

## PASCAL Laser Produces Less Pain Responses Compared to Conventional Laser System During the Panretinal Photocoagulation

Tamer Ahmed, Ahmed Howaidy, Abd Allah El-Amin, Khalid Selim

Department of Ophthalmology, Faculty of Medicine, Aswan University, Egypt

\*Corresponding author: Tamer Ahmed Ali Ahmed; Mobile: +201006508312; Email: tamerahmedali@yahoo.com

### ABSTRACT

**Background:** Majority of patients experience pain during complete the panretinal photocoagulation (PRP). Laser photocoagulation delivery progressed with the introduction of pattern-scanning laser systems (PASCAL). Shorter pulse duration and choroidal penetration are believed to reduce pain during laser treatment.

**Objective:** The purpose of this study was to assess pain response in patients with proliferative diabetic retinopathy (PDR) who underwent either PASCAL or conventional laser.

**Subjects and Methods:** Eighty eyes with newly diagnosed proliferative diabetic retinopathy were randomly divided in to two groups each composed of 40 eyes: group (A) in which patients were received standard argon laser panretinal photocoagulation and group (B) in which patients were received pattern scan multispot panretinal photocoagulation.

**Results:** Mean pain scores were  $0.515 \pm 0.834$  in the PASCAL laser and  $0.128 \pm 1.16$  in the conventional laser group. Numerical pain score was statistically significant higher in conventional group than in PASCAL group ( $p < 0.001$ ). **Conclusion:** It could be concluded that pattern scan multispot laser PRP was associated with more patient comfort compared to conventional PRP.

**Keywords:** proliferative diabetic retinopathy, panretinal photocoagulation, Multispot Panretinal Photocoagulation, PASCAL laser, Conventional argone laser.

### INTRODUCTION

Diabetes mellitus (DM) is a major emerging clinical and public health problem in Egypt with a prevalence of 5–10% in the 1990s. It has been estimated that by the year 2025, nearly 9 million Egyptians (over 13% of the population over 20 years of age) will have DM<sup>(1,2)</sup>.

Since the Early Treatment Diabetic Retinopathy Research Study, panretinal photocoagulation has been the standard of care for treating patients with diabetic retinopathy<sup>(3)</sup>.

Sequential improvements took place in Retinal laser photocoagulation, including introduction of yellow, green, and diode lasers with various advantages of each wavelength<sup>(4)</sup>.

The Pattern Scan Multispot Laser uses a proprietary, semiautomated pattern generation technique that allows rapid delivery of laser pulses, with durations of 10 ms to 20 ms at each spot, as opposed to 100 ms to 200 ms with conventional laser<sup>(5)</sup>.

Almost all patients experience pain during PRP. While some patients may tolerate the pain, the majority does not. One study reported that 64.1% of patients did not complete treatment due to pain and therefore had an increased risk of vision loss. The use of shorter exposure burns may improve patient comfort and compliance<sup>(6)</sup>.

The purpose of this study was to assess pain response in patients with PDR who underwent either PASCAL or conventional laser.

### PATIENTS AND METHODS

This prospective randomized clinical trial study included eighty eyes of 60 patients, 20 patients had

both eyes done. They were newly diagnosed as proliferative diabetic retinopathy (PDR). Patients were recruited from Aswan Ophthalmology Hospital Outpatient Clinic. This study was conducted between January 2017, to June 2019.

### Ethical approval

**Approval of the Ethical and Technical Review Committee of Aswan Faculty of Medicine was obtained.** Informed written consents were taken from all patients for the specific procedure.

The included subjects were randomly divided into two groups each composed of 40 eyes; **Group (A)** in which patients received standard argon laser panretinal photocoagulation using single spots and **Group (B)** in which patients received pattern scan multispot panretinal photocoagulation.

After randomization, group A were treated in Aswan eye & laser center and group B were treated in Aswan university hospital.

Information was collected on age, sex, indication, pre-and post-laser procedure, best corrected visual acuities (BCVA) as well as outcome and complications of treatment and intra- and post-procedure pain sensation.

### Inclusion criteria

Patients with type I or type II diabetes mellitus who were newly diagnosed as proliferative diabetic retinopathy were enrolled if they met the following criteria:

1. Patients older than 18 years of age.

2. Patients with Snellen best corrected visual acuity of 6/60 or better.
3. Adequate pupil dilatation and clear media to perform laser photocoagulation, digital photography and optical coherence tomography scans.

