

Outcomes of Micro Pulse Transscleral Diode Laser Cyclophotocoagulation in Refractory Glaucoma

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ABSTRACT

Purpose: To evaluate the outcomes of Micro Pulse Transscleral Diode Laser cyclophotocoagulation (MP – TSCPC) in terms of surgical success and safety in various types of refractory glaucoma.

Study Design: Interventional case series.

Place and Duration of Study: Ophthalmology department of Rawalpindi Medical University and Allied hospitals from June 2021 to December 2022.

Methods: Sixty eyes of 59 patients with refractory glaucoma underwent MP – TSCPC with A.R.C Fox portable diode laser. Fox Micro cyclo probe delivered 2000 mW for 80 – 84 seconds for each 180 – degree arc 3 mm from the limbus. The duty cycle was 31.3% with 0.5 ms on time and 1.1 ms off time. Best-corrected visual acuity and intraocular pressure were documented pre-laser as a baseline and post-laser at one week and then at 1, 3, and 6 months. Intraoperative and post-laser complications were also noted.

Results: A significant reduction in IOP from baseline was seen at each follow-up. The mean pre-laser and post-laser Best corrected visual acuity was 0.06 ± 0.17 Snellen decimal. Nine eyes had early mild post-laser inflammation, 3 eyes had early hypotony and tonic pupil, and 2 eyes had IOP spike while corneal edema and hyphaema were seen in 1 eye each. Treatment success was seen in 51 (85%) patients at 3 months and 48 (80%) patients at 6 months. Use of antiglaucoma medications decreased from 3.85 ± 0.10 to 1.07 ± 0.16 which was statistically significant ($p = 0.000$).

Conclusion: MP – TSCPC is a safe, effective, and noninvasive method of treatment for refractory glaucoma leading to both persistent reductions of intraocular pressure and decreased need for topical anti-glaucoma medications without significant intraoperative and post-laser complications.

Key Words: Refractory Glaucoma, Optic Neuropathy, Intraocular Pressure, Micro Pulse Transscleral Diode Laser, Cyclo photocoagulation.

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INTRODUCTION

One of the primary causes of irreversible visual loss and the second leading cause of blindness is Glaucoma.¹ Worldwide 4.5 million of the population is legally blind due to glaucoma.^{1,2} It is defined as

progressive optic neuropathy along with elevated intraocular pressure and typical visual field loss.³ The only modifiable factor in the treatment of glaucoma is intraocular pressure. Therefore, intraocular pressure control is vital in the treatment of glaucoma to delay progression.³ Reduction of intraocular pressure can be achieved by medical therapy, laser and filtration procedures.⁴ Medical treatment of glaucoma is the first line of therapy but it has topical side effects of allergic conjunctivitis and ocular surface disease. Patient compliance and financial constraints can lead to poor response to medical treatment. Tachyphylaxis is another reported phenomenon leading to reduced

efficacy of topical antiglaucoma medications.⁵ In advanced glaucoma; progressive optic nerve damage demands filtration procedures for IOP control to preserve residual visual and optic nerve function. Glaucoma surgeries have a positive role in IOP control but bleb-related complications along with endophthalmitis and hypotony risk can compromise long term outcomes.⁶ Glaucoma drainage devices are of concern but may have serious complications. In contrast to filtration procedures, Laser treatment works by decreasing the production of aqueous humor by photoablation of the ciliary body.⁷

Refractory glaucoma is a complex form of glaucoma with progressive optic nerve damage together with deterioration of visual fields due to uncontrolled intraocular pressure even with maximum medical treatment or failed previous conventional glaucoma surgery.⁸ All glaucoma can become refractory to treatment with time but particularly primary angle closure, neovascular, inflammatory, and post-vitreotomy glaucoma are refractory. For eyes with poor visual potential and refractory glaucoma, a cyclo-destructive procedure is done to lower intraocular pressure and relieve ocular pain.^{7,8} An established and effective method for the treatment of refractory glaucoma is Transscleral cyclophotocoagulation (TSCPC).⁹ Two methods of TSCPC exist, the traditional Continuous-Wave CW-TSCPC and the recent Micro-Pulse MP-TSCPC.¹⁰ Conventional CW-TSCPC decrease intraocular pressure by destruction of pigmented ciliary epithelium as well as non-pigmented layer indirectly and by increasing uveo-scleral outflow. Significant collateral damage can cause potential complications such as hypotony, phthisis bulbi, persistent inflammation, hyphaema, choroidal detachment, visual loss, and sympathetic ophthalmia.¹¹ Consequently, conventional CW-TSCPC is held in reserve for eyes with advanced glaucoma and poor visual potential.^{10,11}

