ORIGINAL ARTICLE

Clinical Outcomes of MicroPulse Transscleral Laser Therapy with the Revised P3 Delivery Device

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Abstract

Aim: To evaluate the success and safety of MicroPulse transscleral laser therapy (TLT) on intraocular pressure (IOP) reduction in adults with uncontrolled glaucoma using different total treatment durations, sweep velocities, and a number of sweeps utilizing the revised MicroPulse P3 delivery device.

Materials and methods: A single-center Institutional Review Board (IRB) approved multiple cohort studies of MicroPulse TLT with the revised MicroPulse P3 delivery device, which was conducted in 61 eyes from 40 adults with uncontrolled glaucoma. Eyes that received 50-second (GI, GII, and GIII) and 60-second (GIV, GV, and GVI) treatment applications between May and October 2020 were reviewed. Each hemisphere received a total of five, four, or three sweeps. The patient's IOP and glaucoma medications were monitored over 12 months follow-up. Qualified success was defined as an IOP of ≤21 mm Hg and/or reduction of ≥20% from baseline at 12 months, with no secondary glaucoma reinterventions. Complete success was defined as meeting the above criteria with no increase in glaucoma medications at 12 months. All eyes requiring a glaucoma surgical intervention were considered a failure.

Results: Qualified success was achieved in 83.6% of eyes, while complete success was achieved in 75.4% of eyes. In eyes receiving 50-second applications of five, four, or three sweeps (GI, GII, and GIII), 70, 90, and 91% achieved qualified success, respectively; in eyes receiving 60-second applications of five, four, or three sweeps (GIV, GV, and GVI), 78, 82, and 90% achieved qualified success, respectively. Within each subgroup, mean IOP reductions ranged from 32.8 to 49.4% and were statistically significant ($p < 0.008$). The failure rate was 16.4%, and at least one eye failed in each subgroup.

Conclusions: MicroPulse TLT with the revised MicroPulse P3 delivery device and relatively low total energy levels is safe and effective at lowering IOP. Efficacy appears to increase with longer treatment durations and slower sweep velocities, but statistical differences between age and clinical differences between baseline IOP measurements limit comparison between subgroups.

Clinical significance: There is a lack of literature evaluating the safety and IOP-lowering success of the revised MicroPulse P3 delivery device using different total treatment durations, sweep velocities, and number of sweeps.

Keywords: Cohort, Glaucoma, Laser, MicroPulse transscleral cyclophotocoagulation, MicroPulse transscleral laser therapy.

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Introduction

Glaucoma is a worldwide leading cause of irreversible vision loss. Because it may be asymptomatic until a relatively late stage, diagnosis is frequently delayed.[1,2] By 2020, it was estimated that nearly 80 million people would be affected by glaucoma, of which 11.1 million would be bilaterally blind.[3] Glaucoma treatment consists of topical, surgical, and/or laser therapy. Transscleral diode laser treatments are on the rise as the safety profile, repeatability, and tissue-sparring nature are favored over more invasive surgical options.[2,4,5]

Continuous-wave transscleral cyclophotocoagulation (CW-TSCPC) is an 810 nm laser-based glaucoma treatment that targets pigmented ciliary body tissues and reduces aqueous humor production.[6–8] This, in turn, lowers intraocular pressure (IOP) and slows glaucoma progression.[8] CW-TSCPC was initially performed in eyes with refractory glaucoma and a poor visual prognosis, but success has been demonstrated in patients with moderate glaucoma and good visual acuity.[6–10] Although the IOP-lowering efficacy of CW-TSCPC has been well reported in the literature, various complications such as intraocular hemorrhage, prolonged ocular inflammation, hypotony, phthisis bulbi, visual loss, and postoperative pain have been associated with its use.[6–8]

