Outcomes of Micropulse Transscleral Cyclophotocoagulation in Eyes With Good Central Vision

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Precis: This study is the first to report micropulse transscleral cyclophotocoagulation (MP-TSCPC) use in only good vision patients. MP-TSCPC significantly reduced intraocular pressure (IOP) and glaucoma medication use without any significant reduction in visual acuity at every postoperative follow-up point.

Purpose: To evaluate outcomes of MP-TSCPC in eyes with baseline best-corrected visual acuity (BCVA) of $\geq$20/60.

Methods: A retrospective review of patients who underwent MP-TSCPC at Mayo Clinic and Ross Eye Institute from July 2016 to August 2017 with BCVA of $\geq$20/60, and a minimum of 3 months follow-up.

Results: A total of 61 eyes of 46 patients (68.80 ± 17.12 y) underwent MP-TSCPC with a mean follow-up of 10.2 ± 3.1 months. Mean IOP and mean number of glaucoma medications used were significantly reduced from baseline at every follow-up time point ($P<0.0001$). At month 12, mean IOP was reduced 40.2% from baseline with 85.4% of the patients having an IOP reduction of $\geq$20%, and mean glaucoma medication use reduced by 0.82 ± 0.53 with 79.6% of the patients having a reduction of $\geq$1 medication. There was no significant reduction in BCVA from baseline at any follow-up point ($P>0.05$), except for 10 eyes with a vision loss of $\geq$2 lines and 5 out of 10 eyes had cataract progression. The probability of complete success (IOP range, 6 to 21 mm Hg or $\geq$20% IOP reduction; BCVA loss $\leq$2 lines, no reoperation for glaucoma) was 74.14%, 83.61%, 84.21%, and 75.0% at months 1, 3, 6, 12, respectively. The probability of qualified success (above criteria for IOP, no reoperation and BCVA loss >2 lines) was 81.03%, 91.80%, 94.74%, and 93.75% at months 1, 3, 6, 12, respectively.

Conclusions: MP-TSCPC should be considered earlier in the management of glaucoma and can possibly be offered as an alternative to incisional glaucoma surgeries.

Key Words: micropulse transscleral cyclophotocoagulation, cyclodestruction, primary open-angle glaucoma, intraocular pressure, best correct visual acuity

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Targeting the ciliary body to reduce aqueous humor production through cyclodestructive procedures has long been used in the management of glaucoma. Transscleral cyclophotocoagulation (TS-CPC) is such a procedure in which a semiconductor diode laser emits 810 nm light targeting the pigmented ciliary epithelium. The absorption and buildup of this thermal energy lead to photocoagulative thermal damage and subsequent reduction in aqueous production.[1]

TS-CPC can be performed using either continuous wave therapy (CW-TSCPC), or the more recent approach of micropulse transscleral cyclophotocoagulation (MP-TSCPC). They both utilize the semiconductor diode laser; however, the MP-TSCPC directs the laser to the pars plana instead of the pars plicata and delivers pulses of energy in an "on-off" pulsatile manner.[2] With each "on" pulse, thermal energy builds up and eventually reaches the coagulative threshold in the targeted tissue. The rest, or "off" period, allows the surrounding tissue to cool down, which can minimize the buildup of energy in the collateral tissues. This rest period prevents the collateral tissue from reaching the coagulative threshold, which makes the procedure ultimately less inflammatory and is associated with a lower complication rate compared with traditional CW-TSCPC.[3]

The potential of MP-TSCPC to reduce collateral damage is of utmost importance as it is the inflammation and resulting vision-threatening complications associated with CW-TSCPC that have largely limited the use of transscleral CPC to those patients with poor visual potential or those who are poor candidates for incisional glaucoma surgery.[4] Although reports of MP-TSCPC are still limited, current literature has begun to show promise and has demonstrated safety and efficacy that is comparable with CW-TSCPC and incisional glaucoma surgery.[2,3,5–7] However, these previous studies have still included eyes that have poor visual potential at baseline. To encourage the use of MP-TSCPC earlier in the management of glaucoma, our study is the first that aims to investigate the safety and efficacy of MP-TSCPC in only those patients with good visual potential at baseline.

