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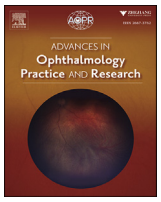

Full Length Article

Micropulse diode laser therapy in refractory glaucoma

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ABSTRACT

Purpose: Description of safety and efficacy of micropulse Transscleral cyclophotocoagulation as a treatment option for refractory glaucoma.

Methods: This is a prospective study including 39 eyes of 31 patients followed for refractory glaucoma, who benefited from transscleral cyclophotocoagulation using a microplused laser. The main indication for the procedure was increased ocular pressure refractory to quadritherapy in various types of glaucoma. The patients were treated using iridex Cyclo G6 laser with a Micropulse P3 infrared probe with a wavelength of 810 nm. The parameters for the procedure were a duration of 90 s per hemisphere with a power of 2000 mW and an energy of 180 J. Both the upper and lower hemispheres were treated in the same procedure, sparing the 3 o'clock and 9 o'clock meridians, and all the patients benefited from a single treatment session. The following parameters were evaluated: ocular pain and overall tolerance; visual acuity; and the evolution of IOP postoperatively up to 9 months.

Results: The glaucoma subtypes treated are as follows: primary open-angle glaucoma (n = 05), chronic angle-closure glaucoma (n = 13), neovascular glaucoma (n = 07), aphakic glaucoma (n = 06), malignant glaucoma (n = 04), post-traumatic angle recession (n = 02), and inflammatory glaucoma (n = 02). The mean pre-operative intraocular pressure was 42.3 ± 5.2 mmHg and the mean post-operative intraocular pressure at 9 months was 16.9 ± 1.9 mmHg. The reduction in IOP was 49.9%. The average number of intraocular pressure-lowering medications used prior to surgery was four, and the average number of medications used at the 9-month post-operative visit was 2.0 ± 1.2 (70.3% of patients were on dual therapy). The overall success rate was 60.5%.

Conclusions: Micropulse transscleral cyclophotocoagulation appears to be a safe and efficient treatment for refractory glaucoma. Its indications should therefore be broadened and proposed early in various situations.

1. Introduction

Refractory glaucoma occurs when the intraocular pressure (IOP) is not low enough to prevent the progression of glaucomatous optic neuropathy despite optimal medical treatment.[1] It then becomes urgent for the practitioner to lower the intraocular pressure in order to relieve the patient's pain and prevent the progression towards loss of visual acuity. These therapeutic options may include, filtering surgery and its components and, in some cases, cyclo-destructive procedures. A new, less aggressive technic, based on alternating photo-coagulation and rest intervals, has come into use since 2010: micropulse transscleral cyclophotocoagulation.[2] It allows for a reduction in the energy dispersion to the structures surrounding the ciliary processes.[3] A diode laser, with a wavelength of 810 nm, is applied opposite to the ciliary body as is the case in standard transscleral cyclophotocoagulation, but the delivery of the beam respects repeated cycles of phases during which the laser operates (ON), alternated with phases of rest (OFF), which allows the ciliary body to cool down in order to reduce tissue damage and damage to adjacent structures.[3] The results and methodologies of the studies evaluating this technic are heterogeneous, but seem to show an efficacy comparable to that of conventional transscleral cyclophotocoagulation but with a better tolerance.[2,4] This method has been successfully used in diode laser photocoagulation for the treatment of retinal pathologies.[5–10] Through this prospective study, we describe our experience with transscleral micropulse diode laser cyclophotocoagulation in cases of glaucoma refractory to optimal medical treatment without prior surgery. We

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also suggest the indication for the micropulse laser in some patients treated for refractory glaucoma.

2. Patients and Methods

We conducted a prospective interventional and non-comparative study spread over a period of one year, from July 2020 to August 2021, in the Adult Ophthalmology Department of the 20 August 1953 Hospital of Casablanca-Morocco. It involved 39 eyes, in patients with persistent ocular hypertension despite quadritherapy (local and oral), and followed regularly at the facility. The main indication was persistent increased ocular pressure despite quadruple therapy. The aim of this study was to lower their IOP in order to preserve their visual potential and relieve their pain. Patients under 18 years of age, patients who had undergone filtering surgery or cyclodestruction or with scleral disorders such as scleromalacia were excluded.