MicroPulse transscleral laser therapy (TLT) (Iridex Corporation, Mountain View, California, United States of America), introduced in 2015, also uses an 810 nm diode laser; however, the laser energy is delivered in rapid and repeated pulses rather than in a continuous-wave fashion. The "off" intervals of the cycled delivery protect the

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structural integrity of the surrounding ciliary body tissues and have shown similar efficacy to CW-TSCPC with a lower incidence of complications and more consistent, predictable effects.[8,11]

MicroPulse TLT is delivered using the MicroPulse P3® Delivery Device, also referred to as the MicroPulse P3 Probe (Iridex Corporation, Mountain View, California, United States of America) when connected to the Cyclo GVI® laser (Iridex Corporation, Mountain View, California, United States of America). The MicroPulse P3 delivery device has evolved to improve stability, the overall size of the footplate, visualization, coupling, and a more consistent treatment application. The original MicroPulse P3 delivery device had two peculiarities: a bulb at the tip that could indent the eyeball and a rounded tip that allowed for an anterior delivery of the laser, which produced more frequent complications such as cataracts, mydriasis, and goblet cell atrophy with dry eyes.[12]

In 2020, Iridex launched the revised MicroPulse P3 delivery device, which contained several updated features. These included a recessed tip with a 600 µm fiber diameter and an additional fluid channel to improve energy coupling to the tissue, a concave "scleral-matching" baseplate to improve stability, a "limbus-matching" baseplate to better identify device orientation and placement, and a reduced platform size to increase ease of placement in patients with narrow eyelid space.[13] The revised MicroPulse P3 delivery device focuses the laser energy ~3 mm back from the limbus or at the pars plana portion of the ciliary body, where less aqueous-producing cells reside. This is different than its CW-TSCPC counterpart, the G-Probe® (Iridex Corporation, Mountain View, California, United States of America), which focuses its laser energy ~1.9 mm back from the limbus or at the pars plicata portion of the ciliary body and historically has been considered an aqueous suppressive treatment. These changes may explain the reduction in overall complications associated with the original MicroPulse P3 delivery device. Also, the recessed laser tip design within the revised probe, as compared to the protruding tip in the original probe, can help prevent conjunctival injury, as well as decrease energy absorption to goblet cells and limbal vasculature.[12,13]

To our knowledge, there are not enough publications about MicroPulse TLT utilizing the revised MicroPulse P3 delivery device. Within this study, we evaluate the safety and success of MicroPulse TLT in adults with uncontrolled glaucoma using different total treatment durations, sweep velocities, and the number of sweeps.

Materials and Methods

A single-center, multiple-collection study of MicroPulse TLT using the Cyclo G6 and the revised MicroPulse P3 delivery device was conducted. Study participants were aged over 18 years and diagnosed with uncontrolled glaucoma, as defined by an IOP above target levels or evidence of disease progression *via* visual field deterioration despite maximal tolerated medical therapy. Eyes that had received MicroPulse TLT between May and October 2020 and completed 12 months of follow-up were included and reviewed. The study was approved by the Mayo Clinic Institutional Review Board (IRB) in 2019 (certificate approval number: 11/11/2019). This research adhered to the tenets of the Declaration of Helsinki, and all patient data has been de-identified.

The clinical outcomes of six treatment groups were reviewed. Groups GI, GII, and GIII received a 50-second treatment application per hemisphere in five, four, and three sweeps at 10-, 12.5-, and 16.7-second sweeps, respectively. Groups GIV, GV, and GVI received a 60-second treatment application per hemisphere in five, four, and three sweeps at 12-, 15-, and 20-second sweeps, respectively (Table 1).

The main outcome measures were qualified success and complete success. Qualified success was defined as an IOP of ≤21 mm Hg and/or reduction of ≥20% from baseline at 12 months, with no secondary glaucoma reinterventions. Complete success was defined as meeting the above criteria with no increase in glaucoma medications at 12 months. Secondarily, failure was defined as any case that required a glaucoma surgical reintervention at any time during the follow-up period.

