Micropulse Trans-scleral Cyclophotocoagulation in Patients With Glaucoma: 1-and 2-Year Treatment Outcomes

Micropulse Trans-scleral Cyclophotocoagulation in Patients With Glaucoma: 1- and 2-Year Treatment Outcomes

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Précis: Micropulse trans-scleral cyclophotocoagulation (TSCPC) is an effective and safe IOP-lowering treatment for patients with primary or secondary glaucoma.

Purpose: To investigate the 1-year and 2-year effect on intraocular pressure (IOP) and safety profile of micropulse TSCPC in patients with glaucoma.

Methods: Patients with glaucoma underwent a standardized micropulse TSCPC (MicroPulse P3 probe, Iridex cyclo G6 laser system, Mountain View, CA) at the University Eye Clinic Maastricht from November 2016 to May 2018. Patients with at least 12 months of follow-up were included.

Results: A total of 141 eyes of 136 patients were included. The mean age was 67.2 ± 14.5 years, and 56.6% of patients were male individuals. The glaucoma subtypes treated were primary glaucoma (n = 99) and secondary glaucoma (n = 42). Prior glaucoma surgery was performed in 59 of 141 eyes (41.8%). The mean preoperative IOP was 23.5 ± 9.4 mm Hg. The mean postoperative IOP dropped to 16.8 ± 8.4, 17.0 ± 7.8, and 16.8 ± 9.2 mm Hg, after 12, 18, and 24 months, respectively. The mean number of IOP-lowering medications used preoperatively was 3.3 ± 1.4. The mean number of medications used at 12, 18, and 24 months was respectively 2.6 ± 1.5, 2.5 ± 1.4, and 2.2 ± 1.5. Postoperative complications included cystic macular edema (n = 2), hypotony maculopathy (n = 1), fibrinous/uveitic reaction (n = 1), and rejection of corneal graft (n = 1), all reversible after treatment. One patient developed persisting hypotony in the late postoperative period.

Conclusions: Micropulse TSCPC is a safe and effective treatment for lowering both IOP and the number of IOP-lowering medications. Micropulse TSCPC can also be considered as a good alternative treatment option for patients after failed incisional glaucoma surgery or patients who are at high risk for incisional surgery.

Key Words: glaucoma, trans-scleral cyclophotocoagulation, micropulse, laser treatment

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Treatment of glaucoma is mainly aimed at lowering intraocular pressure (IOP)[1] by increasing the outflow or by decreasing the production of aqueous humor. Lowering IOP can be achieved by (topical) glaucoma medications, laser treatment, or by glaucoma surgery, that is, incisional glaucoma surgery, minimally invasive glaucoma surgery, or glaucoma tube implantation.[2] For patients with uncontrolled, refractory glaucoma, the last treatment option is often a cyclodestructive procedure: cyclocryocoagulation, cyclodiathermy, or trans-scleral cyclophotocoagulation (TSCPC).[3,4] However, serious complications, for example, persistent hypotony, persistent intraocular inflammation, hyphema, decreased visual acuity (VA), or phthisis bulbi have been shown in several studies[5–7] after these cyclodestructive procedures, which is a reason for many ophthalmologists to avoid these procedures or only use them when all other glaucoma treatment options have failed.

Micropulse trans-scleral cyclophotocoagulation (MP-TSCPC) is a novel laser treatment[8] that claims less destruction of the ciliary body in comparison with conventional cyclodestructive techniques. The micropulse technique consists of conducting laser energy to the ocular tissue for only a short period of treatment time, which minimizes thermal damage in ocular tissue. Several recent studies[9–14] have reported adequate IOP lowering after MP-TSCPC in patients with refractory glaucoma, with fewer severe complications in comparison with TSCPC or cyclocryotherapy. Because of these promising results and lower complication rate, MP-TSCPC could also be attractive to use earlier in the treatment paradigm of glaucoma. However, current evidence on efficacy and safety of the procedure is still limited as the study populations in most of these early studies were small with a limited follow-up period, mostly up to 1 year. Also, there are only a limited amount of studies[12,14] that used standardization of treatment parameters.

In our present study we investigated the long-term outcome of IOP and safety after treatment with MP-TSCPC for patients with various forms and stages of glaucoma.

