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Micropulse Cyclophotocoagulation Outcomes in Primary Open Angle Glaucoma

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Authors' contributions

This work was carried out in collaboration among all authors. Authors DD and RK designed the study. Author DD wrote the protocol, performed the statistical analysis, wrote the first draft of the manuscript, and managed the literature searches. All authors managed the analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Background: Micropulse cyclophotocoagulation (MPCPC) uses a pulsed application of laser energy to produce a more mild and predictable lowering of intraocular pressure (IOP) compared to traditional CPC with fewer adverse events. It is unclear if particular types of glaucoma are better suited for treatment with MPCPC. Primary open angle glaucoma (POAG) is a leading cause of visual disability in the world and is the most common form of glaucoma in the United States. A retrospective, observational clinical study was done in order to determine the efficacy and safety of MPCPC specifically for patients with POAG in an urban patient population at a tertiary referral academic medical center.
Methods: Patients with primary open angle glaucoma who underwent an MPCPC procedure and had never undergone previous cyclodestructive procedures were considered. Patients were followed for 6 consecutive months. IOP, number of topical glaucoma medications, and best corrected visual acuity (BCVA) were recorded prior to the laser procedure, and at follow-up intervals of 1, 3, and 6 months after the procedure. Procedural success was defined as a 20% reduction in IOP, with IOP between 6-21, and no need for subsequent glaucoma filtering surgery. A Wilxocon signed rank test was used to determine statistical significance.
Results: A total of 39 eyes in patients aged 28-82 with POAG that underwent MPCPC were included in the study. Mean baseline IOP was 22.9 mmHg, mean baseline number of drops was

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3.1, and mean baseline BCVA in LogMAR notation was 1.0. The MPCPC procedure produced a statistically significant decrease in IOP of 42.1% ($p<0.001$), 31.0% ($p<0.001$), and 34.0% ($p<0.001$) at 1, 3, and 6 months respectively. The number of required topical glaucoma drops was not significantly reduced at any of the three follow-up time points, but there was a modest trend towards requiring fewer drops. Patients met the criteria for procedural success at a rate of 74.4%.
Conclusions: Our results are consistent with the hypothesis that the MPCPC is safe and effective in lowering IOP in patients with POAG. Further research is needed to determine if MPCPC is equally safe and effective in other forms of glaucoma.

Keywords: Micropulse cyclophotocoagulation; primary open angle glaucoma; intraocular pressure.

1. INTRODUCTION

Glaucoma is the second leading cause of pathologic blindness and the most frequent cause of irreversible vision loss in the world [1-3]. People affected by permanent vision loss secondary to glaucoma often experience significant social challenges, financial burdens, and psychiatric illness. Low vision states lead to worsened mobility and an increased rate of falls in elderly populations [3-5]. Primary Open Angle Glaucoma (POAG) remains the most common form of glaucoma in the United States. Over 3 million people in the United States are estimated to be affected currently, and it is projected that over 7 million Americans will have POAG by 2050 [6-8]. First line therapy for POAG and other open angle glaucomas is topical IOP lowering eyedrops. Glaucoma that is not controlled with topical medications often undergo surgical treatments such as trabeculectomy and tube shunt procedures. These procedures carry significant risk such as endophthalmitis, hypotony, IOP spikes, and numerous bleb related complications [9-11]. In some patients a surgical filtering procedure is not effective enough to slow progression of optic neuropathy, especially in African Americans who experience higher rates of bleb failure after trabeculectomy thought to be from a more robust fibrosis response [12].