Parameters were measured at baseline and postoperatively on day 1, week 1, and months 1, 3, 6, 9, and 12. Data were extracted from electronic medical records (EPIC, Madison, Wisconsin, United States of America) using a standardized data collection form, including patient demographics, best-corrected visual acuity (BCVA), procedure date, laterality, severity, and type of glaucoma upon diagnosis. IOP, number of topical glaucoma medications, complications (hypotony, prolonged inflammation, sympathetic ophthalmia, and nontolerated pain), and failure were measured at each follow-up visit. IOP was measured by the iCare® ic100 rebound tonometry model (iCare IC100; iCare) on postoperative day 1 due to the increased sensitivity of the eye following MicroPulse TLT. At all other time points, IOP was measured using Goldmann applanation tonometry.

Total energy was calculated as the product of power, duty cycle, and exposure duration.[14] Fluence was calculated as the product of power, duty cycle, and dwell time/area.[14] The dwell time is the equivalent stationary pulse duration during which equal energy is deposited per unit area per unit time. It is based on the velocity at which the probe is swept over an arc length of the limbus, or sweep velocity.[14] The area of the 600-µm spot diameter in the revised probe was measured to be 0.0028 cm^2.[14] Groups GI, GII, and GIII received 39 J of total energy per hemisphere, and groups GIV, GV, and GVI received 47 J of total energy per hemisphere. In groups GI, GII, and GIII, fluency was measured at 75, 95, and 126 J/cm^2, respectively. In groups GIV, GV, and GVI, fluency was measured at 92, 114, and 151 J/cm^2, respectively (Table 1).

Table 1: Energy and fluence parameters per hemisphere of all groups; table format adapted from Grippo et al.[14]

Groups	*Power*	*Number of sweeps (sweep dose)*	*Exposure duration (seconds)*	*Velocity (mm/second)*	*Dwell time (ms)*	*Total energy per hemisphere (J)*	*Energy delivered in 600 µm (J)*	*Dose fluence (J/cm^2)*	*Sweep time for 22 m arc (second)*
GI	2.5 W	5	50	2.2	270	39	0.21	75	10
GII	2.5 W	4	50	1.8	340	39	0.27	95	12.5
GIII	2.5 W	3	50	1.3	450	39	0.35	126	16.7
GIV	2.5 W	5	60	1.8	330	47	0.26	92	12
GV	2.5 W	4	60	1.5	410	47	0.32	114	15
GVI	2.5 W	3	60	1.1	545	47	0.43	151	20

Procedure

A single glaucoma surgeon carried out all procedures. Patients were placed in a supine position, and a lid speculum was placed after monitored anesthesia care and application of topical lidocaine gel. All patients were treated with 2500 mW with a wavelength of 810 nm and a duty cycle of 31.3%. A sterile, single-use, revised MicroPulse P3 probe was applied using steady pressure parallel to the visual axis, and the fiberoptic tip was positioned approximately 3 mm posterior to the conjunctival limbus. The probe was moved continuously along the limbus and slid back and forth three, four, or five times, depending on the treatment group. Three and 9 o'clock positions were avoided to protect ciliary neurovascular structures. The average arc length spanned was 22 mm. Patients were discharged with 1% prednisolone acetate four times a day. No preoperative glaucoma medication washouts were performed.

Statistical Analysis

Statistical analysis was performed with the statistical software STATA BE 17. Descriptive statistics were expressed as the mean ± standard deviation for continuous variables and frequency (percentage) for categorical variables. Normality was assessed using both the Shapiro–Wilk test and histograms with normality plots for mean IOP at baseline and 12 months, for which the baseline mean IOP of groups GII, GIII, and GV showed a *p*-value of <0.05. To address nonnormality and perform parametric testing, we assumed the Central Limit Theorem premise of normality of the data distribution with sufficient sample size. Differences with a *p*-value of <0.05 were considered statistically significant. A paired *t*-test was performed for the primary analysis to compare mean IOP from baseline to the 12-month follow-up visit. Multiple comparisons were corrected with the Bonferroni correction method; therefore, a two-sided *p*-value <0.008 was considered statistically significant.