METHODS

This is a prospective, interventional case series of patients with glaucoma treated in the University Eye Clinic of the Maastricht University Medical Center, Maastricht, the Netherlands, between November 2016 and May 2018 and this study followed the principles of the Declaration of Helsinki.

Patients with moderate to advanced glaucoma were offered treatment with MP-TSCPC, as an alternative to standard glaucoma filtration surgery or cyclodestruction, in case of uncontrolled glaucoma despite maximally tolerated topical and/or systemic IOP-lowering medication, or previous glaucoma surgery. Patients with maximal topical and/or systemic IOP-lowering medication and a high risk for conventional glaucoma surgery and/or stable (advanced) glaucoma were also included with the aim to lower their number of IOP-lowering medication. Exclusion criteria were

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active neovascular glaucoma, active uveitis with secondary glaucoma, or scleral thinning > 1 clock hour.

Baseline characteristics included age, sex, glaucoma type, previous glaucoma surgery, lens status, number of glaucoma medications, preoperative IOP (mm Hg), and preoperative corrected distance visual acuity (CDVA).

All patients were treated by a standardized treatment protocol. Treatments were performed by 2 glaucoma surgeons (R.M.P.C.d.C., C.G.M.M.S.) in the operating room. After administering sub-Tenon's anesthesia (a mixture of mepivacaïne 2% and 75^{E} Hyason), patients underwent micropulse TSCPC (MicroPulse P3 probe, Iridex cyclo G6 laser system, Mountain View, CA) at 2000 mW at a duration of 80 seconds (when IOP < 30 mm Hg) or 90 seconds (when IOP > 30 mm Hg) per hemisphere and at a 31.3% duty cycle. Both hemispheres were treated while the MP3 probe was being applied in a continuous movement with steady pressure on the ocular globe. During treatment, 3 and 9 o'clock hours, previous sites of glaucoma surgery (filtering and drainage implant areas), and places of scleral thinning were avoided. In cases of retreatment, the same parameters were used with an increase of power to 2100 mW (second treatment) or 2200 mW (third treatment). Postoperative therapy included topical tobramycin 0.3% combined with dexamethasone 0.1% (Tobradex; Alcon, Fort Worth) eye drops for 9 days and IOP-lowering medications were withdrawn if appropriate. Patients were followed-up postoperatively at 1 day, 1 week, and 1, 3, 6, 12, 18, and 24 months. At all postoperative visits IOP and the number of IOP-lowering medication were recorded. A slit-lamp examination was performed to detect treatment complications, (eg, corneal pathology, anterior chamber reaction, cystoid macular edema, choroidal detachment, or other ocular abnormalities). If patients reported visual complaints also, then CVDA was performed. Hypotony was defined as IOP lower than 6 mm Hg measured at ≥ 2 consecutive follow-up visits. All patients with at least 12 months of follow-up were included in this study.

Treatment success was defined as an IOP reduction of > 20% compared with baseline or a decrease in the number of IOP-lowering medications with stable target IOP.

RESULTS

Baseline characteristics are shown in Table 1. A total of 141 eyes of 136 patients were included. The mean age was 67.2 ± 14.5 years (range, 18 to 92 y); 79 were male individuals (56%) and 62 were female individuals (44%). Primary glaucoma was diagnosed in 99 patients (70.2%) and secondary glaucoma in 42 patients. Secondary glaucoma included inactive neovascular disease (13 patients), vitrectomy with the use of silicone oil (10), uveitis (7), trauma (6), a history of complicated cataract surgery (3), secondary lens implantation (2), or perforating keratoplasty (1). In 59 of 141 eyes (41.8%), prior glaucoma surgery was performed. Prior glaucoma surgery included trabeculectomy (34 eyes), Baerveldt glaucoma implant (20), cyclocryocoagulation (6), Allergan XEN-gel stent implant (4), and InnFocus/Santen MicroShunt (3). In 7 of 59 patients, multiple types of glaucoma surgery were performed before MP-TSCPC. Pseudophakia was present in 67 patients (47.5%), and aphakia in 14 patients (10%). Pretreatment CDVA was lower than 0.05 Snellen (> 1.3 LogMar) in 34 patients, 0.05 to 0.5 Snellen (1.3 to 0.3 LogMar) in 47 patients, and better than 0.5 Snellen (< 0.3 LogMar) in 60 patients.

