MICROPULSE™ DIODE LASER (810NM) VERSUS ARGON LASER TRABECULOPLASTY IN THE TREATMENT OF OPEN-ANGLE GLAUCOMA: COMPARATIVE SHORT-TERM SAFETY AND EFFICACY PROFILE

DETRY-MOREL M., MUSCHART F*., POURJAVAN S*.*

ABSTRACT

Purpose: Prospective, comparative, randomised study aiming at assessing the safety and the intraocular pressure (IOP) lowering effect of Micropulse™ Diode Laser Trabeculoplasty (810nm)(MDLT) and Argon Laser Trabeculoplasty in patients with open angle glaucoma.

Methods: 26 patients (mean age=67 years) were randomly assigned to undergo either MDLT (16 eyes) (66 applications, 100 msec, 0.6 mJ/pulse, 300μm) or ALT (15 eyes) over 180°. In 5 patients, MDLT was done in one eye and ALT in the other eye. Patients were followed for early IOP spikes and anterior segment inflammation. IOP was recorded at 1 day, 1 week, 1 and 3 months and 3 month intervals thereafter.

Results: Both groups were well-matched for age, glaucoma type, previous laser or surgical procedure, pre-treatment meds. Mean follow-up was 5.2±1.7 months for MDLT and 5.5±2.3 in ALT ($p>0.05$). Mean pre-treatment IOP was 20.7± 3.8 mmHg and 21.6±4.2 mmHg in ALT respectively ($p>0.05$). Mean IOP was significantly reduced compared to the pre-treatment level in both groups at the different visits ($p<0.05$). At 3 months, the mean IOP was not significantly different in MDLT (18.6±5.1 mmHg) vs. ALT (16.7±3.3 mmHg) ($p=0.26$) while the mean IOP decrease was significantly less in MDLT (2.5±2.6 mmHg) than in ALT (4.9±3.4 mmHg) ($p= 0.04$). This corresponded to a mean percentage of IOP reduction of 12.2±11.9 % in MDLT and 21.8±11.1% in ALT respectively ($p=0.03$), as well as an IOP drop ⩾20% compared to the baseline IOP observed in 35.7% in MDLT versus 50% in ALT ($p=0.03$). At 3 months, the mean number of meds was significantly lower in MDLT (2.1±0.8) than in ALT (2.8±0.7) ($p=0.03$). MDLT was uneventful in 100% of patients with no thermal pain and no uncomfortable laser flashes. Anterior segment inflammation was absent or mild in both procedures. MDLT was associated with early moderate IOP spike in one eye with POAG.

Conclusion: At 3 months, Micropulse™ diode laser trabeculoplasty induced significantly less IOP reduction than ALT. The percentage of eyes with an IOP drop ⩾20% was also significantly lower with diode laser than with argon laser trabeculoplasty. MDLT induced minimal anterior segment inflammation and seemed to exhibit a good safety profile. Its IOP efficacy should be still confirmed on a larger sample size and by modifying the treatment parameters.

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* *St Luc University Hospital, Université Catholique de Louvain*

submitted: 21-01-08
accepted: 07-05-08

EVALUATION COMPARATIVE A COURT TERME DE L'INNOCUITÉ ET DE L'EFFICACITÉ DES TRABÉCULOPLASTIES AU LASER DIODE ET DES TRABÉCULOPLASTIES AU LASER A L'ARGON

RESUME

But: Etude prospective, randomisée dont le but est de comparer l'innocuité et l'effet pressionnel observé après trabéculoplastie au laser diode micropulsé^{TM} par rapport à ceux de la trabéculoplastie conventionnelle au laser à l'Argon chez des patients porteurs d'un glaucome à angle ouvert.

Méthodes: 26 patients (âge moyen: 67 ans) (31 yeux) ont été assignés au hasard à recevoir des trabéculoplasties au laser diode micropulsé^{TM} (16 yeux) (66 impacts, 100msec, 0.6mJ/impact, 300μm) (MDLT) ou des trabéculoplasties conventionnelles au laser à l'Argon (15 yeux (ALT) sur les 180° de la circonférence de l'angle. 5 patients ont bénéficié de trabéculoplasties au laser diode sur un œil et de trabéculoplasties au laser à l'Argon sur l'autre œil. Une surveillance étroite du segment antérieur à la recherche d'une réaction inflammatoire a été réalisée chez tous les patients. La PIO a été mesurée à 1 jour, 1 semaine, 1 et 3 mois puis trimestriellement.

