The effectiveness and safety of micropulse transscleral cyclodiode photocoagulation therapy in glaucoma patients at Groote Schuur Hospital, Cape Town, South Africa.

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DECLARATION

I, Stephen Manyeruke hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Introduction

Glaucoma is the second leading cause of blindness, both globally and in Africa.[1] Lowering the intraocular pressure (IOP) reduces the rate of progression of the disease.[2] In many middle and low-income countries, poor compliance with medication means that surgery ends up being the principal means of managing glaucoma.[3]

Laser surgical procedures include selective laser trabeculoplasty (SLT), argon laser trabeculoplasty, continuous transscleral cyclodiode photocoagulation (C-TSCPC) with and micropulse transscleral cyclodiode laser photocoagulation (MP-TSCPC). The proposed mechanism of MP-TSCPC is a reduction of IOP by targeting pigmented tissue in the ciliary body epithelium, while non-pigmented structures are given time to recover during the off cycle. There is less collateral coagulative damage when compared to C-TSCPC.[4] There is also increased trabecular and uveoscleral aqueous outflow and a reduction of aqueous production.[5] Continuous trans-scleral diode laser cyclo-photocoagulation has been shown to be effective in lowering IOP.[6] While its use is generally reserved for advanced refractory glaucoma, it has also been accepted for use in early glaucoma.[4,5] Micropulse TSCPC has been shown to be safer, with less inflammation and a lower incidence of hypotony, than non-pulsed C-TSCPC.[6]

This study aimed to assess the efficacy and safety of MP-TSCPC in a tertiary referral hospital in Cape Town, South Africa. It was built on our experience of C- TSCPC.

Materials and Methods

This study was a prospective interventional consecutive case series. Recruitment was done at Groote Schuur Hospital in Cape Town, from 2 January 2020 to 28 February 2021 following tenets of Helenski.[7] Ethical approval from University of Cape Town Human Ethics Committee was obtained. All patients signed consent forms for participation in the study.

Refractory glaucoma is defined as an IOP that does not drop to target pressure and presence of continued optic nerve damage and deterioration of visual fields despite patients being on maximum tolerated anti-glaucoma medications, or a combination with glaucoma surgery.[8]

One eye of any patient with refractory glaucoma as defined above, or a blind (eye with no light perception) glaucomatous eye not on any medications with IOP above 21mmHg, were recruited in the study. These eyes were not candidates for surgery or patients who did not want surgery for their own reasons. Patients with blind eyes who did not want to be on chronic glaucoma medications were also recruited. Consultation with glaucoma specialists confirmed the absence of further acceptable alternative management. Patients with blind eyes who declined to participate in study were offered options of no treatment if they had painless eyes or C-TSCPC for painful blind eyes or use of glaucoma medications if indicated.

Patients with one eye, those below 18 years of age, patients unable to give informed consent and eyes that had undergone intraocular surgery or any laser therapy within 12 weeks of

enrolment were excluded. To avoid worsening of pre-existing conditions, eyes which had signs of ocular infection, inflammation, or extended scleral thinning of >1 clock hour were also excluded

Glaucoma intervention success, as defined by World Glaucoma Association, is a drop in baseline IOP of at least 20%, or a drop in IOP to between 5 and 20mmHg.[9] This is the definition of treatment success in our study and eyes needed to not have additional surgery or additional glaucoma medications. The converse was the definition of treatment failure plus worsening of visual acuity (VA). Retreatment with MP-TSCPC was not considered as failure of treatment but as part of treatment process.

Intraocular pressure is the main modifiable parameter in glaucoma management and its reduction reduces progression of glaucoma.[10] The primary outcome measure was percentage drop in IOP at 4, 12 and 24 weeks. Secondary outcome measures included: reduction of the number of baseline anti glaucoma agents, postoperative complications and the number of patients who required repeat laser therapy at 12 weeks.