MATERIALS AND METHODS

A retrospective chart review was conducted on all patients who underwent MP-TSCPC between July 2016 and August 2017 at Ross Eye Institute, SUNY University at

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Buffalo and Mayo Clinic, Jacksonville. Patients with glaucoma, a baseline best-corrected visual acuity (BCVA) of ≥20/60, and a minimum of 3 months of follow-up were included in the study. Patients with no prior glaucoma surgeries and those with previously failed trabeculectomy, tube shunt, selective, and argon laser trabeculoplasty surgeries were also included. Patients with history of ocular trauma and congenital anterior chamber anomalies were excluded from the study. The study was approved by University at Buffalo Institutional Review Board and the research was conducted in accordance with the Declaration of Helsinki.

Measured Parameters

Data were extracted from Medflow Version 8.2 Electronic Health Record (EHR) and included patient's demographics, surgical procedure date, any prior surgeries, central corneal thickness, presurgical and postsurgical visual acuity (calculated as LogMAR), intraocular pressure (IOP) measured using Goldmann Applanation Tonometer and number of glaucoma medications used. It also compiled any associated postsurgical complications such as hyphema, iritis, corneal edema, vitreous hemorrhage, and cystoid macular edema (CME). The laser settings were also recorded and included duty cycle, power of laser application, and laser time in superior and inferior hemispheres.

The main outcome measures used for data analysis were IOP, visual acuity, and number of glaucoma medications. Parameters were measured at baseline, and at postoperative months 1, 3, 6, and 12. The cumulative probability of complete success was defined as eyes that attained an IOP of 6 to 21 mm Hg or had a reduction of IOP of ≥20% and who also lost ≤2 lines of vision without need for reoperation.[8] The cumulative probability of qualified success was defined as eyes that met the above IOP criteria, but lost >2 lines of vision.[8] Surgical success was determined at postoperative follow-ups of 1, 3, 6, and 12 months. Failure was defined as an inability to meet the aforementioned success rate.

Surgical Procedure

Consent was obtained from all the patients before performing MP-TSCPC procedure. Anesthesia was attained with monitored anesthesia care, topical lidocaine gel, and retrobulbar anesthesia of a 1:1 mixture of carbocaine and marcaine. The Cyclo G6 transscleral diode laser with a P3 probe was used for laser delivery (MicroPulse-P3, Iridex Corporation, Mountain View, CA). All patients were treated with a laser power of 2000 mW and duty cycle of 31.33%. The laser probe was applied in a continuous sweeping motion from 9:30 to 2:30 clock positions with a mean laser duration of 78.39 ± 6.82 seconds in superior hemifield and from 3:30 to 8:30 clock positions with a mean laser duration of 80.17 ± 1.30 seconds in the inferior hemifield. The sweeping motion, or dwell time, was 10 seconds per hemifield sweep. It is important to note the minimal variability of power, dwell time, and treatment time among patients and between surgeons (S.F.S. and S.K.D.). The laser duration was adjusted based on iris color of the patients and eyes with darker iris pigment required slightly lower laser power. The laser application was avoided in 3- and 9-o' clock positions to avoid damage to ciliary nerves. A majority of the patients received a subconjunctival injection of 2 mg dexamethasone, and were prescribed 1% prednisolone acetate QID and tapered as needed.

Statistical Analysis

Statistical analyses were performed using SAS version 9.4, and all tests were used with a nominal significance level of 0.05. BCVA was converted from Snellen visual acuity to LogMAR equivalents. Kaplan-Meier survival plots were based on time from the MP-TSCPC procedure to the first point at which a patient failed to meet criteria for qualified or complete success. Significant differences were defined as $P < 0.05$.

RESULTS

Baseline Clinical Characteristics

Among those eyes that underwent MP-TSCPC at the Ross Eye Institute and Mayo Clinic, from July 2016 to August 2017, a total of 61 eyes of 46 glaucoma patients met the inclusion criteria of a baseline BCVA of ≥20/60 and a minimum of 3 months of follow-up. Baseline clinical characteristics of study participants are identified in Table S1 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307). These patients had a mean age of 68.80 ± 17.12 years and were followed for mean duration of 10.2 ± 3.1 months. Primary open-angle glaucoma was the most common glaucoma type as it was present in 83.61% of eyes. MP-TSCPC was also considered a primary glaucoma procedure for 75.41% of these eyes, as they had no history of incisional glaucoma surgery. Out of 61 eyes included in the study, 10 and 5 eyes had previously undergone trabeculectomy and tube shunt surgeries, respectively. Further, laser procedures such as selective laser trabeculoplasty were done on 33 eyes and alternative laser trabeculoplasty was performed on 2 eyes before MP-TSCPC surgery.

