty

Efficacy

(Figure 1) shows IOP for all patients over time while IOP in mild, moderate, and severe glaucoma is shown in (***Figure 2)***. IOP trend based on failure and success is shown in ***(Figure 3).*** Average IOP reduction at one year in all groups, mild, moderate, and severe were 11.15%, 9.53%, 15.93%, and 7.63% respectively (n=55, $p<0.05$). Patients with successful MLT at one year had a mean IOP reduction of 15.72% ($p<0.001$) while patients with failure MLT had a mean IOP reduction of 4.1% ($p=0.015$). Reductions in IOP in all patient groups for various time points were significant compared to baseline except for mild at one week, one month, and six months; severe at three months; and success at three months. At one year, out of 93 patients who qualified, MLT failed prior to one year in 53 (57%) of patients and succeeded in 40 (43%). Twenty-four (20%) of patients required an additional antiglaucoma medication and 19 (15.8%) required additional antiglaucoma surgery.

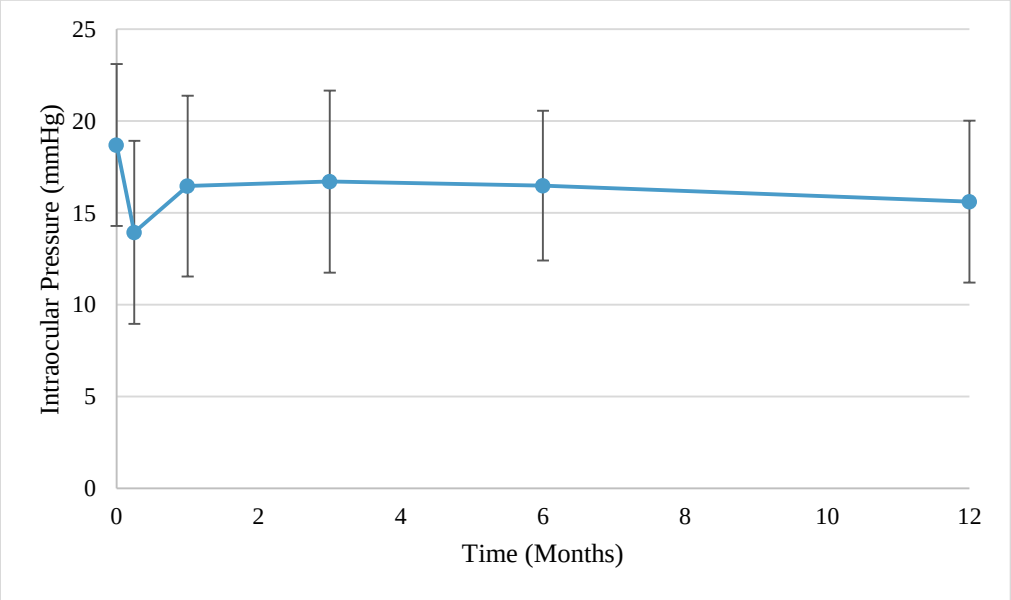

Figure 1. Intraocular pressure over time for all patients

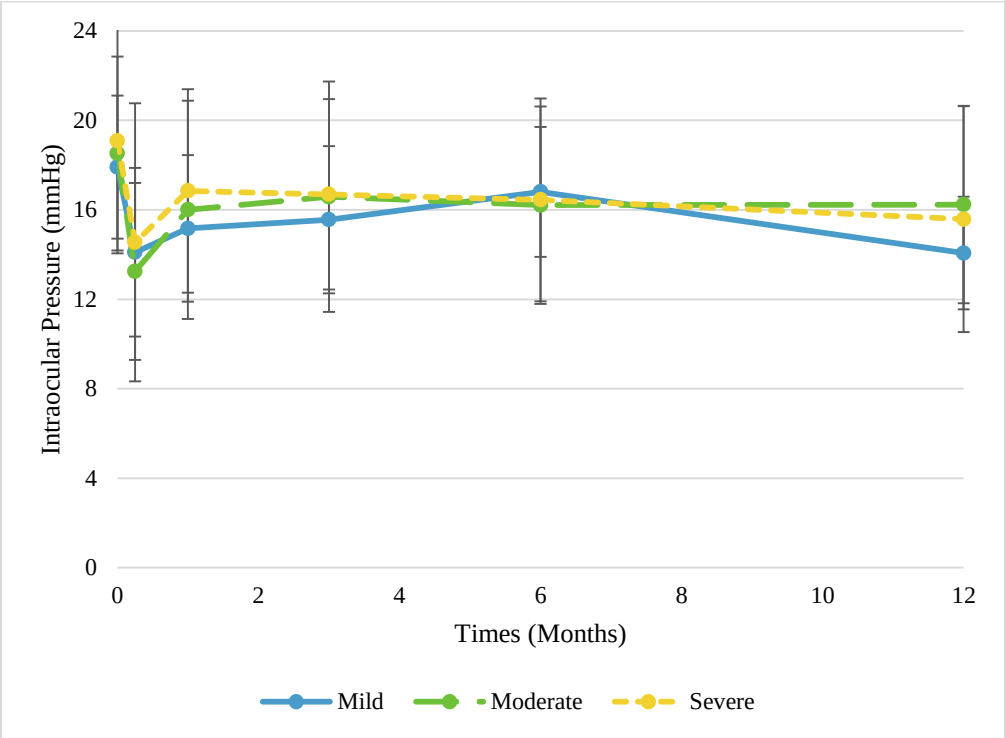

Figure 2. Intraocular pressure over time for mild, moderate, and severe glaucoma groups

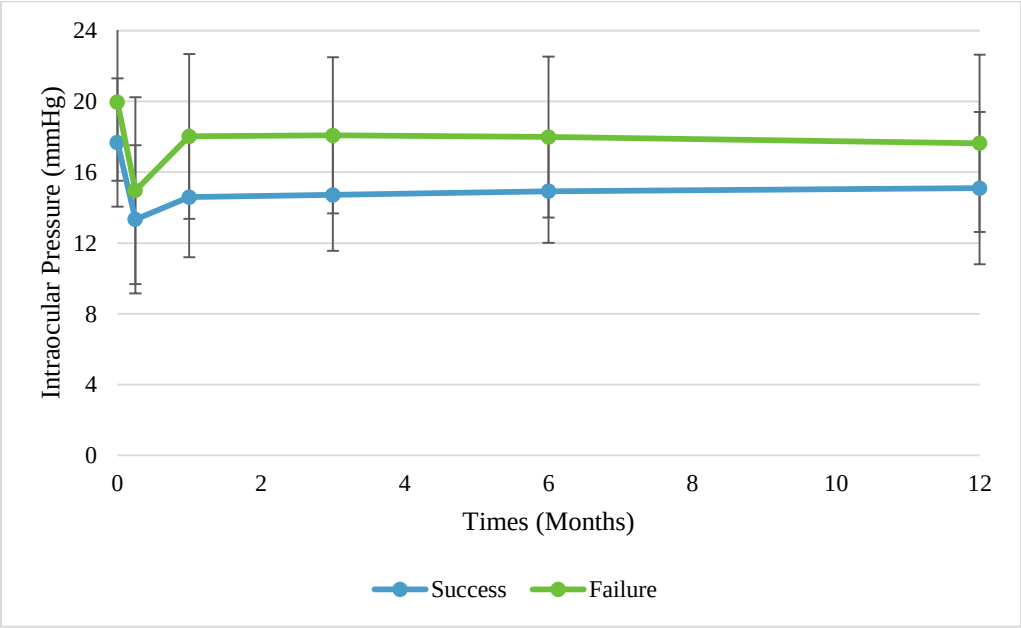

Figure 3. Intraocular pressure over time for success and failure groups

Safety

Only four cases (3.3%) of transient IOP spikes between 5 and 10 mmHg, two cases (1.7%) of self-reported pain, and no instance of PAS were observed. Median BCVA for successful patients was unchanged over the course of treatment ($p < 0.05$).