Résultats: Les 2 groupes étaient bien assortis aussi bien pour ce qui concernait l'âge des patients que le type de glaucome, la notion d'un traitement préalable au laser ou d'une chirurgie filtrante, ainsi que le nombre des médications avant laser. Le recul moyen était comparable dans les deux groupes (5,2±1,7 mois pour les trabéculoplasties au laser diode et 5,5±2,3 mois pour les trabéculoplasties au laser à l'Argon; $p > 0,05$). La PIO moyenne avant laser était de 20,7±3,8 mmHg pour le groupe du laser diode et de 21,6±4,2 mmHg pour celui de l'Argon ($p > 0,05$). Dans les deux groupes, la PIO moyenne a été réduite de manière significative par rapport au niveau de départ aux différentes visites ($p<0.05$). A 3 mois, la PIO moyenne était comparable dans le groupe MDLT (18,6±5,1mmHg) et le groupe ALT (16,7±3,3 mmHg)($p=0,26$), mais la chute moyenne de PIO observée était significativement plus basse avec le laser diode (2,5± 2,6 mmHg) qu'avec le laser à l'Argon (4,9± 3,4 mmHg) ($p= 0,04$), le pourcentage moyen de chute de PIO obtenu étant de 12,2± 11,9 % avec le laser diode et de 21,8±11,1% avec l'Argon ($p=0,03$). Une chute de PIO $\geqslant$ 20% par rapport au niveau pressionnel de départ a été observée dans 35,7% des yeux du groupe MDLT et 50% des yeux du groupe ALT ($p=0,03$). Avec le même recul, le nombre moyen des médications locales antiglaucomateuses a été significativement moins élevé avec le laser diode (2,1±0,8) qu'avec l'Argon (2,8±0,7) ($p=0,03$). Les trabéculoplasties au laser diode n'ont été émaillées d'aucune complication particulière dans 100% des cas et ont été très bien tolérées par tous les patients. Avec les deux lasers, il n'a pas été observé de réaction inflammatoire significative au niveau du segment antérieur de l'œil. Un pic tensionnel modéré précoce a été décelé chez un seul patient porteur d'un GCAO après trabéculoplasties au laser diode.

Conclusion: Les trabéculoplasties au laser diode induisent une chute de PIO significativement plus faible et un taux de réponse (équivalent à une chute de PIO d'au moins 20% par rapport au niveau pressionnel de départ), significativement plus bas que les trabéculoplasties au laser à l'Argon. Le laser diode micropulsé n'induit pratiquement pas d'inflammation du segment antérieur. Son profil de sécurité apparaît excellent. Son efficacité pressionnelle se doit d'être confirmée sur une plus large série et les paramètres du traitement doivent être encore optimalisés.

KEY WORDS

Laser therapy, trabeculoplasty, glaucoma, argon laser trabeculoplasty, selective trabeculoplasty, diode laser trabeculoplasty.

MOTS-CLES

Traitement au laser, trabéculoplastie, glaucome, trabéculoplastie au laser à l'Argon, trabéculoplasties sélectives, trabéculoplastie au laser diode.

INTRODUCTION

Recently approved by the FDA, selective laser trabeculoplasty (SLT) uses the 532 nm frequency-doubled Q-switched neomydium:yttrium-aluminium garnet (Nd:YAG) laser to selectively target pigmented trabecular meshwork cells while delivering less than 1% of the energy of a standard Argon Laser Trabeculoplasty treatment (ALT) and reducing the amount of mechanical and thermal damage to the trabecular beams (10,14-18). Firstly described by D. Ingvoldstad during the ARVO meeting in 2005, the Micropulse^{TM} Diode Laser Trabeculoplasty (MDLT) (IRIDEX corporation, Mountain View, CA) is a minimum-intensity Diode Laser Trabeculoplasty that uses a train of low irradiance (2 W over 300μm spot), 810nm-laser pulses to thermally interact with – not to destroy – pigmented cells and to minimize the damage to the trabecular meshwork (7). Each MDLT application delivers a train of 100 micropulses of 0.6 mJ, each one having 100,000 times longer duration and 100,00 times lower power than the 0.6 mJ SLT's pulse. MDLT is slightly different from SLT on account of this laser aims at creating non-lethal temperature gradients at the pigmented cells, just sufficient to produce inflammation, macrophages recruitment, release of cytokines and a biological cellular healing cascade leading to induction of cell division and metalloproteinases expression in the trabecular matrix. As the Micropulse^{TM} diode laser has a 810 nm longer extinction length than SLT, MDLT could theoretically interact with pigment laden cells, both in superficial and deep layers of the trabecular meshwork (7).