#### **Exclusion criteria:**

1. Patients with previous laser photocoagulation or macular laser treatment prior to the study eye.
2. Patients underwent recent intra-ocular surgeries within the last three months prior to the procedure.
3. Patients with media opacities (e.g. corneal opacity, cataract, vitreous hemorrhage) that interfere with the proper evaluation of the posterior segment.
4. Mean Central macular thickness area more than 300 $\mu$  as measured by optical coherence tomography scans.
5. Patients who are contraindicated to fluorescein angiography (pregnancy, allergy to fluorescein dye, renal failure).
6. Patients with poor glycaemic control, glycated haemoglobin (HbA1c) greater than 10.0 mg/dL.
7. Patients with uncontrolled hypertension, blood pressure greater or equal to 180/110 mmHg.
8. Patients with vitreo-retinal traction.
9. Patients who are planned for intra-ocular surgery within six month from the start of the treatment.

Chosen patients were subjected to the following: (1) Counseling the patient about the procedure and the possible complications of panretinal laser photocoagulation; (2) Detailed general and ocular history; (3) Full ophthalmological examination including best corrected visual acuity, slit-lamb examination, IOP measurement using Goldmann applanation tonometer, and dilated fundus biomicroscopy; (4) Baseline fundus fluorescein angiography; (5) Baseline optical coherence tomography to measure central macular thickness

#### **Treatment parameters**

The pupils were dilated using 1% tropicamide and Cyclophrine (Cyclopentolate HCl 50 mg + Phenylephrine HCl 500 mg) drops and used 0.5% proparacaine-hydrochloride drops is used as topical anesthetic before the procedure. Mainster wide-field lense were used for pan retinal photocoagulation. Treatment parameters including use of a pattern or single spot, type of pattern, power, burn duration, spot size and number of burns per session were

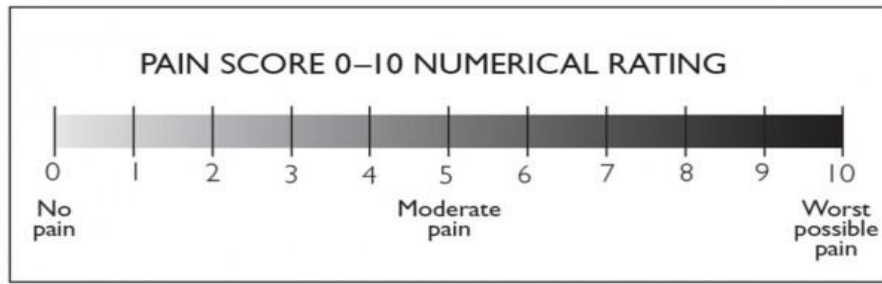
noted. Prior to starting treatment, the operator chose whether or not to do Pascal based on the random distribution after informed consents from all patients. Eighty eyes with PDR were included in this clinical trial divided into two groups: **Group (A):** patients were treated with pan laser photocoagulation for PDR using conventional laser photocoagulation (Ellex Medical Pty Ltd. Integre Pro) which is a 532 nm green-light Diode Solid State Photocoagulator laser. **Group (B):** patients were treated with PRP for PDR with pattern scan multisport photocoagulation using a 532nm laser with computer-guided scanning technology (PASCAL Streamline Photocoagulator, Topcon Medical Laser Systems).

#### **Laser technique**

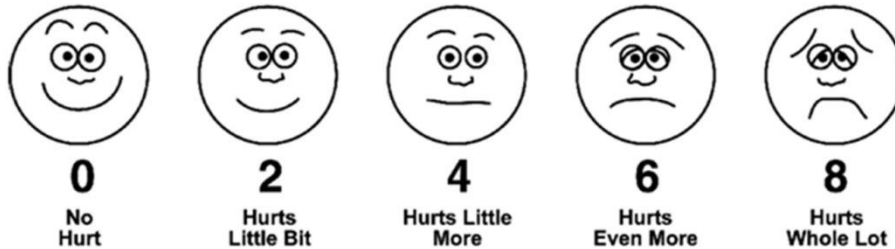
The PASCAL PRP parameters were defined as 200  $\mu$ m spot size, 20 ms pulse duration, and power was adjusted until a gray-white lesion was observed starting from 200 mW. The whole PRP treatment was performed in two sessions, for PRP, the 3 $\times$ 3, 4 $\times$ 4 and 5 $\times$ 5 arrays were most commonly used. Pattern array near-simultaneously setting was used with a single depression of the foot switch. All burns were placed one burn width apart. Conventional laser PRP parameters were defined as 200  $\mu$ m spot size, 100 ms pulse duration, and power increased from 200 mW until a gray-white lesion was attained. Burns were placed one burn width apart. All of the patients completed the entire PRP treatment in two or three sessions. Burn distribution was greater than 2-disc diameters (DD) temporal to the fovea, no closer than one row within the arcades, and burn placement as close to the ora serrata as possible.