Numerous cyclodestructive procedures have been implemented in the past to treat these refractory cases. Cyclocryotherapy, cyclodiathermy, cycloelectrolysis, and continuous-wave cyclophotocoagulation have all been shown to effectively lower IOP via destruction of the ciliary body epithelium and a resulting decrease in aqueous humor production [13-17]. Although effective in lowering IOP, these procedures carry a significant risk of corneal decompensation, prolonged intraocular inflammation, cystoid macular edema, exudative retinal detachment, decreased best corrected visual acuity (BCVA), hypotony, and phthisis bulbi [16-19]. In contrast to conventional continuous-wave cyclophotocoagulation, micropulse cyclophotocoagulation (MPCPC) has been shown to reduce collateral thermal damage to ocular tissues and is associated with lower rates of adverse events [20-24]. Micropulse technology allows for fine control of thermal elevation by splitting the delivery of thermal energy into a series of short repetitive pulses, typically at a 31.3% duty cycle. This pulsed delivery of energy avoids excessive focal heating and burning of the ciliary processes [20-22,25]. Histologic analysis shows that traditional continuous-wave cyclophoto coagulation without micropulse causes focal burns on the ciliary body epithelium, causing a decrease in aqueous humor production [24,25]. MPCPC, however, does not seem to create these changes leaving the ciliary body epithelium histologically unaltered [25]. Postulated theories as to the IOP lowering mechanism of MPCPC include: 1. decreased aqueous production caused by ciliary body damage that is below the discernment threshold of histologic studies, 2. a reactive release of intraocular prostaglandins facilitating uveoscleral outflow, and 3. damage to the vascular supply of the ciliary body resulting in ischemia and resultant decreased aqueous humor production / ultrafiltration.

Multiple studies show that MPCPC is not only equally effective as traditional cyclodestructive procedures, but it also carries a significantly improved safety profile [20-24]. Early studies investigating MPCPC diode laser focused on treating refractory glaucoma: glaucoma that has progressed despite maximum medical and surgical treatment. As the safety profile of the MPCPC laser is further established in the literature, studies are shifting to determining which types of glaucoma and which patient characteristics may benefit from MPCPC prior to the development of severe disease [20,24]. Tekeli and Köse reported in the Eur J of Ophthalmology in March 2020 that MPCPC is effective in treating POAG, pseudoexfoliation glaucoma, and secondary glaucomas [26]. In

POAG patients, they reported a 68.8% success for obtaining IOP at goal. This study explores the safety and efficacy of MPCPC diode laser in treating POAG, specifically in an urban patient population evaluated and treated at a tertiary referral academic medical center. To accomplish this, a retrospective chart review was done that outlines a cohort of patients with POAG who underwent their first MPCPC procedure.

2. METHODS

A retrospective analysis was performed on patient data from the glaucoma services of Truman Medical Center/University Health at the University of Missouri - Kansas City (Kansas City, MO) from January of 2017 to January of 2020. Patients that were included in the study were at least 21 years old, carried a diagnosis of POAG at any severity stage, did not have a secondary cause of optic neuropathy, underwent an MPCPC procedure, had no previous cyclodestructive procedures in the study eye, were compliant with topical glaucoma medications, and had reliable follow-up and testing at clinic visits.

Primary open angle glaucoma patients were considered regardless of both disease severity and previous treatments including medications, lasers, and surgeries. The primary endpoints were IOP, BCVA, and number of topical glaucoma medications. These were recorded at one pre-procedure visit and three separate follow-up clinic visits at 1, 3, and 6 months post-procedure. Combination drops were counted as two separate glaucoma medications. Best corrected visual acuity was recorded in Snellen notation and converted to LogMAR. Any complications during the 6-month follow up time frame including hypotony, persistent intraocular inflammation, need for repeat MPCPC or subsequent filtering surgery were recorded. Procedure success was defined as 20% reduction in IOP, with IOP between 6-21, and no need for subsequent incisional glaucoma filtering surgery.

Each patient was personally evaluated by one of two senior faculty glaucoma sub-specialists. Anesthesia included a retrobulbar block (with 1:1 mixture of 3mL of 2% Lidocaine and 3mL of 0.5% Marcaine) at the beginning of the case. Baseline heart rate and blood pressure measurements were measured before and after the procedure. 810 nm diode laser treatment was administered using the Cyclo G6 probe by Iridex technologies (Iris Medical Instruments, Mountainview, CA, USA) to the perilimbal area of the eye at a 31.3% duty cycle. Parameters such as power, duration, and clock hours treated varied slightly depending on any previous filtering surgery sites, which were avoided in the application of diode laser. The average power used was 2391.7 mW and the average total treatment time was 173.9 seconds. 10 second sweep duration was used per full hemisphere (180 degrees) of treatment. Topical administration of cyclogyl and erythromycin ophthalmic ointment were placed at the termination of each MPCPC.

A non-parametric test, Wilcoxon signed rank test, was used to analyze the results. To adjust for multiple comparisons at the three post-procedure time points a Bonferroni correction was applied. The adjusted alpha level used to determine significance was 0.017.