Results

A total of 61 eyes of 40 patients were included in this study. Sociodemographics and baseline characteristics per treatment group are contained in Table 2. Patient ages ranged from 27 to 90 years, with a mean age of 71.8 ± 9.6 years. Age presented a statistically significant difference between treatment groups ($p < 0.03$). A total of 45 eyes (73.8%) had been previously diagnosed with severe glaucoma. Glaucoma types were primary open-angle glaucoma (POAG) in 53 eyes (86.9%), neovascular glaucoma in two eyes (4.9%), glaucoma secondary to retina surgery in two eyes (3.3%), pseudoexfoliation in two eyes (3.3%), and angle-closure glaucoma in one eye (1.6%). A total of 37 eyes (60.7%) had not undergone any previous glaucoma procedures, and 91.8% of all patients were using glaucoma medications prior to MicroPulse TLT.

The mean IOP (mm Hg) at baseline and 12 months for each subgroup can be found in Table 3. The largest IOP reductions occurred on postoperative day 1, and mean IOP measurements did not rise above baseline over 12 months of follow-up (Fig. 1). All mean IOP reductions were statistically significant ($p < 0.008$) and ranged from 9.60 to 14.09 mm Hg across all groups, with the largest decrease occurring in group GV (Table 3). Percent IOP reductions ranged from 32.8 to 49.4% at 12 months and are displayed in Table 3. Qualified success and complete success were achieved in 83.6% and 75.4% of eyes, respectively. In eyes receiving 50-second applications of five, four, or three sweeps (GI, GII, and GIII), 70, 90, and 91% achieved qualified success, respectively; in eyes receiving 60-second applications of five, four, or three sweeps (GIV, GV, and GVI), 78, 82, and 90% achieved qualified success, respectively.

The mean number of glaucoma medications at baseline and 12 months for each subgroup is also displayed in Table 3. At 12 months, mean medication numbers were reduced to 1.9 ± 1.1

Table 2: Sociodemographics and baseline characteristics; 61 eyes of 40 patients were included in this study; age presented statistically significant differences between treatment groups ($p < 0.03$); mean baseline IOP did not present statistically significant differences between treatment groups

	Group I (n = 10)	*Group II (n = 10)*	*Group III (n = 11)*	*Group IV (n = 10)*	*Group V (n = 11)*	*Group VI (n = 10)*	*p-value*
Age, mean ± standard deviation (SD)	70.1 ± 8.3	63.1 ± 14.2	75.2 ± 6.8	72.9 ± 8.42	74.4 ± 7.24	74.4 ± 6.7	$p < 0.03$
Gender, male, *n* (%)	6 (60%)	5 (50%)	8 (72%)	4 (40%)	6 (54.5%)	5 (50%)	
Glaucoma severity, *n* (%)							
*Severe (*n* = 45)	8 (80%)	8 (80%)	8 (80%)	8 (88.8%)	8 (72%)	5 (50%)	
*Moderate (*n* = 14)	2 (20%)	2 (20%)	2 (20%)	1 (12.2%)	3 (27%)	4 (40%)	
*Mild (*n* = 1)	0	0	0	0	0	1 (10%)	
Ethnicity, *n* (%)							
*Caucasian (*n* = 55)	8 (80%)	9 (90%)	10 (90%)	7 (70%)	11 (100%)	10 (100%)	
*Black (*n* = 6)	2 (20%)	1 (10%)	1 (10%)	2 (20%)	0	0	
Baseline IOP, mean ± SD	29.3 ± 1.9	28.4 ± 7.07	29.1 ± 12.5	27.7 ± 6.3	23.9 ± 2.7	23.3 ± 5.4	$p < 0.20$
Diagnosis, *n*							
*POAG (*n* = 53)	10 (18%)	8 (15%)	7 (13%)	9 (16%)	11 (20%)	8 (15%)	
*Neovascularization (*n* = 2)	0	0	2 (100%)	0	0	0	
*Pseudoexfoliation (*n* = 2)	0	0	1 (50%)	0	0	1 (50%)	
*Secondary to retina surgery for retinal detachment (*n* = 1)	0	1 (100%)	0	0	0	0	
*Secondary to retina surgery for neovascularization (*n* = 1)	0	1 (100%)	0	0	0	0	
*Uveitis-neovascular glaucoma (*n* = 1)	0	0	1 (100%)	0	0	0	