Micropulse technology is an alternative potentially safer approach, developed in recent years. Micro-pulse technology splits a continuous laser beam into shorter-on pulses trailed by longer off phases which are repetitive and allow the cooling down of tissue between bursts. Thus alleviating cumulative thermal build-up and reducing the extent of tissue damage.^{11,12} Hypotony is the main risk factor for cyclo diode therapy.¹³ The rate of hypotony is influenced by energy applied at each laser session rather than the total amount of energy delivered or the number of

applications used.¹¹⁻¹³ Micro-pulse delivers a laser beam by breaking it into a train of pulses with an 'on time' and an 'off time' therefore eliminating focal heating and burning of the tissues.¹³ Due to intermittent off period, the tissue inflammation and destruction is minimum or not at all, consequently no added vision loss results. MP-TSCPC can be used in refractory glaucoma eyes with good visual potential.

Micro-pulse diode laser is an effective method to lower IOP and reduce the number of medications in numerous types of refractory glaucoma but with a variable safety index as shown by some studies.¹⁰⁻¹³ There is little local evidence regarding results of this novel technique. Considering socioeconomic, genetic, and racial differences in our population, the current study was designed to evaluate outcomes in terms of safety and surgical success of Micropulse trans scleral diode laser photocoagulation in various types of refractory glaucoma for 6 months (intermediate-term) follow-up period.

METHODS

Prospective interventional case series of 18 months duration was conducted from June 2021 to December 2022 at the Ophthalmology department of RMU & Allied Hospital. Keeping level of confidence at 95% and margin of error of 6.4%, the expected proportion of population with glaucoma worldwide is 4.5 million.² The minimum sample size calculated for the study was 59 by WHO sample size calculator for descriptive case series. Sampling technique was non-probability consecutive sampling. Sixty eyes of 59 outdoor or indoor patients presenting with refractory glaucoma that could not be effectively treated with maximum tolerated topical or systemic antiglaucoma medication, failed or high risk of failure of previous conventional filtration, or shunt procedure or combined medical and surgical treatment were enrolled. Before enrollment, we informed all patients about non-incisional MP-TSCPC, incisional surgery, and related risks. Only those patients who selected MP-TSCPC were enrolled. We excluded patients with previous intraocular surgery in the last 2 months, any active ocular infection or inflammation, scleral thinning over 1 clock hour, or non-compliant to laser and unable to give follow-up. After approval from the institutional ethical review board, the study followed tenants of the Helsinki declaration, and we took informed written consent from all the patients. The

procedure and its possible side effects were explained to patients in detail.

All patients underwent detailed ophthalmological examinations. Best corrected visual acuity was measured via Snellen chart and converted into decimal notation. Intraocular pressure was measured in millimeters of mercury (mmHg) via a Goldmann applanation tonometer. Dilated fundus evaluation was done through a 90 D lens via slit lamp biomicroscope to document glaucomatous optic neuropathy and cup disc ratio. Visual fields 24 – 2 and Optic nerve head OCT details were also documented.

The statistical analysis was done using IBM SPSS version 21 for Windows. The normality of the data was calculated using the Shapiro–Wilk test. Categorical variables were analyzed and expressed as percentages and frequencies. Quantitative variables were expressed as mean \pm SD. The preoperative and postoperative IOP and BCVA at 6 months were compared by parametric test (paired t-test). Post-operative IOP at successive follow-ups at 1 week, 1 month, 3 and 6 months were compared by repetitive measure ANOVA test. Mean number of glaucoma medications pre-operatively and post-operatively was compared with paired t-test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Mean age of patients was 52.93 ± 17.79 SD (range 3 – 80) years. There were 39 (65%) males and 21 (35%) females. Among types of refractory glaucoma, neovascular glaucoma was the most frequent in 26 (43.3%) eyes followed by primary open-angle glaucoma seen in 16 (26.7%) eyes. Other less frequently seen glaucomas were inflammatory, silicon-oil induced in 5 (8.3%) eyes each, primary angle-closure, and primary congenital glaucoma in 4 (6.7%) eyes each. Forty four (73.3%) eyes had no previous surgical intervention for glaucoma while trabeculectomy was done in 9 (15%), YA Giridotomy in 6 (10%), and Ahmad valve implantation in 1 (1.7%) eye.