All the patients in our study underwent a detailed ophthalmological examination with a medical record and a data sheet for follow-up. The parameters recorded were: ocular pain, visual acuity, IOP, local and general treatment, and possible postoperative complications.

The device we use is the Iridex Cyclo G6 laser with a Micropulse P3 infrared probe with a wavelength of 810 nm (Fig. 1). The procedure is performed on an outpatient basis. After informed consent is taken from the patient and a favourable pre-anaesthetic consultation, the micropulse laser procedure is performed in the operating room, under loco-regional retro bulbar or peribulbar anaesthesia or under general anaesthesia. We set the machine to a duration of 90 s with a power of 2000 mW using the MP3 probe: sterile field and implementation of a blepharostat and disinfection of the conjunctival cul-de-sacs; marking of 3 o'clock and 9 o'clock of the meridians; application of viscoelastic product on the sclera; the probe must be perpendicular to the sclera, the notch oriented towards the limbus and located at 1.5 mm from the limbus; we made 9 trips on the upper hemisphere for 90 s and then 9 other trips on the lower hemisphere for 90 s as well, while avoiding the 3 o'clock and 9 o'clock meridians (Fig. 2).

Postoperatively, we prescribed Dexamethasone and Indomethacin for 15 days, with regular postoperative follow-up. The following parameters were evaluated: ocular pain and general tolerance, visual acuity, and evolution of intraocular pressure (IOP) at Day 1 (D1), Day 14 (D14), Month 1 (M1), Month 3 (M3), Month 6 (M6), Month 9 (M9), and then every 3–4 months once the tone was stable. Tapering off of hypotonic medications was done progressively from the first postoperative month, starting with the oral medications followed by a reduction of the eye drops at the rate of one molecule each month until a constant intraocular pressure is obtained for at least 3 consecutive months. A detailed ophthalmological examination was performed at each review, and all side effects and complications were noted. All patients had their tone measured with a pulsed air tonometer before and after surgery because of the pain and the difficulty of using an applanation tonometer. An average of 3 consecutive measurements at 5-min intervals was taken for each patient. Efficiency is defined by a constant IOP between 10 mmHg and 21 mmHg for at least 3 consecutive months, suppression of at least one hypotonic medication and alleviation of the pain. All patients received a single laser session. In case of failure, other therapeutic alternatives were proposed to the patients, considering the non-necessity of repeating the laser treatment. The data was processed using SPSS version 21 software. The threshold of significance was retained for a value of $P < 0.05$.

Fig. 1. Cyclo G6 iridex laser with a Micropulse P3 infrared probe.

3. Results

Our study included 39 eyes of 31 patients, of whom 17 were male (54.8%) and 14 were female (45.2%). The presentation was unilateral in 23 patients (74.2%), with 13 right eyes (56.5%) and 10 left eyes (43.5%), and eight patients (25.8%) had bilateral presentation. The average age was 57.5 ± 4.8 years.

Clinically, pain was the most common sign, found in all our patients and accounted for the most frequent cause for consultation. A decrease in visual acuity was noted in 71.8% (n = 28 eyes), in particular, 14 eyes had a corrected visual acuity (VA) of “counting fingers at 1 m", 7 eyes had a VA between 1/10 and 2/10, and the other 7 eyes had a VA between 3/10 and 4/10. The remaining 11 eyes (28.2%) were non-functional, reduced to negative light perception.

The aetiologies were dominated by chronic glaucoma in 18 cases (46.1%), of which 05 cases of Primary Open Angle Glaucoma and 13 cases of Chronic Closed Angle Glaucoma, 07 cases (17.9%) of Neovascular Glaucoma (of which 05 cases of Complicated Severe Proliferative Diabetic Retinopathy and 02 cases of Central Retinal Vein Occlusion). There were also 06 cases (15.3%) of aphakic glaucoma, 04 cases of malignant glaucoma (10.25%) which included 3 cases that occurred after posterior segment surgery with gas tamponade and one case of bursting of the eye ball, and 02 cases (5.1%); Angle recession after contusive trauma, and inflammatory glaucoma (recurrent uveitis in Behcet's disease and severe Cogan's syndrome) (Table 1).