3. RESULTS

3.1 Patient Characteristics and Clinic Visits

67 patients met the inclusion criteria of being at least 21 years old, having a diagnosis of POAG, and having undergone a cyclophotocoagulation procedure between January 2017 and January 2020. 20 eyes were excluded due to poor eyedrop compliance, inadequate pre-procedural data, and inadequate follow-up clinical visits. 8 eyes were excluded due to having a prior cyclodestructive procedure. 39 eyes from 35 patients were included in the final statistical analysis. Included patients were between the ages of 28 and 82, with an average age of 59.5 years old. 48.7% of eyes were from male patients, 51.3% female. 61.3% of patients were African or African-American, 25.6% of patients were Caucasian, 5.1% were Hispanic/Latino, 5.1% were Middle Eastern, and 2.6% Asian. 76.9% of patients had prior filtering surgery on the studied eye. Table 1. summarizes the patient characteristics for patients included in this study.

3.2 Primary Endpoints: Intraocular Pressure, Number of Topical Glaucoma Medications and BCVA

The average pre-procedural IOP was 22.9 +/- 7.6. There was a statistically significant reduction in IOP compared to the pre-procedural IOP at all 3 post-procedure follow-up visits. At one month

the mean percent IOP reduction was 42.1% (mean: 13.27 +/- 5.6, p-value: < 0.001). At 3 months the mean IOP percent reduction was 31.0% (mean: 15.81 +/- 5.3, p-value: < 0.001). At 6 months the mean IOP percent reduction was 34.0% (mean: 15.13 +/- 5.9, p-value: <0.001). All of these p-values were less than the adjusted p-value of 0.017.

Table 1. Study patient demographics

Variable	Data (n = 39)
Age (years)	Range: 28-82
Gender	
Male (48.7%)	19
Female (51.3%)	20
Race	
African-American (61.5%)	24
Caucasian (25.6%)	10
Hispanic (5.1%)	2
Middle-Eastern (2.6%)	2
Hispanic (2.6%)	1

The mean number of topical glaucoma medications at baseline was 3.13 +/- 1.0. There was no significant difference in the mean number of topical glaucoma medications used at the 1, 3, and 6-month follow up appointments. The average number of glaucoma drops at 1, 3, and 6 months respectively were 3.24 +/- 0.9 (p-value: 0.41), 3.09 +/- 1.0 (p-value: 0.40), and 2.81+/- 1.5 (p-value: 0.03). There was an overall trend towards requiring fewer topical glaucoma medications, from 3.1 at baseline to 2.8 at 6 months but this was not a significant difference.

Average baseline LogMAR was 1.00 +/- 0.8. There was a statistically significant decrease in BCVA at all three post-operative follow-up visits. At 1 month the mean LogMAR was 1.09 +/- 0.8 (p-value: 0.015). At 3 months the mean LogMAR was 1.24 +/- 0.9 (p-value: 0.007). At 6 months the mean LogMAR was 1.08 +/- 0.8 (p-value: 0.003) Table 2. summarizes the results and analysis for all three primary endpoints: IOP, number of topical medications, and visual acuity. Figs. 1-3 display the changes in these primary endpoints over time.

3.3 Treatment Success Rate

This study defines treatment success as 20% reduction in IOP, with IOP between 6-21, and no need for subsequent incisional glaucoma filtering surgery. The overall treatment success rate in this study was 74.4%. 10 of 39 MPCPC procedures did not meet the above definition of success for the following reasons. Six eyes in the study did not reach a stable IOP under 21 after the MPCPC. One of these eyes required subsequent filtering surgery, and one additional eye underwent subsequent filtering surgery with an IOP at goal (16). Three eyes did not reduce the IOP by at least 20%. There were no cases of hypotony. Table 3. summarizes the causes of treatment failure and further discussion on treatment failures can be found below.