Study patients' details, gender, age, glaucoma classification, duration of glaucoma illness, previous glaucoma interventions, Snellen VA and number of anti-glaucoma agents were recorded at baseline. Eyes were examined with Slitlamp to check for anterior segment diseases and fundus examination was done with 78/90 diopter lens. Goldmann applanation tonometry was used to measure IOP at baseline and at each follow up consultations at 1, 4, 12 and at 24 weeks post MP-TSCPC. Laser power settings, total duration of MP-TSCPC probe application (dwell time) and any surgical complications of the procedure were also recorded on data collection forms. Follow-up observations included Snellen VA, number of glaucoma medications, IOP measurement, slitlamp examination for uveitis and monitoring for any subsequent complications like macular oedema.

The laser administration procedure was performed by the primary investigator. Sub-tenons anaesthesia with 2ml of 2% lignocaine, 2ml of bupivacaine 0.25% and 0.5ml hyalase 150IU/ml was administered after topical anaesthesia with tetracaine drops. Procedures were performed in minor operations theatre. Laser was applied with an Iridex Cyclo G6 IQ191680C (Mountain View CA) glaucoma system, using a single use Micropulse P3 probe at wavelength of 810 micrometres. The probe was placed at the limbus with the footplate facing posteriorly, to cover the scleral landmarks of the ciliary body. A sweeping slow motion of the P3 probe at 10 seconds per hemisphere was repeated 4 times per hemisphere for a total of 80 seconds for both hemispheres. This excluded 9 and 3 o'clock positions, areas of scleral thinning, sites of filtering blebs, or a glaucoma drainage device.

Power settings of between 2000MW or 2500MW were chosen at the discretion of the study doctor, with standard pre-set times of 0.5ms ON and 1.1ms OFF time settings at 31.3% duty cycle. All repeat laser was done using power settings of 2500MW with similar ON OFF laser

settings. It should be noted that there is currently no consensus on recommended power settings. Topical dexamethasone drops were applied at the end of surgery and subsequently four times per day, from 6 hours after the procedure for 7 days. An eye patch was worn for 12 hours. The patients were followed up at intervals mentioned above and referred to glaucoma clinics after 24 weeks for continued care.

Departmental registrars including principal investigator reviewed the lasered eyes using standardised slitlamp examinations. Glaucoma medications were continued post operatively and reviewed at each follow-up appointment using IOP as an indicator to adjust the number of medications. The target was to stop oral acetazolamide and reduce topical glaucoma medications in consultation with the glaucoma specialists if the target IOP was reached. This was mostly done when IOP was lower than 22 mmHg. Slitlamp and retinal examinations were done at each visit and uveitis was specifically checked for and treated when present. Standardised Uveitis Nomenclature (SUN) guidelines were used. Other complications which were checked include: drug reaction to lignocaine or bupivacaine, peribulbar haemorrhage, hypotony, hyphaema and macular oedema. Repeat laser was performed in patients who had less than 20% drop in intraocular pressure or when the IOP was above 21mmHg at 12 weeks. Patient data was coded and entered into IBM SPSS 27 datasheet from which descriptive statistical analysis was conducted. Frequencies and percentages were calculated for categorical values, while mean and standard deviation were calculated for numerical variables.

Results

Forty-two eyes were enrolled in the study. Fourteen were lost to follow up due to the Covid outbreak, leaving 28 eyes. Four of these 14 patients were followed up to 12 weeks, while 10 were never seen after laser. There were 15 (54%) females and 13 (46%) males, with a mean age of 54±15 years (range 26 to 80 years) for whole sample as shown in Table I. Baseline VA varied from 6/24 to no perception of light (NPL), with 82% having vision worse than 6/36 as shown on table II. The duration of glaucoma following diagnosis was between 2 months and 21 years, with a mean duration of 6.5±5.2 years. All eyes except one had glaucoma for more than 1 year. Primary open angle glaucoma (POAG) accounted for 15 out of 28 (54%) of glaucoma diagnosis as shown on Table I.

Twelve eyes had not had any prior surgical procedure while 2 eyes had glaucoma drainage devices, 4 had a history of trabeculectomy and 3 had previous cataract extraction surgery as shown on Table III. Eyes with history of combined surgery are shown on the same table.