TABLE 1. Demographics of Study Population

No. eyes (N)	141
Age (y)	67.2 ± 14.5 (range, 18-92)
Sex, male, n (%)	79 (56)
Glaucoma, n (%)	
Primary	99 (70.2)
Secondary	42 (29.8)
Neovascular	13
Postvitrectomy	10
Uveitis	7
Trauma	6
Complicated phaco procedure	3
Secondary IOL implant	2
Perforating keratoplasty	1
Patients with prior glaucoma surgery, n (%)	59 (41.8)
Trabeculectomy	34
Baerveldt glaucoma implant	20
Cyclo cryocoagulation	6
XEN implant	4
Microshunt implant	3
Lens status	
Pseudophakic	67
Phakic	60
Aphakic	14

IOL indicates intraocular lens.

IOP results and the number of used glaucoma medications are shown in Tables 2 and 3. The mean preoperative IOP was 23.5 ± 9.4 mm Hg [range, 5 to 56 mm Hg (< 30 mm Hg in 110 patients (78%) and ≥ 30 mm Hg in 31 patients (22%)]. Postoperatively, mean IOP significantly dropped ($P < 0.0001$) at 1 day, 1 week, and 1, 3, 6, 12, 18, and 24 months to 17.1 ± 6.1, 13.1 ± 5.8, 15.9 ± 7.5, 16.2 ± 6.4, 16.6 ± 5.6, 16.8 ± 8.4, 17.0 ± 7.8, and 16.8 ± 9.2 mm Hg, respectively (Fig. 1). An IOP between 6 and 21 mm Hg was achieved in 78.2% (111/141), 74.4% (67/90), and 80% (40/50) of patients after, respectively, 12, 18, and 24 months of follow-up. In the 2-year cohort, IOP values between 6 and 21 mm Hg were reached in 80% at 12, 18, and 24 months. The mean IOP reduction in our study was 27.8%, 24.1%, and 28.6% after 12, 18, and 24 months. After 2 years, an IOP reduction of at least 20% was achieved in 66%, 62%, and 60% of patients after respectively 12, 18, and 24 months.

Both preoperative and postoperative IOP levels were significantly lower in the primary glaucoma group in comparison

TABLE 2. IOP and Number of Glaucoma Medications in Total Patient Cohort

	Pre	Day 1	Week 1	Month 1	Month 3	Month 6	Month 12	Month 18	Month 24
No. eyes	141	134	137	139	136	139	141	90	50
IOP (mm Hg), mean ± SD	23.5 ± 9.4	17.1 ± 6.1*	13.1 ± 5.8*	15.9 ± 7.5*	16.2 ± 6.4*	16.6 ± 5.6*	16.8 ± 8.4*	17.0 ± 7.8*	16.8 ± 9.2*
No. medication, mean ± SD	3.3 ± 1.4	3.3 ± 1.4	3.2 ± 1.5	2.9 ± 1.5*	2.7 ± 1.4*	2.6 ± 1.5*	2.6 ± 1.5*	2.5 ± 1.4*	2.2 ± 1.5*

*Significant $P < 0.0001$ compared with preoperative values.
IOP indicates intraocular pressure.

TABLE 3. Treatment Results in 2-year Follow-up Patient Cohort

	Pre	Month 12	Month 18	Month 24
No. eyes	50	50	50	50
IOP (mm Hg), mean ± SD	23.4 ± 8.3	16.9 ± 9.2*	17.8 ± 8.7*	16.8 ± 9.2*
No. medication, mean ± SD	3.0 ± 1.7	2.3 ± 1.6*	2.2 ± 1.6*	2.2 ± 1.5*
Mean IOP reduction, %	—	27.8	24.1	28.6
% Patients with oral acetazolamide	40	12	12	12
% Patients with retreatments	—	18	24	24
% Patients with > 20% IOP reduction	—	62	60	60
% Patients with medication reduction	—	44	44	50
IOP reduction > 20% and medication reduction, %	—	28	26	30
IOP reduction > 20% or medication reduction, %	—	80	76	82

*Significant $P < 0.0001$ compared with preoperative values.
IOP indicates intraocular pressure.

with the secondary glaucoma group ($P < 0.0001$), but there were no significant differences in postoperative treatment effect/IOP change between both groups. In addition, no significant IOP differences were found in postoperative IOP between the different subgroups with secondary glaucoma, or between different lens conditions. Both preoperative and postoperative IOP values were significantly lower in the group after previous glaucoma surgery in comparison with the group with no history of glaucoma surgery ($P < 0.0001$), but there were no significant differences between these groups in treatment effect/IOP change. No significant correlation was found between preoperative IOP and postoperative IOP change, or age and postoperative IOP.