#### **Pain score**

A mean value between numerical rating pain score and The Wong-Baker Faces Pain Rating Scale was used to record the pain score. The Numerical Pain Rating Scale (NPRS) is a subjective measure in which individuals rate their pain on an eleven-point numerical scale, the scale is composed of 0 (no pain at all) to 10 (worst imaginable pain). The Wong-Baker Faces Pain Rating Scale is a pain scale that was developed by Donna Wong and Connie Baker. The scale shows a series of faces ranging from a happy face at 0, or "no hurt", to a crying face at 10, which represents "hurts like the worst pain imaginable"



**Wong-Baker FACES™ Pain Rating Scale**



**Data extraction strategy**

Data were extracted into a predesigned data extraction form. Information collected included age, sex, procedure, best-corrected visual acuity (BCVA), clinical efficacy and outcome, and complications following laser. Data were also collected on the parameters used for the treatment including power, pulse duration, number of burns per treatment session and retinal spot size.

**Statistical analysis**

The data was analyzed using IBM SPSS Statistics 24.0 program. Screening for extreme values in quantitative variables was done using independent t-test. Discrete and categorical variables were screened using frequency distribution, Chi-square test & Fisher Exact Test. Correlation with Pearson correlation. Visual acuities (VA) were converted from Snellen to log Mar to explore changes in vision pre- to post-laser. p value of <0.05 was considered significant and highly significant (p< 0.001).

**RESULTS**

Eighty eyes of 60 patients, 20 patients had both eyes done, were included in this clinical trial; of whom

26 (43.33%) were male, and 34 (56.67 %) were female with a mean age of 54.47 years (SD 8.72, range 31 - 75). there were 40 eyes in the conventional laser group (A) and 40 eyes in the PASCAL group (B).

For eyes in group A, the mean age of the patients was 52.8 (SD 8.78, range 31 - 69) of whom 18 (45%) were for males and 22 (55%) were for females. For patients in group B, the mean age of the patients was 56.14 (SD 9.55, range 35 - 75) of whom 17 (42.5%) were for males and 23(57.5%) were for females.

At baseline, there was no significant difference between the groups (p > 0.05, for all) in terms of age, sex, most recent glycated hemoglobin, DM duration, BCVA, or CMT

Regarding laser parameters for the PASCAL group the mean power of PRP used was 525 mW (SD 125.4, range 350 - 950) and the mean number of spots used were 2820.63 (SD 394.18, range 2200 - 3700). All procedures were done in 2 sessions. For the conventional group the mean power of PRP used was 260 mW (SD 130.7, range 160 - 590) and the mean number of spots used were 2611.42 (SD 285.61, range 1782 - 3121). The majority of cases were done in 2 sessions and only in 5 cases the procedure was done in 3 sessions.

**Table (1):** Comparison between the two studied groups regarding the demographic data and baseline parameters.

Variables	Group A		Group B		P value
Age	52.8 ± SD 8.78		56.14 ± SD 9.55		0.326
Sex	Male	18 (45%)	Male	17 (42.5%)	0.823
	Female	22 (55%)	Female	23 (57.5%)	
DM duration	15 ± 9.75		15 ± 9.25		0.529
Baseline HA1C	7.8 ± 1.75		7.95 ± 1.95		0.824
Baseline BCVA	0.3 ± 0.22		0.3 ± 0.21		0.596
Baseline CMT	250 ± 50		24.6 ± 45.25		0.725

The test used was independent T test. P value is significant if < 0.05.

The power was highly statistically significant higher in PASCAL group than the conventional laser group (P=0.001), the number of spots was statistically significant higher in PASCAL group than the conventional laser group (P=0.03), The number of sessions was statistically significant lower in PASCAL group than the conventional laser group (P=0.022).