In a recent unpublished 3-months prospective pilot study performed in 21 POAG patients randomized to treatment with either ALT or MDLT, MDLT has been found to induce a statistically significant intraocular pressure (IOP) reduction comparable to ALT while post-laser treatment inflammation was clinically minimal and IOP spikes were not observed (7).

The purpose of our study was to compare ALT and MDLT in terms of short, medium-term IOP lowering effect and safety profile in patients with open angle glaucoma.

METHODS

We conducted a prospective comparative study in 26 phakic glaucomatous patients (14 female, 12 male) (31 eyes) with insufficient IOP control and who were randomly (one out of two alternately) assigned to undergo either primary MDLT (16 eyes) or primary ALT (15 eyes) treatment to 180° of the trabecular meshwork. In 5 patients, MDLT was done in one eye and ALT in the other eye.

Both laser treatments were performed by 2 clinicians according to a standard protocol for ALT and a pilot protocol for MDLT. Oral informed consent was obtained in all patients.

ALT was done with an Argon blue-green laser with a wavelength of 510 nm. Approximately 50 spots with a diameter of 50 μm, a duration of 100 msec and an energy ranging from 550 to 900 milliwatts, were applied with one spot size in between the spots, at the junction of the anterior non-pigmented and posterior pigmented trabecular meshwork along the inferior 180° of the iridocorneal angle.

MDLT was performed with the 810 nm Diode laser MicroPulse^{TM} mode which was fitted on a standard slitlamp. A pilot fixed protocol was used consisting in a total of 66 confluent 300 μm diameter invisible laser applications with a power of 2 Watts, a low irradiance (2 W over 300 μm spot = 2.8 KW/cm^2), a time of application of 200 ms and a Duty Cycle of 15% (on-time period). Applications were covering the whole height of the trabecular meshwork over the inferior 180° angle. MDLT interacts with pigmented trabecular cells without producing visible effects, tissue blanching, or bubble formation.

Trabecular pigmentation before laser treatment was graded as absent, mild, moderate or strong.

Post-treatment management of both groups was similar. One drop of apraclonidine 5 mg/ml (Iopidine® Alcon) or brimonidine 2mg/ml (Alphagan® Allergan) was instilled before laser therapy to prevent a post-laser IOP spike. After the laser treatment, topical dexamethason was prescribed 3 times daily during 2 days and progressively tapered during a total of one week. The patients continued with their local antiglaucoma medication except for prostaglandin analogues which were interrupted during one week or more, according to the degree of the

Table 1: *Baseline characteristics of the two laser treatment groups.*

	MDLT	*ALT*	*p*-value
Age (mean ± SD) (years)	66.3 ± 11.4	68.8 ± 11	0.57
Gender	5 fem, 8 male	7 fem, 6 male	0.43
BCVA	0.74 ± 0.3	0.66 ± 0.3	0.34
Pre-treatment IOP (mmHg)	20.7 ± 3.8	21.6 ± 4.2	0.56
Pre-treatment nr of meds	2.4 ± 0.9	2.7 ± 0.7	0.22
Type of glaucoma	11		0.95
POAG	2	11	
Ocular hypertension	1	1	
PXG	2	1	
Pigmentary glaucoma		2	
Previous laser/filtering procedures			*0.12*
Trabeculectomy	0	3	
*Trabeculectomy+DS**	1	0	
Laser peripheral iridectomy	3	3	
Severity of Visual Field defects			*0.83*
Normal	3	2	
Early (MD ⩽ -6dB)	6	5	
Moderated (MD > -6dB, ⩽-12dB)	3	2	
Severe (MD> -12dB)	4	6	
Trabecular Pigmentation			0.74
Absent	4	2	
Mild	8	9	
Moderated	2	1	
Severe	2	3	