IOP Reduction and Medical Therapy

Table S2 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307) provides baseline and follow-up measurements of IOP and the number of glaucoma medications used. The mean IOP was significantly reduced from baseline at months 1, 3, 6, and 12 ($P < 0.0001$). The mean IOP was decreased from 25.69 ± 5.63 mm Hg at baseline to 16.69 ± 4.79 mm Hg at month 1 (33.3% reduction), 15.2 ± 4.15 mm Hg at month 3 (38.9% reduction), 15.33 ± 3.46 mm Hg at month 6 (38.7% reduction), and 15.38 ± 3.74 mm Hg (40.2% reduction) at 12 months' postoperative follow-up visit. An IOP reduction of ≥20% from baseline was seen in 44 eyes (75.86%) at month 1, 55 eyes (90.16%) at month 3, 50 eyes (86.21%) at month 6, and 41 eyes (85.42%) at 12 months postsurgical follow-up visit.

The mean number of glaucoma medications was significantly reduced from baseline at months 1, 3, 6, and 12 months' postoperative follow-up visit ($P < 0.0001$). A mean decrease in number of glaucoma medications from baseline was 0.90 ± 0.52 at month 1, 0.85 ± 0.60 at month 3, 0.80 ± 0.55 at month 6, and 0.82 ± 0.53 at 12 months' postsurgical follow-up. Glaucoma medication use reduced by ≥1 medication from baseline was seen in 49 eyes (84.48%) at month 1, 50 eyes (81.97%) at month 3, 47 eyes (79.66%) at month 6, and 39 eyes (79.59%) at month 12.

Visual Acuity

Table S2 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307) provides baseline and follow-up LogMAR BCVA measurements, and frequency of vision changes by line. There was no significant reduction in LogMAR BCVA from baseline (0.16 ± 0.15) to postsurgical month 1 (0.19 ± 0.16), month 3 (0.18 ± 0.14), month 6 (0.19 ± 0.18), and month 12 (0.22 ± 0.18) ($P > 0.05$). A mean

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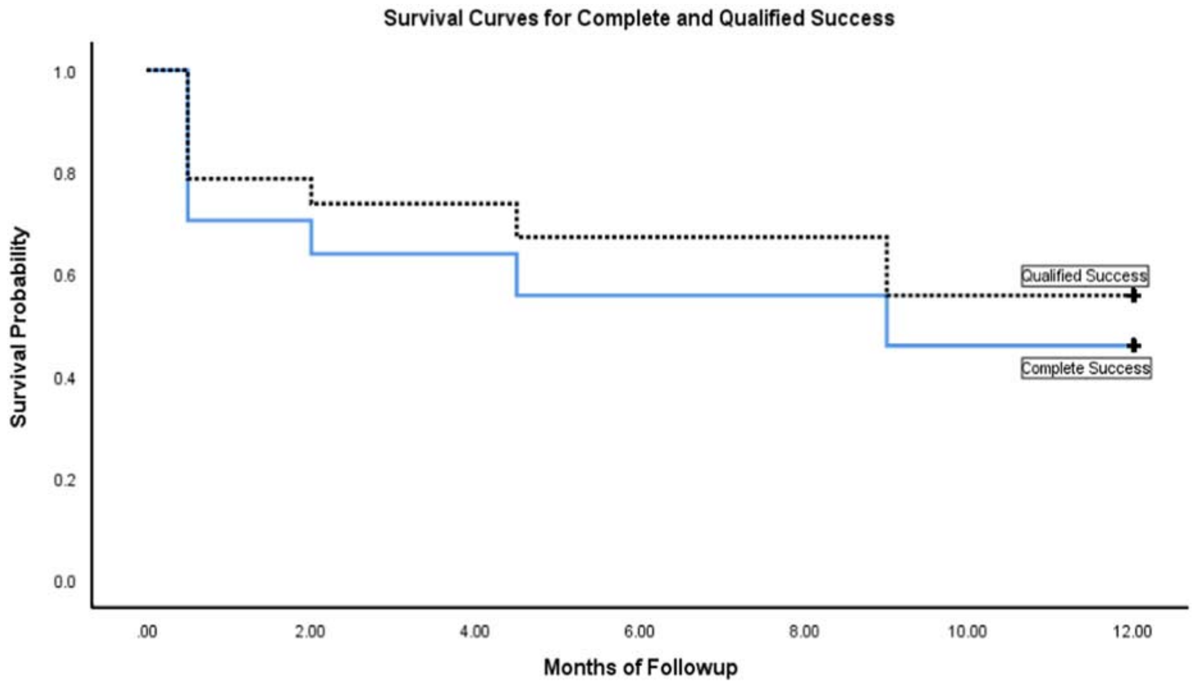