Predictors of success

Univariate binary logistic regression was performed for 26 covariates displayed in ***(Table II).*** Increased pre-op IOP was found to be significantly associated with MLT failure in both Univariate (p=0.013, OR=0.866) and multivariate analyses (p=0.043, OR=0.626). Increased C/D ratio was found to be significantly associated with MLT failure in Univariate analysis (p=0.029, OR=0.086) but not multivariate analysis. Increased pre-op number of medications was found to be significantly associated with MLT failure in multivariate (p=0.044, OR=0.077) but not Univariate analysis. Multivariate analysis excluded variables found to be highly collinear.

Table II. Odds ratios of cofactors in Univariate and multivariate regression analysis predictors of success

	Univariate Logistic Regression					Multivariate Logistic Regression				
Covariate	**P-Value**	**Coefficient Estimate**	**Odds Ratio**	**95% LL**	**95% UL**	**P-Value**	**Coefficient Estimate**	**Odds Ratio**	**95% LL**	**95% UL**
Age	0.857	-0.004	0.996	0.959	1.035	0.153	-0.237	0.789	0.571	1.092
Female sex	0.570	0.238	1.269	0.557	2.890	0.741	-0.569	0.566	0.019	16.667
Asian/Other race	0.243	1.041	2.833	0.492	16.393	Excluded from multivariate logistic regression analysis				
Black race	0.531	0.267	1.305	0.566	3.012	0.403	1.828	6.211	0.086	500.000
Hispanic race	0.758	-0.288	0.469	0.116	1.898	0.646	1.614	5.025	0.005	9146.349
White race	0.425	-0.350	0.705	0.298	1.667	0.74	Reference Variable			
Pre-op IOP	0.013	-0.144	0.866	0.772	0.970	0.043	-0.468	0.626	0.398	0.984
Pre-op number of medications	0.119	-0.290	0.749	0.520	1.078	0.044	-2.564	0.077	0.006	0.930
Body mass index	0.072	0.049	1.050	0.996	1.107	0.089	0.362	1.437	0.947	2.179
Hypertension	0.081	0.886	2.427	0.897	6.536	0.293	-2.295	0.101	0.001	7.246
Diabetes mellitus	0.238	0.524	1.689	0.707	4.032	0.196	-3.627	0.027	0.000	6.452
Family history	0.316	-0.486	0.615	0.238	1.590	0.398	-2.635	0.072	0.000	32.258
Mild VFD	0.816	-0.148	0.862	0.247	3.003	0.268	-3.076	0.046	0.000	10.638
Moderate VFD	0.99	0.006	1.006	0.397	2.551	0.713	0.763	2.146	0.037	125.000
Severe VFD	0.715	-0.182	0.833	0.313	2.217	0.513	Reference Variable			
Spherical equivalence	0.521	0.052	1.053	0.899	1.233	0.53	0.184	1.202	0.677	2.132
Psuedophakic	0.958	0.025	1.026	0.396	2.653	0.115	10.766	55797.897	0.073	3.219E10
Central corneal thickness	0.258	0.007	1.007	0.995	1.019	0.938	-0.001	0.999	0.963	1.035
BCVA	0.777	0.117	1.124	0.500	2.525	0.66	-1.153	0.316	0.002	52.632
Cup-to-disc Ratio	0.029	-2.454	0.086	0.009	0.783	0.392	-4.949	0.007	0.000	500.000
No prior treatment	0.168	0.655	1.923	0.759	4.878	0.603	0.794	2.212	0.111	43.478
Prior ALT or SLT	0.416	-0.427	0.653	0.233	1.825	Excluded from multivariate logistic regression analysis				
Prior glaucoma shunt	0.138	-1.217	0.296	0.059	1.479	Excluded from multivariate logistic regression analysis				
Spots	0.144	-0.005	0.995	0.987	1.002	0.500	-0.013	1.013	0.951	1.025
Power (mW)	0.224	-0.002	0.999	0.997	1.001	0.117	-0.013	1.013	0.971	1.003
Total Energy (J)	0.132	-0.075	0.928	0.841	1.022	Excluded from multivariate logistic regression analysis				