Table 3: Mean IOP decrease and medication numbers in each treatment group at 12 months; IOP decreased from a range of 9.60 to 14.09 mm Hg across all groups. Medications decreased from a range of 0.20 to 1.00 in groups GIII, GV, and GVI

Subgroup	*GI*	*GII*	*GIII*	*GIV*	*GV*	*GVI*
Number of eyes, *n*	10	10	11	9	11	10
IOP, mm Hg						
Mean (SD) at baseline	29.30 (1.90)	28.40 (7.07)	29.09 (12.50)	27.67 (6.30)	23.91 (2.70)	23.30 (5.40)
Mean (SD) at 12 months	19.70 (4.14)	16.00 (2.98)	15.00 (4.19)	16.38 (5.76)	12.11 (1.17)	12.70 (1.87)
Change from baseline	−9.60	−12.40	−14.09	−11.29	−11.80	−10.60
Percentage decrease (%)	32.76	43.66	48.44	40.81	49.35	45.49
Significance (*p*)	<0.008	<0.008	<0.008	<0.008	<0.008	<0.008
Medications, *n*						
Mean (SD) at baseline	2.10 (0.90)	1.90 (0.90)	2.90 (1.10)	2.30 (0.80)	1.70 (1.20)	1.50 (1.50)
Mean (SD) at 12 months	2.50 (0.80)	2.00 (1.05)	1.90 (1.20)	2.50 (0.90)	1.30 (1.00)	1.30 (1.40)
Change from baseline	0.40	0.10	−1.00	0.20	−0.40	−0.20
Significance (*p*)	0.037	0.726	0.341	0.351	0.081	0.195