FIGURE 1. Kaplan-Meier plot of the probability of survival based on complete and qualified success. The cumulative probability of complete success was defined as patients who attained an IOP of 6 to 21 mm Hg or had a reduction of IOP of ≥20% and who also lost ≤2 lines of vision without need for reoperation. A cumulative probability of qualified success was defined as patients who met the above IOP criteria, but lost >2 lines of vision. IOP indicates intraocular pressure. Figure 1 can be viewed in color online at www.glaucomajournal.com.

deterioration of 3 optotypes LogMAR BCVA was noticed between baseline and 12 months (0.06 ± 0.16).

Of the 49 eyes that were followed to 12 months postoperatively, a total of 10 eyes (20.83%) were found to have lost ≥2 lines of vision, with 4 eyes losing equal to 2 lines of vision and 6 eyes (12.5%) losing >2 lines. Among these 10 eyes, 5 eyes had cataract progression that was addressed with subsequent cataract extraction after the study completion. One of the eyes had a history of CME before receiving MP-TSCPC and developed CME after MP-TSCPC. This patient exhibited the most profound decrease in vision between baseline to last follow-up which was 0.57 LogMAR. Two eyes had unexplainable vision loss, which the authors attributed to likely glaucoma progression. The remaining 2 eyes have a history of iritis and mild postoperative inflammation that resolved at subsequent follow-up visits after study completion.

A subgroup analysis was done between eyes with and without history of glaucoma surgery. Fifteen eyes had no previous glaucoma surgery versus 46 eyes that had undergone glaucoma surgeries including trabeculectomy, tube shunt, selective laser trabeculoplasty, and alternative laser trabeculoplasty. The mean change in IOP and number of medications was significantly different from baseline to postsurgical follow-up months 1, 3, 6 and 12 in both the patient groups. The mean visual acuity was not significantly different in both the patient groups from baseline to months 1, 3, and 6. However, in month 12, the mean visual acuity was significantly reduced in patients with prior glaucoma surgery, but was not significantly reduced in the other group. (Table S3, Supplemental Digital Content 1, http://links.lww.com/IJG/A307). Of the eyes without prior glaucoma surgery, 8 were phakic and 7 were pseudophakic, versus 17 phakic, 27 pseudophakic, and 2 aphakics in the eyes with prior glaucoma surgery. In terms of patients with vision loss of ≥2 lines, there was 1 phakic eye in the group without prior surgery versus 7 phakic and 2 pseudophakic in the prior surgery group.

Complications

Complications during follow-up are listed in Table S4 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307). The most common complication was cataract progression, seen in 40% of the eyes that were phakic at baseline, followed by postoperative iritis (3.3%) and CME (3.3%). There was 1 case of hypotony maculopathy, which developed in the same patient that had preprocedure CME. There was one case each of corneal edema and hypotony (<5 mm Hg on 2 visits after 90 d). There was no incidence of phthisis bulbi, endophthalmitis, sympathetic ophthalmia, hyphema, or vitreous hemorrhage.

Success Rate

The cumulative probability of complete success was 74.14%, 83.61%, 84.21%, and 75.0% at 1, 3, 6, and 12 months, respectively. The cumulative probability of qualified success rate was 81.03%, 91.80%, 94.74%, and 93.75% at 1, 3, 6, and 12 months, respectively. The rate of complete and qualified success was significantly different at all these time points ($P < 0.0001$). Figure 1 depicts the demonstration of Kaplan-Meier plot for the probability of complete and qualified success.