Table 2. Complete Results Summary of all three primay endpoints: IOP, number of topical medications, and visual acuity at 1, 3 and 6 months

Variable	Mean	Standard Deviation	Absolute reduction from baseline	Percent reduction from baseline	P-Value (compared to baseline)
Intraocular Pressure (IOP), mmHg					
IOP baseline	22.92	7.58	NA	NA	NA
IOP 1 month	13.27	5.59	9.65	42.11 %	< 0.001*
IOP 3 months	15.81	5.28	7.11	31.02 %	< 0.001*
IOP 6 months	15.13	5.87	7.80	34.02 %	< 0.001*
Number of Topical Glaucoma Drops					
# of meds baseline	3.13	0.98	NA	NA	NA
# of meds 1 month	3.24	0.89	-0.12	-3.68 %	0.414
# of meds 3 months	3.09	0.96	0.03	1.10 %	0.395
# of meds 6 months	2.81	1.15	0.32	10.09 %	0.032
Best Corrected Visual Acuity (BVCA), LogMAR Notation					
LogMAR baseline	1.00	0.83	NA	NA	NA
LogMAR 1 month	1.09	0.81	-0.09	-9.17 %	0.015*
LogMAR 3 months	1.24	0.92	-0.24	-24.07 %	0.007*
LogMAR 6 months	1.08	0.81	-0.08	-7.78 %	0.003

** indicates statistical significance*

Table 3. Breakdown of causes of treatment failure

Cause of Treatment Failure	
IOP > 21 (No Subsequent Filtering Surgery)	5
IOP >21 AND Subsequent Filtering Surgery	1
Subsequent Filtering Surgery with IOP 6-21	1
IOP Reduction < 20%, IOP between 6-21	3
Hypotony	0
Total	10
Treatment Failure Percentage	25.6% (10 of 39 eyes)

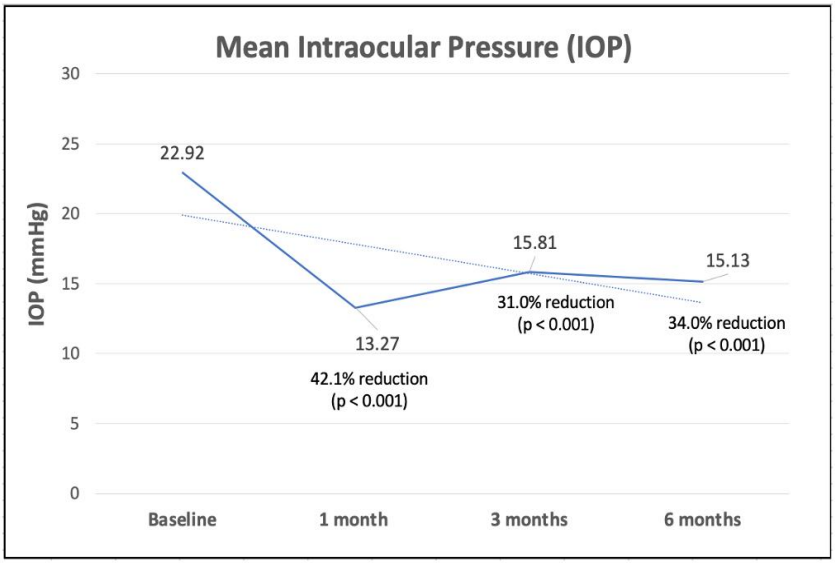

Fig. 1. Average intraocular pressure over time at 1, 3 and 6 months after micropulse cyclophotocoagulation

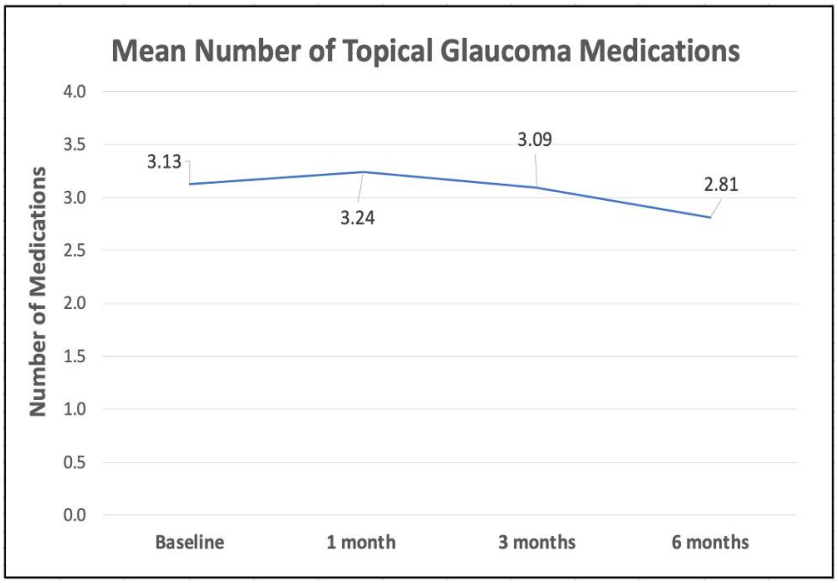

Fig. 2. Average number of required topical glaucoma medications over time at 1, 3, and 6 months after micropulse cyclophotocoagulation