The ophthalmological examination revealed an altered ocular surface in four patients (12.9%), corresponding to superficial punctate keratitis. Cataract was more or less advanced but without dislocation or subluxation of the lens in the 21 phakic patients, and 4 patients (12.9%) were pseudophakic but without abnormal implant position or surgical sequelae, all of whom had angle-closure glaucoma. There was no surface alteration or presence of vitreous in the anterior chamber or at the angle in 6 aphakic patients. Fundus analysis was possible in only 50% of the patients, who showed a very advanced excavation of the papilla.

The mean pre-operative IOP was 42.3 ± 5.2 mmHg. All patients were on quadritherapy on admission, consisting of oral acetazolamide and 3 different tension lowering eye drops. The procedure was performed under loco-regional anaesthesia in most patients. Only 5 patients (12.8%) received additional sedation and only one patient was treated under general anaesthesia. In addition, 04 patients (10.2%) received intravascular analgesics immediately after the procedure.

With a mean follow-up of 11.2 ± 3 months, pain was alleviated in 87.10% of cases at 48 h and 92.30% (36 eyes out of 39) after 7 days, with a good tolerance to the laser at 98% (Fig. 3).

89.9% of the participants had a decrease of the IOP at the end of the first month under quadritherapy and 79.5% under triple therapy in the 3rd month. However, the rate of the patients who maintained a stable IOP dropped to 70.3% of patients under dual therapy at 6th and 9th month. Thus, there was a mean reduction of tension lowering medications of 2.0 ± 1.2 molecules (Fig. 4).

The mean preoperative IOP was 42.3 ± 5.2 mmHg. The evolution of IOP was 39.9 ± 2.1 mmHg at Day 14; 28.6 ± 1.9 mmHg at first month; 17.2 ± 3.2 mmHg at 3rd month; 16.7 ± 2.0 mmHg at 6th month; and 16.9 ± 1.9 mmHg at 9th month (Fig. 5). On average, the reduction in IOP was 49.9%.

Depending on the etiology and at 9 months postoperatively, the success rate under dual therapy was 100% in traumatic glaucoma, neovascular glaucoma, and primary open angle glaucoma. 75% (3 of 4 cases) in malignant glaucoma, 50% in aphakic glaucoma, and inflammatory glaucoma, and 23.07% (3 of 13 eyes) in angle closure glaucoma. The overall success rate was 60.50% (Fig. 6).

Concerning visual acuity: of the 28 functional eyes, 14 eyes had an

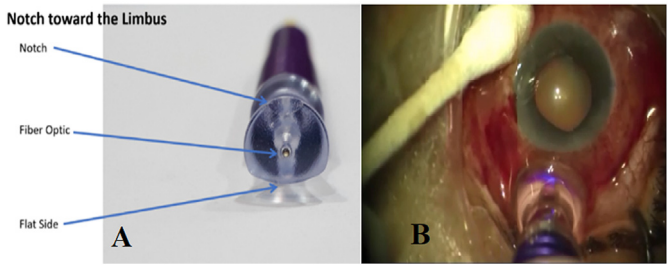

Fig. 2. A: MP3 probe head with Notch, Fiber Optic and Flat Side; B: notch position at 1.5 mm from the limbus during the procedure.

improvement in acuity, gaining 2 lines on average. On the other hand, there were two cases of macular oedema at day 7 (one case in a primary open angle glaucoma and one case in an aphakic glaucoma), revealed by a visual decline and confirmed by OCT. Only the aphakic oedema case responded well to intravitreal injection of Dexamethasone implant after 3 months.

The main immediate complication was anterior chamber inflammation, found in 4% of patients, which regressed after 7 days. No phthisis bulbi, scleral complications, bleeding or sympathetic ophthalmia were noted.

Table 1
Distribution of the aetiologies of IOP increased according to the types of glaucoma involved.