The mean IOP at baseline was 40 ± 12mmHg. At 1-, 4-, 12- and 24-weeks post MP-TSCPC therapy, mean IOP's were 23±10mmHg, 25±11mmHg, 32±12mmHg and 27±13mmHg respectively as shown on table IV. This represents a percentage drop in baseline IOP of 40% (3-70%), 35% (0-77%), 30% (0 to 59%) and of 35% (7-79) at 1, 4,12 and 24 weeks respectively as shown on graph I.

The six eyes which were not on any glaucoma medications at baseline had mean IOP of 49mmHg at baseline. They had a 27% drop in mean IOP at 24 weeks, and 3 out of 6 (50%) of them having IOPs below 21mmHg at 24 weeks. The study showed that 19 out of 28 (68%) of study eyes had above 20% drop in baseline IOP and 11 out of 28 (39%) had IOP's below 21mmHg at 24 weeks. Success (as defined above) for MP-TSCPC was found in 71% (20/28) of the study eyes. The mean IOP at 24 weeks, for eyes with a baseline IOP of between 21 and 30mmHg, was 16mmHg corresponding to a 37% reduction in baseline IOP in this subgroup. The eight eyes that did not meet the definition of success at 24 weeks had a higher mean baseline IOP of 47mmHg and a mean IOP reduction of 16% at 24 weeks.

The greatest percentage reduction in baseline IOP was 49%, and occurred in the six eyes with secondary open angle glaucoma due to pseudoexfoliation. Primary open angle glaucoma, which constituted 54% of eyes, showed a 32% reduction in baseline mean IOP at 24 weeks. The seven patients who had repeat laser had a 37% reduction in mean baseline IOP at 24 weeks, while those without repeat laser had a reduction of 34%.

The average number of anti- glaucoma agents for the whole sample was 2.8±1.6, which reduced to 2.3±1.5 at 24 weeks (18% less). There was a drop of one anti glaucoma agent in 11 out of 28 (39%) eyes, while 4 patients had an increase of one agent. One patient was able to stop all three glaucoma medications. Twelve eyes 12 out of 28 (43%) were on acetazolamide at baseline, while only 5 out of 28 (18%) needed to continue this at 24 weeks, representing a discontinuation rate of 25%. All the seven patients who stopped acetazolamide had IOP below 22mmHg at 24 weeks. Four patients stopped one topical antiglaucoma agent each. The agents stopped were timolol, brimonidine, travoprost plus timolol and brinzolamide

No significant MP-TSCPC-related complications were noted during the procedure, or the follow up period except complaints of pain during peribulbar injections and subconjunctival haemorrhage. Visual acuity remained stable in 23 out of 28 (82%), while 3 out of 28 (11%) showed an improvement in VA of one line or more. Worsening of VA was noted in 2 out of 28 (7%) eyes, of which one had defaulted treatment for four weeks. The other developed recurrent herpetic kerato-uveitis after defaulting acyclovir prophylaxis. The later could also be considered laser induced uveitis since laser therapy can induce uveitis.

Discussion

This case series demonstrated efficacy of micropulse in reducing IOP which led to reduction of number of glaucoma medications. There were no significant complications.

The mean percentage drop in IOP post MP-TSCPC showed a downward trend, from 40% at one week to 35% at 24 weeks. This downward trend is reflected in similar studies.[11,12,13,14] Regeneration of ciliary epithelium may account for this diminishing efficacy.[15] This study demonstrated a mean 35% drop in baseline IOP, which is higher than the 30.6% in Vig et al.

study and 27% in Chang et al. retrospective studies that used MP-TSCPC of 2000MW with treatment duration of 80 to 90 seconds and 160 seconds respectively.[13,14]These studies had baseline IOPs of 26±11mmHg and 27.8±7.6mmHg respectively which are lower than in current study. The 35% drop in baseline IOP in our study is comparative to the 36% mentioned in a retrospective study of Nguyeni et al. who used 2000MW to 2500MW power settings, but included up to 5 re-treatments using 3000MW C-TSCPC and 180 seconds of probe application.[16] More re-treatments and longer probe application in our study could have led to a greater drop in baseline IOP.