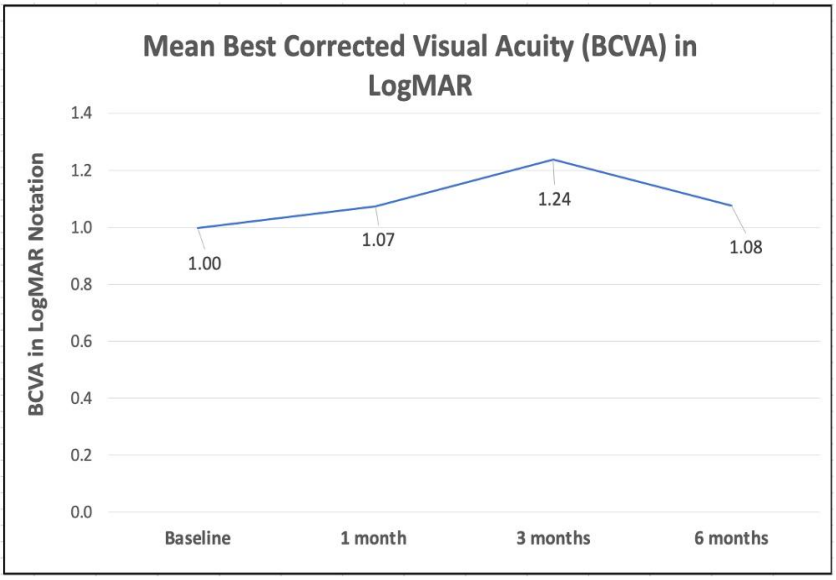

Fig. 3. Average visual acuity over time at 1, 3 and 6 months after micropulse cyclophotocoagulation

4. DISCUSSION

This study was conducted through Truman Medical Center, a county hospital and tertiary care facility located center in Kansas City, MO. The patient population in this study was primarily African American (61.5%). Thirty of 39 eyes (76.9%) in this study had prior trabeculectomy or tube shunt procedures and required further IOP lowering to stave off further progression of optic neuropathy. Most MPCPC studies in the literature have primarily focused on treating end-stage and refractory glaucomas. This study is similar in that the majority of patients had refractory disease, however, there is a paucity of studies regarding the efficacy of MPCPC in different types of glaucoma. In order to evaluate this clinical question, this study looks only at patients with POAG. There is one study to these authors' knowledge that has broken down the efficacy of MPCPC in different types of open angle glaucomas. Tekeli and Köse reported in the Eur J of Ophthalmology in March 2020 that MPCPC is effective in treating POAG, pseudoexfoliation glaucoma, and secondary glaucomas [26]. In POAG patients, they reported a 68.75% success for obtaining IOP at goal: IOP ≤18 with 20% IOP reduction.

In this patient population MPCPC diode laser was effective at lowering IOP in patients with POAG. The IOP lowering effect was 42.1% ($p<0.001$), 31.0% ($p<0.001$), and 34.0% ($p<0.001$) at the 1, 3, and 6-month follow up periods respectively. The definition of success used in this study was based on credible MPCPC studies in the medical literature: IOP between 6-21, 20% IOP reduction, and no future filtering surgery required [22-23]. The overall treatment success rate was 74.4%. These results are consistent with the hypothesis that the MPCPC is an effective treatment for POAG.

There were various reasons accounting for the 10 (25.6%) of MPCPC treatments that did not meet the definition of treatment success. Six eyes did not reach an IOP < 21. One of these eyes required subsequent filtering surgery, four were treated with additional MPCPC procedures, and one was treated with topical medication only. Out of the 4 eyes that received repeat MPCPC procedures, 3 of the repeat procedures resulted in an adequate IOP. This indicates that repeated MPCPC is tolerable and beneficial, and need for a repeat procedure is not uncommon. One eye in the study underwent subsequent filtering surgery even with IOP at goal (16) because the follow-up testing revealed further progressive glaucomatous damage. Both eyes that required incisional filtering surgery received Ahmed glaucoma implants. Three eyes were also counted as treatment failure due to IOP lowering less than the desired 20%, but all three of these eyes had IOP between 6-21.