DISCUSSION

The reduction in IOP and glaucoma medication use in our patients supports the increasing reports in the literature demonstrating the efficacy of MP-TSCPC. In our study, IOP significantly dropped by 40.2% and glaucoma medication use dropped by 0.82 from baseline to 12 months follow-up ($P<0.0001$). Both parameters also have a statistically significant reduction at months 1, 3, and 6 ($P<0.0001$). These results support previous studies of MP-TSCPC which have reported an IOP reduction from baseline to last follow-up of 26.5% to 59.9%, and a reduction in medication use of 0.5 to 1 medications.[2,3,5,7,9–11] There were no patients who had IOP control without medications. The efficacy of MP-TSCPC from previous studies to date are outlined in Table S5 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307).

Although the reports on MP-TSCPC are still limited and long-term results remain to be seen, the effectiveness of MP-TSCPC is comparable with traditional CW-TSCPC, which specifically in good vision patients, has shown an IOP reduction of 48.3% from baseline.[12] In a prospective study of 48 patients, Aquino et al[2] directly compared MP-TSCPC and CW-TSCPC with 24 patients randomized to each group over a mean follow-up period of 17.5 months. In the MP group, 52% of the patients achieved an IOP between 6 and 21 mm Hg with >30% IOP reduction from baseline compared with only 30% in the CW group. Not only is the effectiveness of MP-TSCPC is in line with that of diode TS-CPC, it is also comparable with incisional glaucoma surgery. In the landmark tube versus trabeculectomy study, there was a 51% and 50% reduction from baseline IOP in the tube and trabeculectomy group, respectively at 1 year of follow-up.[12] Although our study IOP reduced from baseline by 40.2% at 12 months, less than the aforementioned rates, other MP-TSCPC studies have reported an IOP reduction as high as 51%.[3]

As reports of the efficacy of MP-TSCPC continue to grow, reports of the effect on vision remain limited. In our study, the first MP-TSCPC study in only patients with good baseline vision of ≥20/60, there was no significant reduction in vision from baseline at any time-point and the majority of the patients did not lose vision. Although 10 eyes (20.83%) of patients were found to have lost ≥2 lines of LogMAR visual acuity at month 12, it is important to consider that 5 of these 10 eyes had cataract progression. It is unclear whether the cataract progression is increased due to surrounding inflammation resulting from the MP-TSCPC or whether these cataracts would have progressed irrespective of the MP-TSCPC procedure. Among the 10 eyes that lost ≥2 lines of vision, 1 eye developed CME and hypotony maculopathy; however, this eye had CME before the MP-TSCPC procedure as well. Both CME [7] and cataract progression have been previously reported as complications of MP-TSCPC.[3] Further, these complications are not limited to MP-TSCPC and have been reported with the use of CW-TSCPC and incisional glaucoma surgery.[13,14] Two eyes had unexplained vision loss and 2 eyes showed reduced visual acuity due to prolonged iritis and inflammation. A longer, more aggressive course of prednisolone acetate prescribed postoperatively may have reduced the frequency of postoperative inflammation.

Out of the 10 eyes that lost vision ≥2 lines, the majority of these cases were phakic (7 eyes) with prior glaucoma surgery (7 eyes). Patients with prior failed glaucoma surgeries often have associated vision loss, and we feel that our results are similar to this subgroup of glaucoma patients. Also, out of 25 phakic eyes, 10 eyes had cataract progression and 5 of them had a vision loss of ≥2 lines which required cataract extraction. Although cataract progression can occur after incisional glaucoma surgery as well,[13,14] there appears to be a very high rate of cataract progression after MP-TSCPC based on this data, and therefore should be properly addressed in the preoperative consent of phakic patients. Other possible mechanisms of vision loss with MP-TSCPC are corneal edema, mydriasis, and change in effective lens position.

Our frequency of 20.83% of eyes losing ≥2 lines at 12 months is comparable with a previous retrospective study by Emmanuel et al[9] in which 26.2% of 84 eyes lost ≥2 lines and a study by Williams et al[3] of 79 eyes of 79 patients in which 17% of the patients lost ≥2 lines in 3 months. In contrast, a retrospective study by Tan et al[5] of 40 eyes had no eyes lose any vision from baseline after the MP-TSCPC procedure with a total follow-up of 17.3 months. It is difficult to make direct comparisons to previous studies as our study is the only study solely in better sighted eyes at baseline; however, the treatment time is important to consider. The studies by Williams and colleagues and Emmanuel and colleagues had a mean treatment time of 300 seconds and 319 seconds, respectively, whereas our study had a mean treatment time of 158.56 seconds. Visual outcomes from previous studies of MP-TSCPC have been outlined in Table S5 (Supplemental Digital Content 1, http://links.lww.com/IJG/A307).