The six treatment naive glaucoma eyes had lower percentage drop in baseline IOP compared to patients who had refractory glaucoma. Their mean baseline IOP was higher than refractory glaucoma patients and 50% of them had angle closure glaucoma while the rest had POAG. The 27% reduction among these 6 patients was similar to a 27% reduction in baseline IOP recorded by Chang et al. in a study that used MP-TSCPC as initial therapy during covid outbreak in Taiwanese patients with mild to moderate glaucoma.[14] Their study used a comparable laser setting of 2000MW and a longer probe application time of 180 seconds.

The 32% drop in baseline IOP at 24 weeks for POAG is lower than the 38.5% reduction in Tekeli et al.'s study, which used a longer 180 seconds of total laser treatment in a Caucasian population.[17] Our study comprised of a predominantly African population. The drop in the whole group's mean IOP of 35% at 4 weeks, is within the range of 31-46% mentioned in other studies, but different powers and varied total time of laser treatment were used in other studies.[18,19] This shows that our laser parameters could be said to be as effective as parameters used in other studies. A metanalysis of randomised control studies showed that timolol and latanoprost can reduce IOP by a range of 26 to 30%.[20] This case series study showed an overall 35% reduction in IOP which compares favourably with these topical medications even though the populations and study designs are different.

The mean drop in baseline IOP was higher in the 7 patients who had repeat laser, than those who only had a single episode of MP-TSCPC (37% versus 34%), likely because of additive effect of laser. There were no additional laser complications in patients who had repeat laser. The short duration of the study did not allow for multiple repeat laser therapies. Some studies have shown that repeated laser can be applied, even up to 5 times, with favourable results.[21-23]

This study had a comparable drop in baseline IOP to the retrospective study done by Coetzee et al. at our institution, Groote Schuur Hospital, but using C-TSCPC. Her study showed a drop in IOP of 36% at 6 months.[24] Of note however, was a drop in VA reported in 25% of the patients at 6 months in Coetzee et al. study, which is higher than the 6% in our study. This could be attributed to less coagulative energy being used with MP-TSCPC than the continuous mode. Micropulse laser therapy in our study appears to be safer.

The mean IOP at 24 weeks of 27mmHg can be too high to halt glaucoma progression. This IOP is higher than in other studies, which all reported mean IOPs below 20mmHg at 6 months as shown on Table V.[11,18,19,25-27] However their baseline IOPs were mostly below 30mmHg, unlike our study's baseline of 40mmHg. The 6 eyes with a baseline IOP below 30mmHg in this study, showed a mean IOP of 16mmHg (41% drop) at 24 weeks post laser. This demonstrated very favourable outcome for eyes with IOP below 30. A randomised study comparing IOP outcome against baseline IOP would help to explain this outcome.

Our study had fewer subjects (39%) who stopped at least one anti glaucoma agent at 24 weeks compared to 73% mentioned by Chang et al.[14] Their study used 2000MW power and 160 seconds of probe applications which means use of higher energy than in our study. Their patients had a lower 6 month (24 weeks) mean IOP of 20.3mmHg compared to 27mmHg in the current study. Higher mean IOP at 24 weeks in current study could account for the lower reduction in the number of anti-glaucoma medications. Zaarour et al. showed a discontinuation rate of 30.6% at 6 months among patients using acetazolamide, while Vig et al. had a 38% discontinuation rate of acetazolamide at 6 months post MP-TSCPC.[11,13] We had a lower discontinuation rate of 25%, possibly due to the higher mean IOP.

The overall success rate in this study was 71%. Average success rates quoted in the literature range from 25% to 95%, however direct comparisons are difficult due to varied MP-TSCPC protocols, different sample populations and different definitions of success.[6,24,28,29]

The success rate was lower in eyes with higher baseline IOP's, which is contrary to a study by Sarrafpour et al, which showed their percentage drop was greater in patients with higher baseline IOP's. They however used a longer probe dwell time of 100s and also titrated laser power according to stage of glaucoma, with 2500MW being reserved for eyes with advanced glaucoma.[17]

There was a lower percentage (6%) of patients who lost a line on Snellen VA in our cohort, compared to the 16.5% who lost at least 2 Snellen lines in a single surgeon study at Wills Eye Hospital.[19] The Wills study used a total laser duration of 120s to 360s, which means higher energy delivered to ciliary body than in our study. They reported a higher 51% drop in baseline IOP. A larger reduction in IOP has potential to decrease IOP to levels that increase the risk of hypotony maculopathy and its associated sequelae, but can also produce the target IOP. The shorter total duration (80s) of probe application used in our study resulted in fewer complications possibly due to less energy being delivered to the ciliary body.