Mean pre-laser IOP was 32.90 ± 6.47 mmHg (range 24 – 49). Mean post-laser IOP was 16.48 ± 7.69 in 1st week (49.9% reduction), 17.20 ± 6.33 (47.7% reduction) in 1st month, 18.13 ± 5.78 (44.8% reduction) at 3 months and 19.23 ± 5.13 (41% reduction) at 6 months ($P = 0.000$). One-way repeated measure ANOVA test showed a significant reduction

in IOP from baseline IOP at each consecutive follow-up with Wilk's lambda value of 0.169 ($F = 93.35$), partial eta squared value of 0.831, and p-value of < 0.001 which was highly significant. Figure 1 is showing a line plot of mean IOP pre-laser and post-laser at different follow-up intervals.

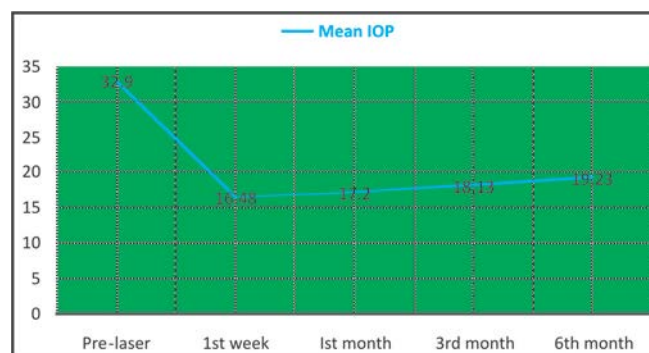


Figure 1: Mean IOP Pre-Laser and Post-Laser.

We had 56.7% functional eyes with useful visual potential. The mean pre-laser and the mean post-laser BCVA was 0.06 ± 0.17 Snellen's decimal. BCVA was preserved in all patients (100%) with no complete loss of vision in any eye. Hence, BCVA was stable in 6 month follow-up period.

Pre-laser 14 (23.3%) eyes were on oral therapy with a quadruple topical antiglaucoma regimen, and 23 (38.3%) eyes were on a quadruple and triple antiglaucoma regimen each. Post-laser 32 (53.3%) eyes were using no medications, 5 (8.3%) eyes were single, 13 (21.7%) eyes double, 7 (11.7%) eyes triple, and 3 (5.0%) eyes were on a quadruple regimen. The number of antiglaucoma medications decreased significantly during 6 month's follow-up period. The mean antiglaucoma medications decreased from 3.85 ± 0.10 to 1.07 ± 0.16 at 6 months which was statistically significant ($p = 0.000$). The use of systemic antiglaucoma medications like oral acetazolamide was discontinued in all 14 patients at 1 month post-laser.

Surgical success was seen in 51 (85%) eyes at 3 months and 48 (80%) eyes at 6 months. Retreatment was needed in 12 (20%) eyes at 6 month follow-up period. Treatment was successful in all cases (100%) of primary open-angle, angle-closure, and primary congenital glaucoma while success was seen in 80% of neovascular glaucomas and 60% of silicon oil-induced and inflammatory glaucomas.

No serious post-laser complications were noted in the follow-up period. The mean intraoperative pain

scoring by visual analogue scale (VAS) was 3.58 ± 1.92 SD (range 0 – 8). It is a painful procedure so it should be performed with local/regional anesthesia.