Type of glaucoma/etiology		Number (Percentage %)
Chronic Glaucoma		n = 18(46.1%)
Primary Open Angle Glaucoma	n = 05	
Chronic angle-closure glaucoma	n = 13	
Neovascular Glaucoma (NVG)		n = 07(17.9%)
Severe proliferative diabetic retinopathy	n = 05	
Central retinal vein occlusion	n = 02	
Aphakic Glaucoma		n = 06(15.3%)
Malignant Glaucoma		n = 04(10.25%)
Posterior segment surgery	n = 03	
Bursting of the globe operated	n = 01	
Post-traumatic angle recession		n = 02(05.1%)
Inflammatory glaucoma		n = 02(05.1%)
Uveitis in Behcet	n = 01	
Cogan syndrome	n = 01	
Total		n = 39(100%)

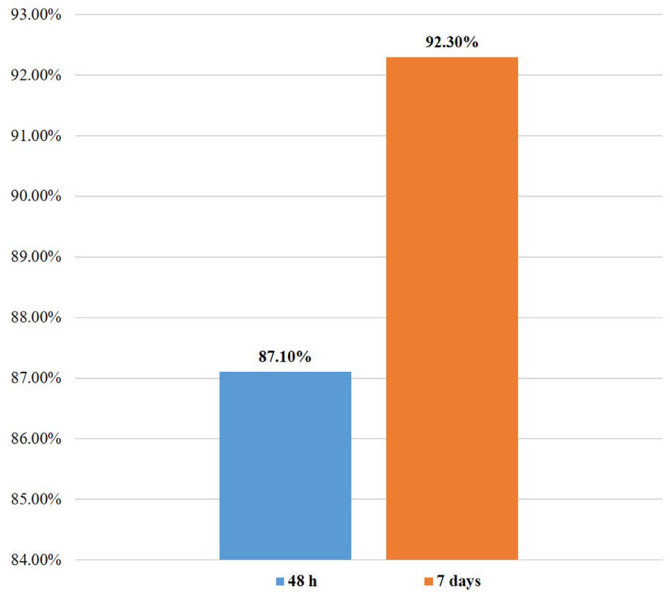

Fig. 3. Evolution of the pain in post-operation.

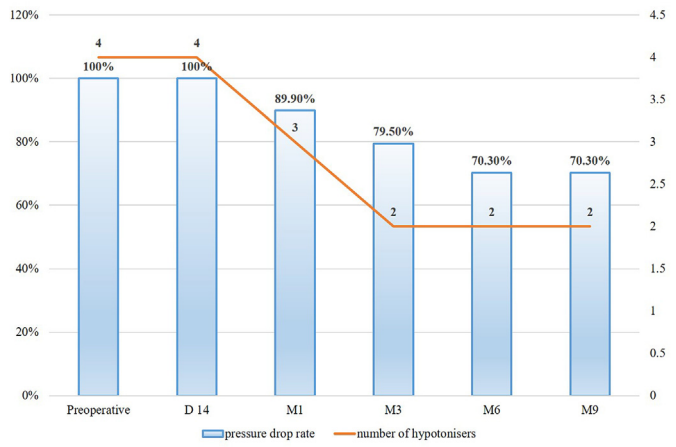

Fig. 4. Evolution of the rate of patients with IOP reduction according to the reduction of hypotonisers

4. Discussion

The management of increased ocular pressure refractory to maximal medical treatment, poses a challenge for practitioners. The goal is to achieve an optimal intraocular pressure in order to stop the progression of optic neuropathy and to alleviate ocular pain. Other than surgery, transscleral cyclodestruction using Nd: YAG laser was the technique of choice in the treatment of refractory glaucoma, followed by cyclocryotherapy as second choice. Despite many advantages and some efficacy, the use of the Nd: YAG laser resulted in many postoperative complications, such as severe inflammatory reactions as well as significant loss of visual acuity.[11,12] Transscleral micropulse of the ciliary body using a diode laser (810 nm) has been shown to be equally effective with less postoperative inflammatory reaction due to the fact that the absorption by the melanin of the pigmentary epithelium is three times higher for a wavelength of 810 nm compared to a wavelength of 1064 nm, as such, in order to obtain same histological effect, the level of energy required is lesser with the diode laser.[13] In this case, the aim is destroying the ciliary body by targeting the melanin contained in the pigmented epithelium of the ciliary body, thus resulting in a decrease in the secretion of the aqueous humor and, consequently, lowering the intraocular pressure. A second component for the mechanism of action, involving an increase in the aqueous humor drainage through the uveoscleral pathway, has also been reported.[14] A third mechanism of action for the Micropulse has recently been proposed by Johnstone[15] et al., after an experimental study on monkeys (m. Fascicularis).[15]