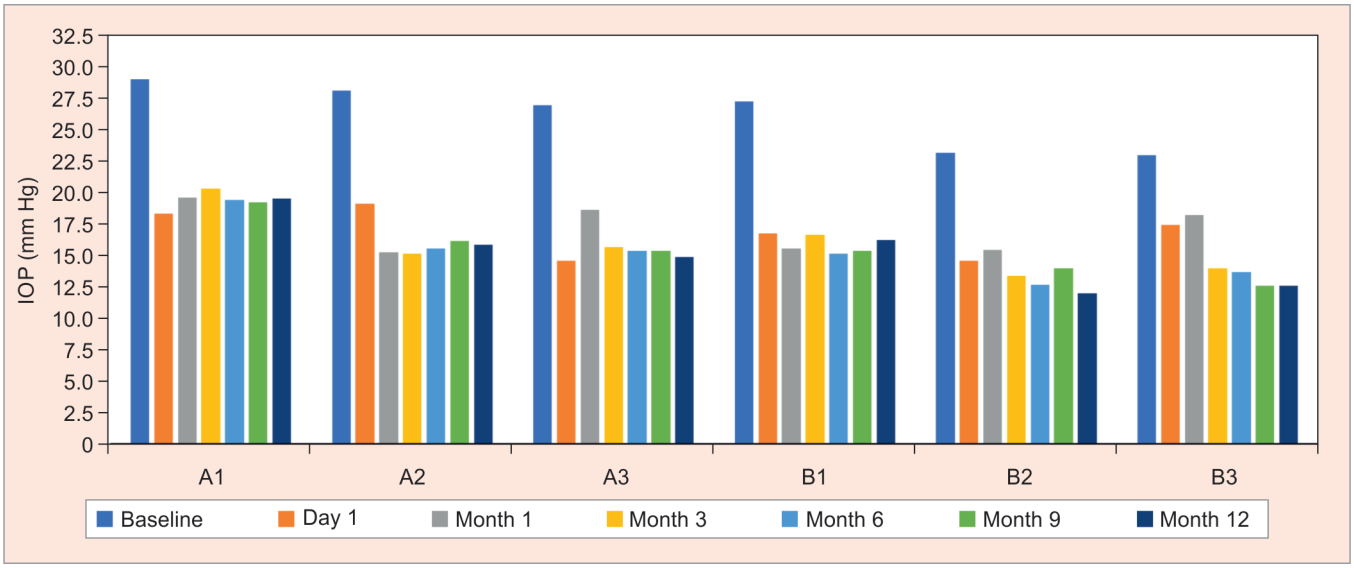

Fig. 1: Intraocular pressure (IOP) progression over 12-month follow-up; the mean IOP for each subgroup did not exceed baseline at any point in time

($p < 0.341$), 1.3 ± 1.0 ($p < 0.081$), and 1.3 ± 1.4 ($p < 0.195$) in groups GIII, GV, and GVI, but medication increases were experienced in all other treatment groups. Apart from subgroup GI, mean medication numbers at 12 months were not statistically significant.

Two eyes experienced a vision decrease of 2 lines or fewer in groups GI and GIII (combined with a rise in IOP of >21 mm Hg), both of which received surgical reinterventions. BCVA remained consistent in 43 eyes (70.5%) and improved in 16 eyes (26.2%). While no intraoperative or postoperative complications were reported, 10 eyes (16.4%) required a surgical reintervention to prevent glaucoma progression and were managed accordingly (Table 4). Failure occurred at least once in all groups, with the largest proportion of failures occurring in group GI (Table 4).

Discussion

MicroPulse TLT is a noninvasive glaucoma treatment that has been documented to be effective at reducing IOP and the total number of glaucoma medications used by patients.[15,16] The lack of publications reporting the efficacy of the revised MicroPulse P3 Probe led us to conduct this study. Our study exhibits that MicroPulse TLT performed with the Cyclo GVI laser and the revised MicroPulse P3 Probe can reduce IOP to <21 mm Hg and/or by at least 20% in glaucoma patients with various disease types and stages at 1 year postoperatively, although this reduction may be attributed to the observed increase in glaucoma medication in certain subgroups. Balendiran et al. treated 19 patients with POAG without a prior history of incisional glaucoma surgery randomized in two groups of 100 (total energy of 78.25 J) or 120 seconds (total energy of 93.9 J) with the revised P3 delivery device. At 6 months follow-up, they reported that the 120-second group had a mean IOP reduction of 37.8 ± 19.8%.[17]

Comparison of the revised MicroPulse P3 Probe to the original MicroPulse P3 probe is limited due to the wide range of treatment parameters employed. Additionally, the revised MicroPulse P3

Table 4: Management of failures; 10 eyes (16.4%) required surgical reinterventions; failure was observed across all groups, with the highest frequency occurring in GI

Group	*#Failures*	*Required surgical reintervention*
GI	3	Goniotomy w/iStent reposition (1); repeat MicroPulse TLT (2)
GII	1	Goniotomy w/iStent reposition
GIII	1	Ahmed ClearPath
GIV	2	XEN gel stent (1); declined (1)
GV	2	Congenital glaucoma (CE) w/goniotomy (1); XEN gel stent (1)
GVI	1	CE w/goniotomy