Forty one (68.3%) eyes had no intraoperative complications while 19 (31.7%) eyes had conjunctival chemosis or congestion which was treated with antibiotic-steroid drops post-laser. Forty one (68.3%) eyes had no post-laser complications. Nine (15%) eyes had mild early post-laser inflammation, 3 (5%) eyes had early hypotony and tonic pupil each, 2 (3.3%) eyes had IOP spike, while corneal edema and hyphaema were seen in 1 (1.7%) eye each. Post-laser anterior chamber inflammation was mild and it was controlled with post-laser topical steroids. Early hypotony also responded to topical and periocular steroids. Hence, persistent hypotony was not seen in any eye. IOP spike was controlled with antiglaucoma medications and post-laser topical steroids were tapered in 2-3 weeks to cater steroid responsiveness. Corneal edema resolved in 1-week post-laser with topical steroids. Hyphaema was seen in the neovascular glaucoma eye and it resolved in 3 weeks post-laser with cycloplegics and topical steroids. No case of phthisis bulbi, macular edema, scleral complication, or sympathetic ophthalmia was noted.

DISCUSSION

Management of elevated intraocular pressure in refractory glaucoma is a challenge for practitioners.⁹ CW-TSCPC is reserved for eyes with minimal or no visual potential with refractory glaucoma to alleviate ocular pain and control IOP because of its postoperative complications like inflammation and hypotony.¹⁰ Recently, micropulse TSCPC has been projected for refractory glaucoma eyes with good visual acuity. It causes local tissue remodeling.¹¹

Three mechanisms are proposed for MP-TSCPC; first by targeting the melanin pigment in ciliary epithelium resulting in decreased production of aqueous humor, second by an increase in the drainage of aqueous humor via uveoscleral pathway, and third by acting on longitudinal fibers of ciliary muscle. It causes modification of trabecular meshwork and outflow tract of aqueous humor by displacing scleral spur posteriorly and inwards.^{12,13} In our current study involving patients with advanced refractory glaucoma, MP – TSCPC was effective and safe with a success rate of 85% at 3 months which decreased to 80% at the 6-month follow-up. A statistically significant decrease

in IOP and the number of antiglaucoma medications was noted with the preservation of BCVA in functional eyes. No major side effects were noted.

Mohsen et al, described a success rate of 53.2% at 6 months with a smaller number of patients.¹⁴ Yelenskiy et al, demonstrated a success of 71% at 12 months.¹⁵ Issiaka et al, stated a success rate of 79.5% at 3 – month follow-up.¹⁶ William et al, had a success rate ranging between 66.1% and 74.7%.¹⁷ Aquino et al, had a comparative study with a success rate of 75% at a 12-month follow-up.¹⁸ Another study showed a success rate of 81.4% at 6 months and 73.3% at a 12 – month follow-up period.¹⁹ Our study had a comparable success rate of 85% at 3 months and 80% at 6 months to Yelenskiy, Aquino, Karen and William et al, with a comparable sample size. The differences in success rates can be explained by different laser parameters with variable treatment durations and possibly by different definitions of success in each study.^{12,13} Due to the progressive drop of patients till 12 months follow-up, the long-term success rate cannot be identified. These results demonstrate good intermediate-term efficacy of MP-TSCPC.

Our study showed a statistically significant decrease in intraocular pressure ranging from 49.9% in 1st week, 47% at 1 month, and 41% reduction at 6 months. Karen et al, showed a reduction range of 15.9% to 44.0% which was comparable to our results.¹⁹ Emanuel et al, reported a reduction rate of 41.2% at a 1 – month follow-up comparable to our results with a mean IOP of 16.3 mmHg versus 17.20 mmHg in our study.²⁰ Tan et al, reported a lower reduction rate of 31.7% in 1 month as they used a 100-sec treatment duration.²¹

Besides IOP reduction, a significant decrease in the number of both topical and oral antiglaucoma medications was seen from 3.85 to 1.07 at 6 months follow-up. Karen et al, reported a decrease in topical medications from 3.53 to 3.11 and oral from 0.72 to 0.27 at the 6-month follow-up. As more than 50 percent of patients were using oral tablets in this study and only 30.8% needed tablets at 9 months that's why the number of topical antiglaucoma medications did not decrease as significantly as in our stud.¹⁹ Emanuel reported a decrease from 3.3 to 1.9 at the 1 – month follow-up comparable to our study.²⁰ Issiaka et al, reported discontinuation of oral acetazolamide in all patients after 1 month similar to our study and a 50% decrease in the number of medications (from 2.0 to 1.2) at 9 months¹⁶.