The mean preoperative numbers of IOP-lowering medication was 3.3 ± 1.4 (range 0 to 5). The mean postoperative numbers of IOP-lowering medication at 1, 3, 6, 12, 18, and 24 months were significantly lower at all time points ($P < 0.0001$), that is, 2.9 ± 1.5, 2.7 ± 1.4, 2.6 ± 1.5, 2.6 ± 1.5, 2.5 ± 1.4, and 2.2 ± 1.5, respectively. Preoperative oral acetazolamide (Diamox) was used in 56 of 141 patients (39.7%) and could be reduced to 18 of 141 eyes (12.8%), 11 of 90 eyes (12.2%), and 7 of 50 eyes (14.0%) after, respectively, 12, 18, and 24 months. In the patient group with 2 years of follow-up, 44%, 44%, and 50% of patients needed fewer medications after treatment after respectively 12, 18, and 24 months. In this group, oral acetazolamide was used in 20 of 50 patients preoperatively, and in 6 of 50 patients, after 12, 18, and 24 months, meaning 70% of patients could stop this medication. No correlations were found between the number and class of preoperative medications and the postoperative IOP-lowering effect.

A preoperative CDVA > 0.05 on the Snellen chart was present in 107 of 141 eyes; 34 of 141 eyes had a preoperative CDVA < 0.05 on the Snellen chart (range no light perception −finger counting). Evaluation of CDVA for the 1-year cohort was done in eyes with a preoperative CDVA > 0.05 on the Snellen chart. Postoperative CDVA at 1 year of follow-up was available in 77 of 107 patients with a preoperative CDVA > 0.05 (1.3 LogMar) on the Snellen chart. In this group, the mean Logmar VA was 0.36 (range, −0.18 to 1.30) preoperatively and 0.46 (range, −0.18 to 1.30) after 1 year of follow-up. In this group, 35 of 77 patients (45.5%) lost 1 to 2 lines of VA. Loss of > 2 lines VA was seen in 19 of 77 eyes (24.7%), caused respectively by retinal disease (6), progression of glaucoma (6), cataract (3), and unexplained vision loss (4). Postoperative CDVA at 2 years of follow-up was available in 24 of 37 eyes with a preoperative CVA > 0.05 on the Snellen chart. In this group, the mean Logmar VA was 0.27 (range, −0.18 to 1) preoperatively and 0.32, 0.36, and 0.30 (range, −0.18 to 1.30) after 12, 18, and 24 months of follow-up. In this group, 15 of 24 eyes (62.5%) lost 1 to 2 lines of VA. Loss of > 2 lines VA was seen in 6 of 24 eyes (25%), caused, respectively, by retinal disease (4), glaucoma (1), and cataract (1).

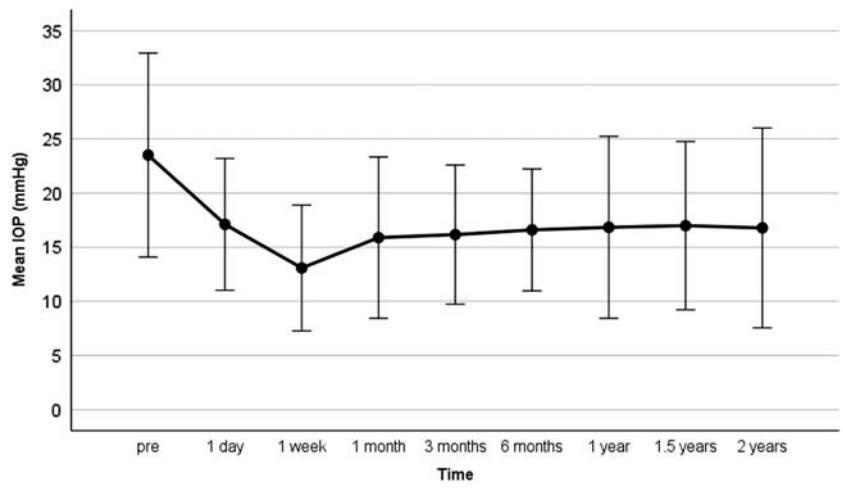

FIGURE 1. Mean IOP (±1 SD) at various preoperative and postoperative visits in total study cohort. IOP indicates intraocular pressure.