* deep sclerectomy

observed anterior segment inflammation. Patients were subsequently evaluated at 1 day, 1 week, at 2 weeks if needed, 1 and 3 months and 3 month intervals thereafter in both groups. At each follow-up visit, visual acuity, IOP and number of medications prescribed were recorded, and any complications were treated appropriately. Anterior chamber inflammation was graded as absent, mild (between 20 and 50 cells by field) or moderate (more than 50 cells by field).

Pretreatment IOP was defined as the average IOP of the 2 visits preceding the date when laser trabeculoplasty was performed. In addition to the observed IOP reduction observed at each visit, we used an additional success criterion based on an IOP reduction 20% or more of the pretreatment IOP.

Data were analyzed statistically using a 2-tailed unpaired *t* test, chi-square test, Anova test to compare outcomes between groups. Analysis was performed with the StatView 4.5 programme (Macintosh). The level of significance was considered to be 0.05.

RESULTS

The baseline characteristics of the 2 groups are listed in Table 1.

The MDLT (16 eyes) and ALT (15 eyes) groups were similar in age (mean age ± SD= 66.3 ± 11.4 years in MDLT, 68.8 ±11 years in ALT), gender, best corrected visual acuity (BCVA), pre-treatment glaucoma diagnosis, previous laser and/or filtering procedures, severity of glaucomatous visual field defects, trabecular pigmentation, pre-treatment laser IOP, as well as pre-treatment number of glaucoma medications.

The mean follow-up time (± SD) was 5.2±1.7 months for patients in the MDLT group and 5.5±2.3 months in the ALT group (p= 0.64), with a range of 2 to 11 months in both groups.

The graph 1 shows the IOP evolution in the two laser treatment groups. The mean IOP was significantly reduced compared to the pre-treatment level in both groups at the different visits. Mean IOP (±SD) was not significantly different in MDLT and ALT group at the different interval visits.

Table 2: *Summary of the IOP results between the two laser treatment groups at 3 months.*

	MDLT	**ALT**	*p*- value
Mean IOP (±SD) (mmHg)	18.6 ± 5.1	16.7 ± 3.2	0.26
Mean IOPo -IOP(mmHg)	2.5 ± 2.6	4.9 ± 3.4	***0.04***
Mean % of IOP reduction	12.2 ± 11.9	21.8 ± 11	***0.03***
IOP reduction ⩾20 %	35.7 % (5/14 patients)	50 % (7/14 patients)	0.38

Legend:IOPo= baseline IOP

Table 3: *IOP reduction (mmHg) at the last visit according to the trabecular pigmentation*

Trabecular pigmentation	**MDLT**	**ALT**	*p*-value
Absent	1.5 ± 2.6	1.5 ± 2.1	0.4
Mild	2.7 ± 3.0	3.8 ± 1.6	0.36
Moderate	4 ± 2.1	5	0.7
Strong	3 ± 2.8	7.8 ± 6.2	0.4

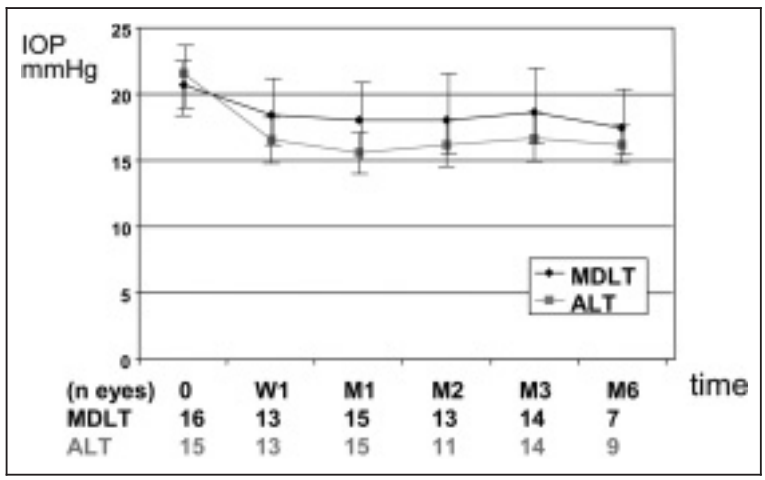
At 3 months follow-up visit including 14 eyes of the MDLT group and 14 eyes in the ALT group, mean IOP was 18.6±5.1mmHg in MDLT and 16.7±3.3 mmHg in ALT (p=0.26) while the mean IOP decrease was significantly less in MDLT (2.5±2.6 mmHg) than in ALT (4.9±3.4 mmHg) (p= 0.04). This corresponded to a mean percentage of IOP reduction of 12.2±11.9 % MDLT and 21.8±11.1% in ALT respectively (p=0.03), as well as an IOP drop ⩾20% compared to the baseline IOP observed in 37.5% in MDLT versus 50 % in ALT (p=0.03) (Table 2).