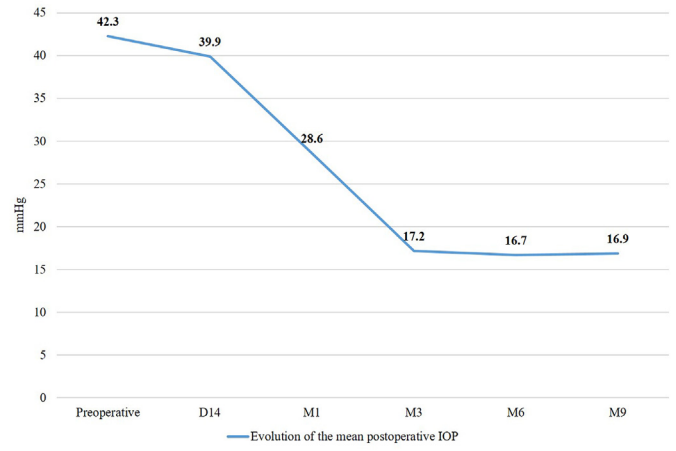

Fig. 5. Evolution of mean postoperative IOP.

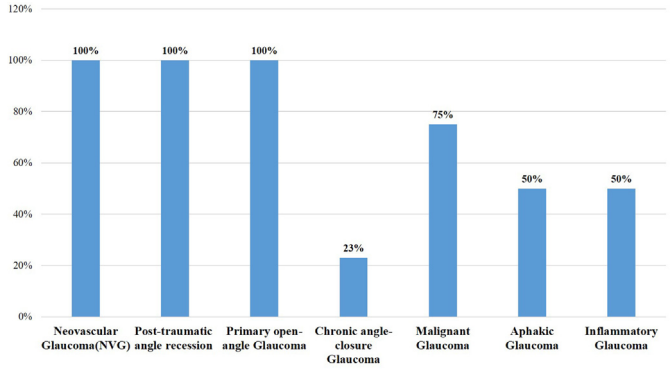

Fig. 6. Rate of IOP decrease according to the type of glaucoma.

According to the authors, the pigmented epithelium is not necessarily involved in the mechanism of action. In contrast, Micropulse would actually act on the longitudinal fibers of the Ciliary muscle (CM), causing a displacement of the Scleral Spur (SS) in a posterior and inward direction, which in turn modifies the configuration of the trabecular meshwork (TM) and the outflow tract of the aqueous humor. This effect is similar to that of pilocarpine, which causes enlargement of the trabecular spaces and expansion of the Schlemm's canal area, reducing the tendency towards collapse or narrowing of the canal lumen, thus, facilitating the drainage of aqueous humor.[16] It is difficult to conclude at this point if one of these suggested mechanisms of action has the most effect on IOP or whether the IOP lowering effect of this technique is in fact a combination of all mechanisms.

In the literature, the average power adopted was 2000 mw, with a variable duration ranging from 50 s to 130 s, an average of 90 s per hemi meridian while avoiding the 3 o'clock and 9 o'clock meridians, and this was respected in our study.[17]

There is no standard protocol concerning the dosage and duration of postoperative steroid therapy. However, this treatment is important and justified given the intensity of the inflammatory reaction in all patients treated by diode laser. Some authors prescribe steroid therapy inform of eye drops and ointment for a period of 3 weeks.[18,19] In our study, the synergistic use of Dexamethasone and Indomethacin allowed for rapid and effective treatment of post-laser inflammation by preventing post-operative oedema and was prescribed over a shorter period of time of 2 weeks.