In the early postoperative period (< 3 mo), the following complications occurred in 5 of 141 eyes (complication rate, 3.5%): fibrinous anterior chamber reaction (1), hypotony maculopathy (1), rejection of corneal graft (1), and cystic macular edema (2). All of these complications were reversible after treatment (prolonged use of topical steroid treatment or reducing glaucoma medication). In the late postoperative period only 1 of 141 eyes (0.7%) developed a hypotony with an IOP of 3 mm Hg. This patient had an ophthalmic history of congenital cataract, aphakia, vitrectomy with the use of silicone oil (and oil removal) after retinal detachment and neovascular glaucoma and developed a numerical hypotony 2 months after second treatment. No visual complaints and no signs of hypotony maculopathy were present.

In this study, 42 of 141 eyes received 47 retreatments. After 12 months, 43 retreatments were performed in 39 of 141 eyes (27.6%). After 18 months, 27 retreatments were performed in 25 patients (27.8%). In the patient group with 2 years of follow-up, retreatment was performed in 9 (18%), 12 (24%), and 12 (24%) patients after, respectively, 12, 18, and 24 months with a mean number of retreatments of 1.17 (14 retreatments in 12 patients). The mean time between treatment and retreatment was 176 ± 115 days. In 23 of 42 patients (54.8%), treatment success (> 20% IOP lowering or less medication) was already achieved after the first treatment. Retreatment in this patient group was performed to gain additional IOP lowering or further reduction of medication. After retreatment(s) 27 of 42 patients (64.3%) achieved treatment success. No success after retreatment could be reached in 15 of 42 (35.7%) patients. Conversion to other glaucoma surgery was necessary for 6 of 15 patients (3 Baerveldt implants, 2 cyclocryotherapy, and 1 phacoemulsification with iStent implantation). There were no significant differences in the rate of retreatment or retreatment success in patients with primary glaucoma compared with secondary glaucoma. In addition, lens status, prior glaucoma surgery, or time between treatment and retreatment were no significant factors to predict the rate of retreatment or retreatment success/failure.

Treatment success at 12, 18, and 24 months was achieved in, respectively, 102 of 141 eyes (72.3%), 74 of 90 eyes (82.2%), and 40 of 50 eyes (80.0%). In the patient group with 2 years of treatment follow-up (Table 3), success was achieved in 80%, 76%, and 80% after, respectively, 12, 18, and 24 months.

DISCUSSION

In this study we studied the outcome of IOP and safety after treatment with MP-TSCPC in patients with glaucoma. Success (> 20% IOP reduction or less medication with stable target IOP) was achieved in 80% of patients after 2 years of follow-up. An IOP reduction of > 20% was achieved in 60% of patients, and 50% of patients could reduce their number of glaucoma medications. In 30% of patients, both targets were reached (> 20% IOP reduction and fewer medications).

In the study of Zaarour et al,[14] treatment parameters were similar to our treatment protocol, which makes the study very comparable with ours. They found success rates (IOP between 6 and 21 mm Hg or > 20% IOP reduction) of 73.3% and 66% after, respectively, 12 and 15 months, similar to those found in our study. In the study of Nguyen et al,[15] success (> 20% IOP reduction) after 1 treatment was achieved in 76.8% of patients after 12 months of follow-up, a higher rate compared with our study. However, in our study, the mean IOP reduction after 2 years of follow-up was still 28.6%. Studies of Zaarour et al,[14] Sarrafpour et al,[16] and Nguyen et al[15] showed somewhat higher IOP reduction percentages (30.3% to 46%) at 1 year. A possible cause could be the higher amount (2000 to 2500 mW) and longer duration (90 s/hemisphere) of energy used in the studies of Sarrafpour and colleagues and Nguyen and colleagues. It is known that a higher amount and longer application of laser energy results in lower IOP after micropulse TSCPC. In our study, we used standard 2000 mW and a maximum amount of energy of 2200 mW was used during a third treatment. A second reason may be found in patient characteristics. Patients treated in our study were mainly white. Although we did not document iris color or pigmentation level in our patients, it is possible that laser effects in well-pigmented eyes, for example, in an Afro-American or Arabic population, could be higher in comparison with less pigmented eyes. A third possible reason for a smaller IOP reduction could be the fact that also medication reduction above IOP reduction was a reason to perform micropulse TSCPC in a part of our patient population. The use of glaucoma medication decreased in our study from 3.3 preoperatively to 2.2 after 2 years of follow-up. This medication reduction is higher when compared with the studies of Sarrafpour (0.6 reduction) and Zaarour (0.5 reduction) and is comparable with the study of Yelenskiy (1.0 reduction).[13,14,16]