As summarized in the table 3, the mean IOP reduction had a tendency to increase with the degree of trabecular pigmentation, although to a greater extent in the ALT group.

Table 4 shows the IOP results in bilateral treatments (5 patients, 10 eyes). Both mean pre-treatment IOP and mean IOP at the last visit were not significantly different between the eye treated by MDLT and the other eye having received ALT.

Antiglaucoma medications were not significantly reduced compared to their pre-treatment number. At 3 months, the mean number of medications was 2.1±0.8 for patients treated with MDLT and 2.8±0.7 for patients having received ALT, the difference between the two groups being statistically significant (p=0.03) (table 5).

Analysis of complications have revealed that week 1 and 2 post-treatment anterior segment inflammation was mild (between 20 and 50 cells by field) to absent and comparable in the two treatment laser groups. A transient IOP spike of 9 mmHg had only been observed at week 1 post-laser treatment in one patient with



Graph 1: IOP evolution at the different interval visits in the two laser treatment groups.
Legend: W=week; M= month(s)

Table 4: *IOP reduction (mmHg) in bilateral treatments.*

	MDLT	**ALT**	*p*-value
Mean IOP (±SD) first visit	21.2 ± 3.1	22.0 ± 4.2	0.77
Mean IOP last visit	20.3 ± 5.2	19.2 ± 5.5	0.75

Table 5: *status of antiglaucomatous medications at 3 months before and after laser treatment in the two sample groups*

	MDLT	**ALT**	*P*- value
Mean nr (± SD) time 0	2.4 ± 0.9	2.7 ± 0.7	0.22
Mean nr (± SD) 3 month visit	2.1 ± 0.8	2.8 ± 0.7	***0.03***

early POAG treated with four topical medications and with a pre-treatment IOP of 26 mmHg in the MDLT group.

MDLT treatment was uneventful in 100% of patients with no thermal pain and no uncomfortable laser flashes.
BCVA was not significantly reduced at 3 months as well as the last visit and comparable in the two laser treatment groups (0.7±0.3 in MDLT group, 0.6±0.3 in ALT group, p= 0.17).

DISCUSSION

Laser trabeculoplasty represents one of the current alternatives for glaucoma treatment that has been proven to be relatively safe and effective in lowering IOP since more than 25 years. In 1995, Latina et al described selective laser trabeculoplasty as an alternative method to conventional argon laser trabeculoplasty to lower IOP in patients with open angle glaucoma (4) Selective photothermolysis takes place when thermal damage is limited to the target, i.e melanin, by using a specific laser wavelength with a laser exposure time equal to or shorter than the thermal reaction time of melanin in such a way that the heating process happens so quickly that there is no time for heat transfer (8). In this way, pulsed lasers with low threshold radiant exposures, like SLT and MDLT, can selectively target pigmented trabecular meshwork cells and avoid collateral damage to the adjacent non-pigmented cells. Unlike SLT which is theoretically associated with large thermal transient and shock waves which propagate causing disruptive effects, the MDLT cannot theoretically produce selective photothermolysis. The interpulse separation of MDLT is long enough to allow the temperature to return to baseline prior to the arrival of the next pulse and to prevent cumulative thermal rise. As a consequence, MDLT could not theoretically produce micro-explosions, pigment dispersion, IOP spikes and risk of IOP increases in eyes with heavily pigmented trabecular meshwork (6,7,20).