Our post-operative follow up was simple. Briefly summarizing our observations, certain types of glaucoma are more sensitive to the therapy, as evidenced by the 100% success obtained with dual therapy at the end of follow-up. These include post-traumatic glaucoma with angle recession, neovascular glaucoma and primary open-angle glaucoma. In fact, it appears in these cases that the best therapy is one that lowers the production of aqueous humor. The success in malignant glaucoma (although the initial management remains primarily surgical to try to equalize the pressures) consolidates the result on the secretion reducing effect of the laser. However, in case of chronic inflammation with enough advanced fibrosis (as in aphakic glaucoma and inflammatory glaucoma) and above all a permanent obstacle to the flow of aqueous humor (the case of angle-closure glaucoma), the there is a disequilibrium with a tendency development of persistently increased ocular pressure which then often requires the addition of filtering surgery. The overall success rate was 60.50%, under dual therapy at 9 months postoperatively, and with a single laser session. We keep our patients under dual therapy in view of the difficulty in long-term follow-up, for fear of a recurrence of ocular increased pressure which could not be controlled in time. These are also patients with visual potential in whom the hope of continuing to see still remains.

Royer et al.[18] obtained pain alleviation in 87% of patients in all types of glaucoma. Martin et al.[20] obtained 96.7% in their series of 30 painful and blind eyes. Their best predictive factor of success for the sedation of ocular pain is the reduction of the intraocular pressure by more than 30% compared to its initial value. We had rates comparable to those of the literature, notably an alleviation of pain in 87.10% of the participants at 48 h and 92.30% (36 eyes out of 39) at day 7.

Regarding intraocular pressure, several investigations have demonstrated the efficacy of cyclophotocoagulation with a range of from 27% (Yelenski et al.[21]) to 63% (Abderrahman et al.[22]). In our study, with an IOP reduction rate of 49.9% at 9 months post-laser and with dual therapy, the result is very satisfactory when compared to that obtained by Mohsen et al.[22] (53.2% reduction) with a comparable sample of patients, although they used more tension reducing molecules at month 6 post-laser. The study is also comparable to the result of Tarib[23] with a reduction rate of 56.08% but a smaller sample of patients. The average of the evolution of IOP in some recent studies varies around 20 mmHg at Month 1[23,24], with good regression at Month 3[23,24] and normalizes at Month 6 around 16 mmHg. [24,25] These figures are consistent with those of our study, demonstrating the good long-term efficacy of transscleral micropulse laser.

Another objective in our study was the reduction of the number of pressure reducing molecules or their suppression when the intraocular pressure was stable. All our patients, after one month postoperatively, stopped the oral acetazolamide, with approximately 89.9% of patients having lowered their intraocular pressure. The decrease was done each month by removing one eye drop molecule depending on the decrease or not of the intraocular pressure, until a pressure of between 10 and 21 was obtained for 3 months. A few studies report the rate of decrease in the number of tone reducing molecules: Tarib[23] reports 53.07% (1.60 ± 0.91 molecules) at 6 months, Sarafpour et al.[25] reports 19% (2.5 ± 1.0) decrease at 1 year. In our study, we obtained a 50% (2.0 ± 1.2 molecules) decrease in molecules in 70.3% of patients at 9 months. Our results are close to those of Tarib,[23] and better than those of Sarrafpour et al.[25] This is explained by the use of the same machine parameters during the laser session and the comparable profiles of the patients, contrary to the data of the study by Sarafpour et al.[25]

The probability of a successful treatment is variable, but generally high, with an efficacy rate of 75%–89.5%.[2,4,24,26,27,28] The efficacy rate of the laser in our study is 60.5%, by far the best in comparison with the studies done by Mohsen et al.[22] and Sarrafpour et al.[25] The difference can be explained by the definition of success in each study, but also by the parameters, notably the energy delivered and the power used. Thus, for an energy of 100 J, Sarrafpour et al.[25] in their study including 73 eyes, obtained an efficiency rate of 30%, while Mohsen et al.[22] obtained better (efficiency of 40%) using an energy of 105 J. In our study, with a maximum energy of 180 J, efficiency rate is 60.5%. There seems to be a correlation between the energy delivered and the efficiency rate of the diode laser. In a meta-analysis, Hauber et al.[26] underlined that the higher the total energy levels delivered in a session, the lower the intraocular pressure. With regard to power, according to the study by Sarrafpour et al.,[25] the reduction in intraocular pressure was associated with the power used and the preoperative intraocular pressure, while the reduction in medication was associated with the initial drug load. Notably, they observed a 57% reduction in intraocular pressure at 2500 mW of power and a 30% reduction at 2000 mW of power. In our study, with a power of 2000 mW, the reduction of intraocular pressure is 49.9%, and it should be noted that this reduction concerns 70.3% of our patients under dual therapy at 9 months and after a single session of laser therapy. However, there is no established consensus on the energy to be delivered, the power, the number of impacts, and the duration of application time. Several other factors may account for differences in treatment outcomes, as some subtypes of glaucoma may be more difficult to treat. Tan et al.[2] noted that half of their treatment failures were in patients with neovascular glaucoma. However, their statistical analyses did not identify predictors of treatment failure. Whereas in our study, failure was mostly in angle-closure glaucoma (23%), and somewhat less in aphakic and inflammatory glaucoma (50% success in each category). That said, by

