Yellow Micropulse Laser 577-nm vs Infrared Diode Micropulse Laser 810-nm For the Treatment of Diabetic Macular Edema

Protocol

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Faculty of Medicine, Cairo University Postgraduate Research Program Template

1- *Proposed* study Title:

Yellow Micropulse Laser 577-nm vs Infrared Diode Micropulse Laser 810-nm For the Treatment of Diabetic Macular Edema

2- Degree: MSc

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10- Background and Rationale:

Diabetic eye disease refers to a group of eye problems that people with diabetes may face as a complication of this disease. All can cause severe vision loss or even blindness. Diabetic eye disease may include:Diabetic retinopathy, Cataract, Glaucoma. [1]

Diabetic macular edema (DME) is one of the main causes of vision disturbance in diabetic retinopathy, which is a clinically significant microvascular complication of diabetes. Anti-vascular endothelial growth factor (VEGF) therapy is becoming the mainstay of treatment for DME. However, to achieve sustained long-term improvement in visual acuity, conventional laser photocoagulation, vitrectomy and steroid therapy are also expected to play a role in the treatment of DME. [2]

Pattern scan laser in proliferative diabetic retinopathy and diabetic macular edema allows laser treatment that is less time consuming and less painful. Now, it is possible to deliver a subthreshold micropulse laser that is above the threshold of biochemical effect but below the threshold of a visible, destructive lesion thereby preventing collateral damage. The yellow pattern 577-nm micropulse laser converts each laser shot into a “pulse envelope” consisting of a sequence of extremely short pulses of laser (10–20 ms) with intervening periods of zero laser energy to the treatment site. When the multi-spot pattern mode is used, the pulses are not produced simultaneously; however, they formed in rapid succession with low-energy pulses during each laser shot. Laser generated in this way is typically 10–25% of the visible threshold power. Previous studies have shown that subthreshold laser performed in this way was sufficient to show a consistent retinal pigment epithelium-confined photothermal effect, and also to allow the inner retinal temperature to remain below the threshold of coagulative damage, sparing the transparency of the retina and lowering the risk of hemorrhage.[3][4]

The commercially available diode lasers emit at a wavelength of 810 nm, which is in the near-infrared range of the spectrum. A feature of the 810-nm wavelength is its deep penetration into the choroid, but it is not clear if this characteristic is relevant in micropulse treatment. For all indications requiring a treatment near the foveal avascular zone, the 810-nm laser has the advantage that the laser energy will relatively spare the inner neurosensory retina and affect mainly the deeper layers.[5][6][7][8]

The use of micropulse laser in Diabetic Macular Edema DME was initiated by Friberg and Karatza in 1997. Luttrell and colleagues in 2005 published, for the first time an account of their experience of using subthreshold MP 810 nm diode laser for DME with complete and contiguous treatment of the entire edematous area without tissue damage. Micropulse laser has been demonstrated to be as efficacious as the conventional laser. [9][10][11][12][13]

11- Objectives:

To detect the effect of Yellow Micropulse Laser 577-nm vs Infrared Diode Micropulse Laser 810-nm In the Treatment of Diabetic Macular Edema

12- Study Design:

Prospective comparative study.

13- Laser Procedure:

A 7×7 Pattern laser will be used to paint the retina. A 160 μm will be used to increase the treatment area, ensuring therapeutic delivery to all of the targeted tissue. A 5% duty cycle meaning that each MicroPulse of energy is "on" for 100 μs followed by 1900 μs in the "off" mode. To ensure there is enough time for the surrounding tissues to cool to eliminate the possibility of thermal damage to the inner retina. This cycle is repeated multiple times within one laser shot.

14- Ethical Committee approval:

Yes

15- Study Methods:

a- Population of study & disease condition:

Diabetics (type1 or 2) more than 10 years durations.

B-Inclusion Criteria:

Diabetics (type 1 or type 2) more than 10 years durations with bilateral DME

Age: 20-80 years

c- Exclusion criteria:

Any non diabetic macular edema

Corneal opacities

Significant cataract

Intraocular surgery within the past 6 months

Previous intravitreal injections of any drug within the past 6 months

d- Methodology:

All patients meeting inclusion criteria in outpatient retina clinic, will have a full ophthalmological assessment including:

Past and present History.

Full Slit lamp examination.

Fundus examination.

OCT Macula Bilaterally

One eye of the same patient (randomly selected) will undergo laser treatment with Yellow Micropulse Laser 577-nm and the other eye (randomly selected) with Diode Micropulse Laser 810-nm.

e- Possible Risk:

None.

f- Primary Outcomes:

To detect the effect of Yellow Micropulse Laser 577 vs Infrared Diode Micropulse Laser 810 and their effect On Diabetic Macular Edema

As regards:

Visual acuity

Macular thickness via OCT

G-Secondary Outcomes:

h- **Sample Size:**

30 diabetic patients from outpatient retina clinic in Cairo university hospital.

i- Source of Funding:

Private-funding

16- Time Plan

Start Date: December 2017 for 6 months.

17. References:

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(13) *Ulbig MW, McHugh DA, Hamilton AM*. Diode laser photocoagulation for diabetic macular oedema. Br J Ophthalmol. 1995;79:318–21.