The safety of MP-TSCPC becomes more apparent when comparing it with other glaucoma management procedures. Our rate of vision loss of ≥2 lines of 20.83% at 12 months is less than previous studies of CW-TSCPC in which up to 33% of the patients with a baseline BCVA ≥20/60 have lost ≥2 lines.[12,15] The rate of vision loss is also less than that of tube shunts and trabeculectomy at 1 year, which had 32% and 33% of vision loss, respectively.[12] The safety of MP-TSCPC is further demonstrated when considering that our study had no cases of phthisis bulbi, endophthalmitis, sympathetic ophthalmia, or vitreous hemorrhage. These are complications that have been reported multiple times with the use of tube shunt and trabeculectomy.[14] Complications reported among other studies of MP-TSCPC include pain, anterior chamber inflammation, hyphema, corneal edema, persistent hypotony, CME, and IOP spike. In the previously mentioned study by Williams et al,[3] 2 patients also developed phthisis bulbi; however, 1 eye had NVG, which has been associated with increased failure with MP-TSCPC,[5] and 1 eye had nanophthalmos. Vision loss to no light perception has also been reported in 4 cases, but 3 of these cases had poor baseline vision with 1 case having light perception vision at baseline,[9] and 1 case having had hand-motion vision.[3]

The case for the use of MP-TSCPC in patients with good vision becomes stronger when considering that 46 of the 61 eyes, or 75.41% of our patients, did not have a history of incisional glaucoma surgery and underwent MP-TSCPC as a primary procedure for uncontrolled or progressing glaucoma on maximal topical medications. Among these 46 eyes, 8 eyes (21.05%) lost ≥2 lines of vision at month 12, similar to our overall rate of 20.83%. This rate, though marginally higher, is comparable with vision loss in those patients who have undergone tube shunt or trabeculectomy as a primary procedure. In the recent Primary Tube Versus Trabeculectomy study, a multicenter randomized clinical trial, 125 eyes underwent tube shunt and 117 eyes underwent trabeculectomy without any history of incisional ocular surgery. Among the tube shunt group, 13% of eyes lost ≥2 lines of visual acuity and among the trabeculectomy group,

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11% lost ≥ 2 lines of visual acuity.[16] Although direct comparison between a randomized clinical trial to a retrospective study cannot be made, and although there are multiple baseline differences among the eyes in the Primary Tube Versus Trabeculectomy study and our study especially with a significant difference in sample size, the comparable loss of vision should begin to encourage clinicians to consider MP-TSCPC as an early treatment option in the management of glaucoma.

Apart from proven efficacy and safety, MP-TSCPC provides multiple logistical advantages when compared with incisional glaucoma surgery. Similar to CW-TSCPC, MP-TSCPC eliminates the need for a sterile operating room, provides less postoperative activity restriction, virtually no risk of infection and is a portable technology.[17] These advantages can prove fruitful in areas with limited resources, can increase the efficiency of daily practice, and as such, a study examining the cost-benefit analysis of MP-TSCPC compared with other glaucoma procedures in the near future would be beneficial.

The limitations of our study include its retrospective nature, lack of a comparative group, limited sample size, and relatively short follow-up duration. A prospective study examining both the efficacy and safety of MP-TSCPC in good vision patients and the efficacy and safety of MP-TSCPC versus incisional glaucoma surgery would add beneficial knowledge to the current literature.

Long considered primarily as a treatment for reserved eyes with poor visual potential, our study supports the case for MP-TSCPC as a feasible procedure in patients with good baseline vision and we feel could be offered earlier in the management of pseudophakic patients with glaucoma. The significant reduction in IOP and glaucoma medication use, limited vision loss, less vision threatening complications, and multiple logistical advantages, demonstrates MP-TSCPC as a safe and effective procedure to consider in patients with good baseline vision and can possibly be offered as an alternative to incisional glaucoma surgeries.

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