Although the literature has shown variable rates of efficacy of the procedure, SLT is considered to be as relatively safe and effective in lowering IOP as conventional ALT in patients with POAG and other forms of secondary open angle glaucoma while it offers the potential benefit of repeatability (2,3,5,15-17,21). Mean reduction in IOP has ranged from 2-14 mmHg at 1 month, 3-6 mmHg at 3 months and 5-7 mmHg at 6 months. 5-year data have also shown that SLT could be as effective as ALT in lowering IOP in eyes with primary open-angle glaucoma that are receiving maximally tolerated medical therapy (9). However some authors have suggested that post-SLT IOP elevations could be a serious adverse event in some glaucomatous patients, especially those with heavily pigmented trabecular meshwork, taking multiple medications and having previous ALT treatment (6,20). Among hypotheses for explaining such post-SLT IOP rises, increased 24-hour post-treatment inflammation and excessive early pigment dispersion due to the selective targeting of the pigmentary trabecular cells associated with a large spot size of 400 μm have been expressed (1,20).

To the best of our knowledge, this is the first paper dealing with the short term comparative efficacy and safety between MDLT and ALT.

Our prospective study has compared two small sample sizes (which had indeed limited the statistical power of our data) but well-matched groups of glaucomatous patients randomly allocated either to minimum-intensity diode laser trabeculoplasty or to standard argon laser trabeculoplasty. We have found that both treatment groups showed a statistically significant IOP drop from baseline at 1, 3 and 6 months while there was no statistically significantly difference in IOP between the two laser treatment groups at the different visits. At this stage, the power of our study was probably insufficient to rule out that a statistically negative result was obtained by chance alone. Due to the relatively high number of drop-outs at 6 and 9 months, we have focused our results on the 3-month visit where 14 eyes could be analyzed in each group. At this time, both mean IOP reduction (2.5±2.6 mm Hg in MDLT group versus 4.9±3.4 mmHg in ALT group) and mean percentage of IOP reduction (12.2±11.9 % in MDLT group and 21.8±11.1% in ALT group) were in favour of argon laser trabeculoplasty. Furthermore, as a 20% IOP reduction from baseline is usually considered as a criterion for responsiveness to any treatment, the IOP efficacy induced by MDLT should be considered as being questionable at this stage of our study. So at 3 months, the percentage of eyes that have exhibited an IOP reduction 20% of the pre-treatment IOP was lower in the MDLT group (35.7 %) than in the ALT group (50%).

We have also found that the IOP reduction seemed to be related to the trabecular pigmentation, but possibly to a greater extent in the ALT study arm (19,20). On the other hand, we have found that at 3 months, the mean number of topical glaucomatous meds was significantly lower in the MDLT treatment group than in the ALT.

Both groups exhibited a comparable safety profile, especially related to the anterior chamber cellular reaction which was minimal to mild and the prevalence of post-laser IOP spikes. We could only detect a moderate IOP spike at the 1st week visit in one POAG patient having been treated with MDLT. Therefore and until further confirmation, close monitoring of early IOP spikes is still mandatory both with MDLT and ALT.

Our preliminary IOP results with Micropulse^{TM} Diode Laser Trabeculoplasty appear to be noticeably worse than David Ingvolstad and coll. have recently reported in a Pilot study including 21 eyes of 21 patients with POAG randomised to treatment with MDLT or ALT. At three months, the authors have observed a similar 18.5% and 18.9% IOP reduction from baseline in MDLT and ALT study arms respectively, corresponding to a mean IOP drop of 4.5 mmHg in MDLT and 4.6 mmHg in ALT (7).

All our patients have been treated according to a standard fixed protocol which needs to be further refined, especially by changing the irradiance treatment parameters and reducing the spot size from 300μm to 200μm in a first step. Because the procedure does not apparently produce any visible inflammation, questions regarding the use of post-laser treatment steroids and the early temporary discontinuation of prostaglandin analogues should be further elucidated.

Clearly the IOP efficacy of MDLT should be still confirmed on a larger sample size and by modifying the treatment parameters.

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Correspondence and reprints:
Prof. M. Detry-Morel
Cliniques Universitaires St Luc
Avenue Hippocrate, 10
B-1200 Bruxelles
BELGIUM