No major complications were noted such as phthisis bulbi, persistent hypotony, sympathetic ophthalmia, or macular edema. Hyphaema was seen in 1 patient of neovascular glaucoma with poor visual potential. Hyphaema was also reported in the literature in eyes of neovascular glaucoma and chronic persistent uveitis.²² These results were comparable to Karen et al, study¹⁹ except for a decrease in CDVA which was seen due to early post-op inflammation. As mild early post-op inflammation was also seen in 9(15%) patients but it was not associated with any decrease in BCVA. Our population was non-white races so genetic and racial differences can explain this. The complications rate described by Williams et al, was higher with post-operative inflammation for ≥ 3 months in 21 patients, hypotony in 7, phthisis bulbi in 2, and CDVA decrease of ≥ 2 lines in 13 patients.¹⁷ Emanuel et al, had prolonged post-op inflammation in 46% and CDVA decrease of ≥ 2 lines in 26% of patients. This could be due to differences in treatment protocols and durations.²⁰ Emanuel et al, used an average treatment duration of 300sec(range of 120 – 360) while William et al, used 319 sec(range of 180 – 360). Karen et al,¹⁹ and Issiaka et al,¹⁶ used a fixed duration of 180 sec analogous to our study and achieved comparable IOP lowering and post-laser complication rates to our study. They had 2 cases of macular edema, not seen in our study and post-op inflammation was seen in 4% of patients which resolved in 7 days. Tan et al,²¹ and Aquino et al,¹⁸ used a treatment duration of 100 sec for all patients and they had slightly lower IOP reductions. They both included patients with visual acuity of 6/60 or worse.^{18,21} Karen et al, had a mean CDVA of 0.86 by log MAR (a range of 0 – 2.1).¹⁹ Our study also had a broad range of visual acuity with a mean of 0.06 (4/60) (a range of 0.01 to 1.00) snellen's decimal (1/60 to 6/6) and 56.7% of eyes had useful visual potential with stabilization of BCVA in all patients. Issiaka et al, reported 1/3rd of patients with non-visual potential pre-treatment and visual gain of 2 lines in 50% of patients.¹⁶

In our study, 73% had no previous glaucoma surgical or laser intervention, and only 15% had prior glaucoma incisional surgery, the success rate in these eyes was comparable to eyes with no prior incisional surgery. Karen et al, also reported comparable success rates in both glaucoma surgery and non-surgical patients.¹⁹ Hence, this procedure can be done in eyes with failed glaucoma surgeries or patients with advanced glaucoma and limited options and fearing complications.

To summarize our findings, types of refractory glaucoma more sensitive to MP-TSCPC were primary-open angle, angle closure, congenital (100%), and neovascular glaucoma (80%). Less sensitive were inflammatory, silicon oil-induced, and steroid-induced glaucoma. Our findings are consistent with Issiaka et al, study success rates in different types of glaucoma.¹⁶ This can be explained on basis of different mechanisms of MP-TSCPC in intraocular pressure reduction.

Several treatment protocols are mentioned in the literature.^{23,24} Literature shows higher the treatment energy and the longer the duration of treatment, the better control or reduction of intraocular pressure is achieved. It also depends on preoperative intraocular pressure but a longer duration of 300 or more seconds can be associated with more complications.²³

Our limitations are a small sample size with intermediate-term follow-up and absence of control group. More studies with larger sample sizes and long-term follow-ups to establish the long-standing longevity of this laser need to be conducted.

CONCLUSION

Novel non-invasive MP-TSCPC is a safe and effective technique for IOP reduction and a decrease in the number of topical and oral antiglaucoma medications without significant intraoperative and postoperative complications.

Conflict of Interest

Authors declared no conflict of interest.

Ethical Approval

The study was approved by the Institutional review board/Ethical review board (**147/IREF/RMU/2021**).

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Authors' Designation and contribution

Ambreen Gul; Assistant Professor: *Concepts, Design, Literature search, Data acquisition, Data analysis, Statistical analysis, Manuscript*

preparation, Manuscript editing, Manuscript review.

Saira Banmo; Senior Registrar: *Concepts, Design, Data acquisition, Manuscript review.*

Raffaq Saleem; Postgraduate Resident: *Concepts, Design, Data acquisition*

Fuad Ahmad Khan Niazi; Professor: *Concepts, Design, Manuscript preparation, Manuscript editing, Manuscript review.*