Strengths and limitations

The strengths of this study included the laser procedures being done by the primary investigator, who reviewed all patients at one week post treatment. This reduced variations in the technique and settings thus making it easier to compare outcomes. The investigator

reviewed all patient notes, booked follow up appointments and reviewed all patients at the conclusion of the study. This was a prospective study which reduced recall bias and all required information was captured. There were low rates of complications possibly due to the low laser duration in our study.

The limitations of this study include, VA being measured with Snellen charts than Logmar charts. This reflects the normal practice in our clinic. LogMAR charts could have helped to determine loss or gain of single optotypes. The Covid outbreak limited sample size and led to missed appointments by study subjects. The study relied on self-reporting by patients of compliance with medications. The cost of the single use P3 probe limited sample size. The duration of probe application could have been higher to produce higher IOP reduction.

Conclusions

In this small cohort of patients, MP-TSCPC was effective in reducing IOP in refractory glaucoma eyes and eyes that were naive to anti glaucoma medications, with a success rate of 71%. Repeat laser resulted in a greater reduction in IOP. The study demonstrated reduction in mean number of glaucoma medications at 6 months. There were no reported complications. This study proves effectiveness of MP-TSCPC at Groote Schuur Hospital and that the service should be offered to more glaucoma patients. Further larger randomised studies are required with variable laser settings, longer duration of treatment, more repeat lasers and investigate any other variables that can affect effectiveness.

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TABLES AND GRAPH

Table 1. Baseline Patient Information

Patient Demographics	
Age (mean ±SD) (years)	54±15
Male n (%)	13(46%)
Female n (%)	15(54%)
Total n (%)	28 (100%)
Baseline IOP	40±12mmHg
Glaucoma diagnosis	n (%)
Primary Open Angle Glaucoma	15 (53.5%)
Secondary Open Angle Glaucoma	6 (2.4%)
Chronic angle Closure Glaucoma	2 (7.2%)
Neovascular Glaucoma	5 (17.9%)
Total	28 (100%)

Table II. Baseline Snellen Visual Acuity

Visual acuity	Frequency	Percentage
NPL	12	42.9
PL	3	10.7
HM	4	14.3
CF	4	14.3
6/36	2	7.1
6/24	3	10.7
Total	28	100.0

Table III. Previous eye surgery

Previous Surgery	Number (%)
No surgery	12 (42.9%)
Cataract Surgery	3 (10.7%)
Trabeculectomy	4 (14.3%)
Yag peripheral iridotomy	2 (7.1%)
Glaucoma Drainage surgery (GDD)	2 (7.1%)
Selective Laser trabeculoplasty (SLT)	1 (3.6%)
GDD plus cataract surgery	1 (3.6%)
GDD plus cyclodiode	1 (3.6%)
SLT plus cataract surgery	1 (3.6%)
Pars Plana Vitrectomy	1 (3.6%)
Total	28 (100%)

Table IV. Mean IOP changes post MP-TSCPC with time

	Pre MP-TSCPC	1 week post MP-TSCPC	4 weeks post MP-TSCPC	12weeks post MP-TSCPC	24 weeks post MP-TSCPC
Mean	40	23	25	32	27
SD	12	10	11	12	13

Table V. Reported 6th month (24 Weeks) IOP outcomes in other studies

STUDY	BASELINE IOP in mmHg	6 MONTHS IOP in mmHg	PERCENTAGE IOP drop at 6 months
Zaarour K[11]	26.0±7.9	16.7±6.2	35%
Sarrafpour S[18]	23.2±5.5	15.8±11.8	32%
Emanuel ME[19]	27.7±10.3	13.0±6.9	53%
Giancarlo A[25]	22.2±7.9	15.8±6.9	29%
Sahira Wasim[26]	34.0±13.4	16.8±12.5	51%
Lee H[27]	28.4±8	18.6±6.6	35%

Graph I. Percentage drop in IOP post MP-TSCPC