rationalizing all the parameters, the micropulse laser can be used to effectively treat milder cases of glaucoma and, in some cases, it can be offered earlier. Moreover, Nguyen et al.[29] came to the same conclusion.

Eleven eyes (28.2%) were non-functional before laser treatment, and of the remaining 28, 14 patients (50%) showed a gain with an improvement in visual acuity of at least 2 lines on the Snellen scale. Thus, overall, 36% of our patients had an improvement in visual acuity. Emanuel et al.[24] obtained a 16% gain on 84 eyes and Sarrapfour et al.[25] had a 12.5% gain on 73 eyes. This is certainly a better rate, but it should be noted here that compared to other studies, only about one third (1/3) of our patients had no visual potential at the start of treatment.

Several complications have been reported in the literature, depending on the parameters of the settings and the profile of the patients treated. They are dominated by anterior chamber inflammation, which is first, and which is most often moderate and resolves with local anti-inflammatory treatment, followed by conjunctival hyperaemia.[23–25] Our treatment protocol with dexamethasone in the immediate post-laser period has allowed us to considerably reduce its incidence, with 4%. The colour of the iris, in particular dark irises, is often incriminated as a factor predisposing to postoperative inflammation, something that was contradicted by Medow et al.,[30] who, in endoscopy, did not find any difference in ciliary pigmentation between dark and light eyes. Ocular burns are less described in the diode laser cycloenhancement and this is due to the use of a probe that allows exerting a scleral pressure to increase the percentage of energy transmitted to the ciliary body while decreasing the backscattering to avoid lesions of adjacent tissues. [31] In our series, we have no cases of ocular burns. Another factor described is the presence of *peri*-limbal pigmentation, which would be a threat to the success of the treatment because if the conjunctival pigmentation absorbs enough energy to cause surface burns, then there is less energy transmitted to the ciliary processes.[32] A hyphaemia, particularly in neovascular glaucoma, as well as chronic persistent uveitis and ocular hypotonia, have been described.[33] No occurrences of sympathetic ophthalmia were documented similar to Nd: YAG laser cyclophotocoagulation. (7 cases).[34]

Limits of our work: This study is a first in our centre, and our preliminary results have not been compared with other therapeutic alternatives. Also, the number of patients included is insufficient to permit definitive conclusions since there was no randomization of treatment options, the study is therefore limited by selection bias. The Micropulse laser's general effectiveness is well known, but it is still unknown what causes treatment failure and how various glaucoma subtypes could react differently to treatment.

5. Conclusions

The Micropulse transscleral cyclophotocoagulation is an innovative treatment for glaucoma. It is easy to handle, very effective, and has low iatrogenicity. With an increasingly reported success rate, it's included in the management of refractory glaucoma, thus acting by decreasing the volume of aqueous humor secretion and avoiding, if not delaying, filtering surgery and its complications. Therefore, its indications should be broadened and it should be recommended early in various situations.

Study approval

The authors confirm that any aspect of the work covered in this manuscript that involved human patients or animals was conducted with the ethical approval of all relevant bodies and the study was performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from the patient for publication of this case report and accompanying images.

Author contributions

The authors confirm contribution to the paper as follows: MI: as first and corresponding author made substantial contributions to the conception, the design of the work, the acquisition, analysis and interpretation of data; KZ, ASYS: writing the paper, analysis and interpretation of data; AM: the design of the work, analysis and revision of the work; LB, RR, AA: analysis and revision of the work; MEL B: made a significant contribution to the final revision of the paper and approved it.

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Declaration of completing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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