Legend

Table II. Odds ratios of cofactors in univariate and multivariate binary logistic regression analysis predictors of failure.
LL: Lower limit 95% confidence interval of odds ratio
UL: Upper limit 95% confidence interval of odds ratio
CCT: Central corneal thickness
BCVA: Best corrected visual acuity
VFD: Visual field defect
ALT: Argon laser trabeculoplasty
SLT: Selective laser trabeculoplasty
IOP: Intraocular pressure
Asian/other race was excluded as n<10
Prior ALT/SLT and prior glaucoma shunts were excluded as they were highly collinear with no prior treatment
Total energy was excluded as it was highly collinear with spots and power

DISCUSSION

This study was designed to determine the efficacy and safety of adjunct MLT in mild, moderate, and severe glaucoma and look for any predictors of MLT success. We also hypothesized that MLT results would be at least similar to the published IOP outcomes of adjunct SLT and demonstrate less post-operative complications.

Efficacy

IOP reduction following MLT in this study are consistent with the reported range of 7.5 to 22.1%.[1,3-9] Although our study is on the lower side of reported reductions, our patient population started with the baseline IOP of 18.69 mmHg while studies reporting higher reductions had patient populations with a baseline IOP around 25 mmHg.[1,3] Our pre-treatment IOP was the mean of the last three clinic IOP measurements, while except for Fea at al [3], all the other studies used a single pre-MLT IOP value [1,4-9]. Final IOP of patients in our study was lower than Fae et al.[3] who reported the highest reduction of 22.1% with a final IOP of 19.5 mmHg and similar to those reported by Lee et al.[1] who reported the second highest reduction of 19.8%.

The reported success of MLT varies wildly from 2.5% to 75% based on various definitions of success and follow-up times.[1,3,6,9] The success rate in our study of 43%, is close to 35.7% reported by Detry et al. of 35.7%.[9] Lee et al. reported a success rate of 73%; however this success rate was based on IOP reduction at one month follow-up.[1] Fae et al. published a success rate of 75%; however their target IOP was 21 mmHg while ours was 18 mmHg.[3] In our study, 20% of patients required additional antiglaucoma medications while 15.8% needed more surgeries, which is consistent with other investigations.[3,6,7]

Ocular Predictors

The only study analyzing the effect of ocular characteristic on MLT outcomes is by Babalola who focused on spot size and energy.[7] Our study found no such correlation between total energy and IOP reductions at one year (r=.152, p=.288). This may be due to the fact that our baseline energy delivered was higher than suggested by Ahmed et al. and Babalola.[7,8] Therefore, it is possible that we have found an "upper limit" of effective energy in MLT. Similar upper limit has been reported with SLT.[12] From our study we can state that energy beyond 1000 mW and 140 spots may not provide extra benefits to patients.

Increased pre-op IOP was found to be a significant predictor of failure. This is contrary to a majority of reports for SLT that indicate increased pre-op IOP as a predictor of success.[12-16] We selected a target IOP of 18 mmHg in accordance with AGIS.[11] Most patients were treated before their IOP's were >20 mmHg, so our study findings may not compare well to other studies with higher baseline IOPs.[12-16] We postulate that , higher pre-op IOP despite maximum medical therapy in our patients may be indicative of poor trabecular meshwork function and thus limited MLT response.