The overall rate of adverse events was low. There were no cases of iatrogenic corneal decompensation, prolonged intraocular

inflammation, cystoid macular edema, exudative retinal detachments, or hypotony. Only minor side effects were noted such as conjunctival injection, subconjunctival hemorrhage, and anterior chamber inflammation. These minor complications were only seen at the 1-week and 1-month post-procedure follow-up appointments; they were all resolved by the 3-month follow up appointment.

This study does show a decrease in BCVA vision over the 6 months after MPCPC, but this is in large part to a small number of outliers in the data set. Only 3 of 39 patients had an increase in LogMAR of 0.5 or greater at the 6-month follow-up appointment. The pre-procedure and the 6-month mean BCVAs in LogMAR are 1.00 and 1.08 respectively. When converted to Snellen acuity this is equivalent to 20/200 pre-procedure, and 20/240 6-month post-procedural BCVA. Although this reported decrease in BCVA is statistically significant, it may not be clinically significant in many patients. 76.9% of eyes in this study have had previous filtering procedures with subsequent disease progression and inadequate IOP control. This suggests the study patient population had a significant glaucomatous disease burden pre-procedure. Most patients in this study also had comorbid ocular conditions including cataracts, corneal opacities, ocular surface disease, and diabetic retinopathy.

One outlier of note had a pre-procedure BCVA of 20/200 (LogMAR 1.0) and at 6 months post-procedure had BCVA of hand motion (LogMAR 2.2). This is a difference of 1.2 in LogMAR notation, which is certainly an outlier compared to the 0.08 average difference in LogMAR seen at 6 months post-procedure. Additionally, one year after the procedure (six months after the final post-procedure follow-up visit) this patient's vision was back to his baseline of 20/200 vision. This patient's poor vision at the 6-month follow up visit was due to significant ocular surface disease, which improved with treatment. This highlights the significant ocular comorbidities and resulting visual acuity fluctuation in our patient population. These comorbidities certainly contributed, at least partially, to the decrease in visual acuity seen in our study.

There was not a significant reduction in the number of glaucoma medications at all 3 follow-up time points, however, the amount of topical medications required did trend downwards. At the pre-procedure clinic visit the average number of topical eyedrops was 3.13, and at the 6-month follow up visit the average number of drops was 2.81. This measure shows both that MPCPC may decrease the burden of drop administration for some patients, and that the significant IOP lowering effect of MPCPC was not confounded by topical medications.

The main limitation of this study was a small sample size. The sample size was affected greatly by poor follow-up in clinic over the 6-month post-procedure study window. Limiting the study to POAG patients also decreased the sample size, as many MPCPCs in our clinic are done for other glaucoma diagnoses including neovascular, traumatic, and other secondary glaucomas. Another limitation was the short follow up time period of 6 months. Longer term studies regarding MPCPC show that it has a waning effect over time [27]. Other limitations include variable severity of glaucoma among patients, variable treatment parameters used, and influence of outside confounders such as ocular comorbidities on IOP and BCVA measurements. The sample size could be increased in future studies with improved patient follow-up, multi-center trials, or longer-term trials.

5. CONCLUSION

Many studies have demonstrated that MPCPC is effective in treating refractory glaucomas, however, these studies did not differentiate the underlying glaucoma diagnoses [20-24]. This study shows that MPCPC is an effective means of lowering IOP in patients with POAG. This study is consistent with the medical literature in that MPCPC has a good safety profile. Adverse events were few, mild, and lasted for a short duration in a primarily African American patient population (62.5%), who tend to have more robust inflammatory responses with both cyclodestructive and filtering procedures [12,28]. Additional studies are needed to investigate MPCPC efficacy in other specific types of glaucoma, patient and disease traits that will benefit most from treatment, the precise mechanism of MPCPC, and optimization of treatment parameters. Such work may help practitioners safely lower IOP with this non-invasive technique and ultimately improve long-term outcomes for patients with glaucoma.

CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline patients' consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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