**Table (2):** Comparison between the two studied groups regarding the PRP parameters.

Variables	Group A	Group B	P value
Power (mW)	260 ± SD 130.7 range 160 - 590	525 ± SD 125.4 range 350 - 950	0.001 **
Number of burns	2611.42 ± SD 285.61 range 1782 - 3121	2820.63 ± SD 394.18 range 350 - 950	0.03*
Number of sessions	2.1 ± 0.3	2.0 ± 0	0.022*

- Independent T test.

Regarding the pain score on both groups as shown in table (3): mean value between numerical rating pain score and The Wong-Baker Faces Pain Rating Scale was statistically significant higher in conventional group than in PASCAL group.

**Table (3):** Comparison between the two studied groups regarding the pain score.

		group A	Group B	P-value
Pain score*	Mean±SD	1.28 ±1.16	0.51 5±0. 834	0.000**

- Independent t-test.

- P-value significant<0.05.

**Complication:**

Regarding complications in both groups as shown in table (4):

Iris burn occurred in 2 (5%) patients in conventional laser group and 6 (15%) patient in PASCAL group. Mild vitreous hemorrhage occurred in 2 (5%) patients in conventional laser group and 1 (2.5%) patient in PASCAL group, rubeosis iridis only occurred in 1 (2.5%) patient in PASCAL group. One patient in the PASCAL group developed both rubiosis iridis and mild vitreous hemorrhage (2.5%). There was no statistically significant difference in complications between the two study groups.

**Table (4):** Comparison between the two studied groups regarding the complication.

		group A	Group B	P-value
Complications # No (%)	none	36 (90%)	31 (77.5.9%)	1.000
	Iris burn	2 (5%)	6 (15%)	
	Mild vitreous Hge	2 (5%)	1 (2.5%)	
	Rubeosis iridis	-	1 (2.5%)	
	Mild vitreous Hge+ Rubeosis iridis	-	1 (2.5%)	

- Fisher's Exact test

**DISCUSSION**

Laser photocoagulation is painful for some patients. This pain may result in some patients not completing their treatment. Various methods for pain prevention have been recommended (such as oral or topical nonsteroidal anti-inflammatory drugs (NSAID)). Possible causes of pain include thermal diffusion into the choroid, stimulation of the ciliary nerves in suprachoroidal space, thermal diffusion to the RNFL or direct thermal damage to the posterior ciliary nerves (7).

In our present study, the mean pain scores were 0.51 5±0. 834 in the PASCAL laser and 1.28 ± 1.16 in the conventional laser group. Numerical pain score was statistically significant higher in conventional group than in PASCAL group (p<0.001)

**Al-Hussainy et al.** (8) conducted a prospective study in 20 patients indicated for PRP for various reasons. In a single session, they applied 500 conventional laser shots with 0.1 s duration, 300 µm spot size to the superior or inferior region, and 500 conventional laser shots with 0.02 ms duration, 300 µm spot size to the rest of the retina. Although greater power was required to induce moderate burns with 0.02 s pulse durations, pain assessment indicated that shorter durations caused less pain.

**Nagpal et al.** (9) performed PRP using PASCAL in one eye and a 532 nm conventional laser in the fellow eye in 60 patients with bilateral symmetric PDR or severe NPDR. Following treatment, patients scored their pain using a visual analog scale (VAS). The average score was 4.6 in

the conventional laser group, compared to 0.33 in the PASCAL group.

**Muraly *et al.*** <sup>(10)</sup> comparing PASCAL and a conventional laser, patients were asked to rate their pain as mild, moderate, or severe after treatment. The number of patients reporting mild, moderate, and severe pain in the PASCAL group was 40, 10, and 11 respectively, while in the conventional group these numbers were 11, 25, and 14, respectively.

In **Salman** <sup>(11)</sup> study no complications related to laser treatment were noted in any patient. No effects were observed on blood vessels if the array inadvertently involved a retinal area traversed by blood vessels. None of the patients experienced bleeding of either retinal or choroidal origin. No effects were observed due to the doctor being unable to avoid old laser burns in re-treatments <sup>(11)</sup>.

## CONCLUSION

Pattern scan multispot laser PRP resulted in less pain sensation and increased patient comfort compared to conventional PRP.

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