Increased number pre-op medications was also found to be a significant predictor of failure in SLT.[15] Some classes of medications may share a similar proposed mechanism of laser trabeculoplasty in terms of cytokines and molecular events, which could compete with and thus reduce the potential full effect of trabeculoplasty.[17,18] It has also been postulated that prostaglandin analogs may counteract the full effects of SLT by promoting uveoscleral outflow which leads to hypoperfusion of the trabecular meshwork.[19] It is also possible that patients on multiple medications have more recalcitrant forms of glaucoma with

unresponsive trabecular meshwork. This suggests MLT may work better as a primary rather than adjunctive therapy, as proposed for SLT.[15,16]

We found that increased C/D ratio (glaucomatous cupping) was a significant predictor of failure. Increased glaucomatous cupping has been shown to correlate with IOP.[20,21] Therefore, our finding that increased C/D ratio is associated with MLT failure may be due to higher pre-op IOP.

These findings indicate that severe glaucoma patients may not respond as well to MLT as their mild and moderate counterparts do. VFDs, CCT, refractive errors, prior treatment, number of laser spots delivered, were found to be insignificant predictors of success, similar to prior SLT studies.[12-16]

Systemic Predictors

We have shown that age, gender, race, BMI, hypertension, diabetes, family history, did not significantly influence success. Similarly, Babalola also found no correlation between age, sex, and MLT outcomes.[7] In addition, SLT studies have not demonstrated any systemic predictors of outcomes.[12-16]

Safety

MLT was found to be a safe treatment in our study consistent with prior reports on its safety.[1,3-9] Adjunct SLT has been reported to have IOP spikes >10 mmHg in 10% of patients with POAG and >5 mmHg in 21% of patients as well as prolonged anterior chamber inflammation.[22,23] Damji et al [24]. reported PAS formation in 1.1% of patients treated with SLT while we observed no PAS or >10 mmHg IOP spikes.

Comparison of Efficacy to SLT

In a one year randomized clinical trial Damji et al [24]. Reported SLT to have a 24.59% reduction in IOP at one year, but the patient population also had a larger baseline IOP of 23.84 mmHg compared to this study's population baseline IOP of 18.69 mmHg. Final mean IOP at one year was actually lower for our MLT patient population at 15.87 mmHg compared to SLT's 17.97 mmHg.[24] They defined success as IOP reduction >20% and no additional glaucoma treatments.[24] Our study defines success as an IOP reduction ≥10% or IOP ≤18 mmHg, whichever was lower, and no additional glaucoma treatments. The difference in definitions is due to the lower baseline IOP of our study. In their study 18% of patients who received SLT required an additional antiglaucoma medication and 19.1% required additional surgery with an overall success rate of approximately 40%.[24] In our study, 20% of patients who received MLT required an additional antiglaucoma medication, 15.8% required additional surgery, and overall success was 43%. MLT appears to be as effective as SLT.

Limitations

Limitations of this study include the inherent weaknesses of all retrospective studies. Retrospective chart review does not allow for full experimental control and results may be influenced by various factors such as compliance and patient follow up. Any significant correlations found cannot be definitive proof of underlying mechanisms. While we seek to explore the efficacy of MLT, confounding factors such as prior treatments, existing medical treatment, and compliance could all affect the outcomes measured in this study. Our patient population consisted of those diagnosed with uncontrolled POAG, therefore, results may not apply to patients with ocular hypertension, or those receiving repeat MLT. Lastly, we did not compare MLT and SLT. A well-designed, long-term prospective study is needed to compare the efficacy of MLT to SLT.

CONCLUSION

Adjunct MLT is modestly efficacious and safe treatment that may offer additional long term IOP control for patients with POAG who are not responsive to medical treatment. Patients with mild and moderate glaucoma may respond better to adjunct MLT than those with severe glaucoma. Finally, adjunct MLT is as efficacious as adjunct SLT and as safe, if not safer.

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