The second goal of our study was to investigate the safety of the MP-TSCPC procedure in these patients by evaluating the number and duration of postoperative complications.

VA decreased > 2 lines on the Snellen chart in 24.7% and 25% of patients after, respectively, 1 and 2 years of follow-up. Most of the VA losses were related to retinal disease, cataract, or glaucoma progression. At 1 year, 6 patients showed vision loss without explainable cause. We think this may be because of variation in VA measurements during follow-up (eg, 2 of 4 patients showed improved vision after a 2-y follow-up) or likely glaucoma progression. In the studies of Varikuti et al[12] and Sarrafour et al,[16] decreases in VA were found in 20.83% and 18.8% of patients after, respectively, 12 and 6 months of follow-up.

In our study, early postoperative complications occurred in 5 of 141 eyes, all reversible after treatment. One patient developed a persistent hypotony in a late postoperative stage (5 mo after second treatment), without any complaints or signs of hypotony maculopathy. Mild prolonged postoperative inflammation or transient hypotony were also found in other studies.[10–12,14,15,17] Major complications like persistent hypotony or phthisis bulbi were not found in the studies of Zaarour and colleagues, Nguyen and colleagues, and Sarrafour and colleagues. The studies of Williams et al[17] and Emanuel et al,[10] showed higher complication rates of postoperative inflammation, hypotony, and phthisis. Post-treatment mydriasis is another possible complication after TSCPC, which may lead to clinical findings like glare or other visual discomforts. This observation has now been described several times,[18–20] however was not mentioned in all studies.[8,10,13,14,17,21] No cases of pupillary mydriasis after micropulse TSCPC were observed in our study; however, this may have been overlooked and could perhaps be a reason for unexplained visual loss in several cases. Another limitation of our study is the fact that VA was only monitored after patients experienced visual complaints, and no screening for (sub)clinical macular edema was performed in patients without visual complaints. In our study, clinical

macular edema with transient visual impairment was found in 2 of 141 eyes. In other studies, the visual loss has been described. In the study of Zaarour et al,[14] in which the same treatment parameters were used as in our study, a transient visual decline in the early 1-month postoperative period was found, whereas VA on the longer term was comparable with preoperative levels and remained stable after 12 and 15 months. Other studies[10,17,22] described that use of higher energy levels or longer treatment time during mp-TSCPC could have a higher influence on VA, although VA loss was also limited by fluctuation in VA in glaucoma populations. No other complications were found in our study.

Although there were significant IOP differences between patients with primary and secondary glaucoma in both preoperative and postoperative IOP levels, there was no significant difference in the amount of IOP lowering after TSCPC between both groups. This indicates that TSCPC could be a good alternative for invasive incisional glaucoma surgery in patients with secondary glaucoma and for patients for whom incisional surgery could be difficult to perform, for example, because of scarred or lower quality of conjunctival tissue.

In our data, no significant differences were found in IOP-lowering effect and complication rate of TSCPC in relation to lens status. Especially in regard to patients with aphakia, this shows that TSCPC is a good and safe alternative for invasive incisional glaucoma surgery for high-risk patients (increased risk for complications like hypotony or expulsive hemorrhagic bleeding).

In summary, our data show that after 2 years of follow-up, micropulse TSCPC is a safe and effective treatment for lowering IOP and decreasing the number of IOP-lowering medications. Micropulse TSCPC can also be considered as a good alternative treatment option for patients after failed incisional glaucoma surgery or patients who are at high risk for incisional surgery.

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