*CE, cataract extraction

probe is used at a power output of 2500 mW, in comparison to 2000 mW with the original probe. The efficiency of laser energy delivery between the two probe designs was not 1:1. While the original MicroPulse P3 Gaussian ball fiber tip was more efficient in energy delivery, it posed a significant safety risk while sweeping the delivery device on the conjunctiva. The revised MicroPulse P3 probe loses the efficiency of the Gaussian ball tip but removes the risk of conjunctival damage during the laser application; therefore, an increase in laser power was needed to "normalize" the loss of efficiency. Although the safety profile and IOP-lowering efficacy of this study appear to compare favorably to that of the original probe.[9,16–19] Direct comparison is limited due to different power outputs.[20,21]

Previous studies have stated that differing treatment durations and total energy while maintaining duty cycle and power constant during MicroPulse TLT may produce significantly different outcomes.[14,22,23] Sanchez et al. found that shorter durations of treatment result in fewer side effects and fewer hypotensive effects, while longer treatment durations have a tendency to increase complication rates, demonstrating a dose-effect relationship.[22,23] The authors also proposed that the ideal total energy level of MicroPulse TLT with the original probe falls near 150 J, with energy levels beyond this producing higher complication rates.[22,23] These findings are partially corroborated in our study, as participants subjected to 60 seconds of treatment experienced greater IOP reductions and fewer reinterventions compared to the 50-second cohort; however, vision-threatening complications were not experienced in either group. We assume that the lack of complications in our patients was due to the low total energy used in both groups (39 and 47 J). When compared to a higher energy setting of 112 J with the original MicroPulse P3 probe,[22–25] our study produced a comparably higher IOP-lowering efficacy and better safety profile, albeit with unfavorable medication results.

The lack of vision-threatening complications observed within our study is promising. Although slight BCVA decreases were observed in two eyes requiring surgical reinterventions, these findings are likely attributed to their glaucoma progression and not inherent to MicroPulse TLT. A history of multiple glaucoma procedures in the first subject and old age (78 years) in the second subject likely contributed as well. On the contrary, BCVA improvement was observed in one-quarter of the subjects. Failures were observed across all treatment groups and occurred more than once in groups GI, GIV, and GV. The average age of all subjects who experienced failure was 73.8 ± 7.6 years, which falls close to the study's initial average. This makes age an unlikely contributing factor to failure. Possible contributing factors to subject failures include treatment duration and sweep velocity.

Grippo et al. suggested a dose metric combining all treatment parameters, including power, time, total energy, and sweep velocity, to be a more accurate estimator of MicroPulse TLT treatment outcomes.[14] In this metric, fluence was found to covary with IOP reduction, with a sustained plateau occurring from 52.4 to 69.2 J/cm^2.[14] Our study evaluated fluence values between 75 and 151 J /cm^2 and a general inverse relationship between fluence and IOP was observed, although the comparison was limited by baseline characteristic differences among treatment groups. Nonetheless, fluence is a promising metric that may increase the precision of MicroPulse TLT outcomes and encourage the use of different sweep velocity and exposure duration parameters in future studies.

Limitations

Comparison between many subgroups ($n = 6$) is limited due to the small sample size of each group ($n = 10$).

Patients' baseline characteristics were not balanced at the time of the analysis, which limited the analysis of mean postoperative IOP.

The missing data handling method was not established prior to conducting the study. Therefore, caution is advised when interpreting estimated mean IOP reduction.

Conclusion

Overall, MicroPulse TLT using the Cyclo GVI and revised MicroPulse P3 Delivery Device is a safe and effective method for lowering IOP. The revised MicroPulse P3 Delivery Device appears to operate well under a comparatively lower energy range of 39 to 47 J due to its sleeker design that sits posteriorly over the pars plana. A general trend between IOP reduction and slower probe movements was observed. Prospective randomized control trials are needed to determine the effect of total treatment duration, sweep velocity, and number of sweeps or to evaluate discrete spot applications with MicroPulse TLT.

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