Cohort Study

Hybrid threshold laser to treat diabetic macular edema: A retrospective analysis single center cohort study

Ameen Marashi a, Aya Zazo b, *

a Marashi Eye Clinic, Aleppo, Syria
b Faculty of Medicine, University of Aleppo, Aleppo, Syria

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ABSTRACT

Background: Diabetic patients suffers from reduction of vision that one of its main causes is clinically significant macular edema (CSME).

The purpose of this study to determine if hybrid threshold can reduce macular thickness in Diabetic Macular Edema.

Materials and methods: This study is a retrospective analysis single center cohort study. 12 eyes in 10 patients diagnosed with diabetic macular edema using SD-OCT treated with Hybrid threshold laser as the leaking microaneurysms were treated with threshold laser on the 5% duty cycle settings.

A complete fundus exam, including best-corrected visual acuity changes, and monthly measuring retinal thickness using SD-OCT for 24 weeks follow up.

Results: Reduction of retinal thickness from 336.58 ± 86.26 μm to 264.33 ± 61.41 μm (p = 0.02) at 24 weeks follow up without significant changes of best-corrected visual acuity from 0.16 LogMAR to 0.08 LogMAR (p = 0.2) with minimal scar formation in 24 weeks follow up.

Conclusion: 532 nm Hybrid threshold laser reduces macular thickness up to 20% and stabilizes diabetic macular edema for 24 weeks follow up.

1. Introduction

Clinically significant macular edema (CSME) cause early-onset reduction of vision in patients with diabetes [1]; however, CSME presented a central including the fovea or noncentral foveal sparing where the former induces reduction of visual acuity (VA). However, noncentral CSME patients presented with good VA, but a VA reduction may occur as Noncentral CSME can progress to central.

The first line therapy treatment of central CSME is an intravitreal injection of AntiVEGF when it is associated with a reduction of vision [2], which has proven its safety and efficacy; however, focal laser photocoagulation may reduce the risk of visual loss, especially in cases of noncentral CSME [3].

Conventional laser treatment induces retinal burns that can damage both retinal pigment epithelium and photoreceptors, which will induce retinal scars that may extend to the fovea and cause visual loss, subretinal fibrosis, or choroidal neovascularization.

Inducing retinal tissue reaction by threshold laser burn may limit the destruction of photoreceptors and retinal pigment epithelium, which interim cause minimal scar that won’t expand [4].

Although the subthreshold diode micropulse photocoagulation is safe, it may not resolve the edema completely [5].

In this clinical trial, we will evaluate new laser parameters to treat diabetic macular edema, which we will use both threshold and subthreshold diode microsecond laser using subthreshold diode 532 nm laser.

2. Materials and methods

This study is a retrospective analysis single center cohort study, which follows Helsinki’s declaration. The study is registered at clinicaltrials.gov (NCT03226951). The study received approval from the institutional review board. Patients obtained written consent after explaining the possible complications.

2.1. Study participant

Inclusion criteria.
2.3. Statistical methods

Clinical data were obtained and analyzed using MS Excel. The means are used to investigate the variance between the mean six months outcome and mean baseline values for macular thickening and visual acuity.

The processes were established in accordance with STROCSS 2021 guidelines [6].

Table 1

| Characteristics of patients at presentation. According to the Hybrid threshold laser. In addition, there was no evidence of extending laser burn scar in the threshold treated area of leaking microaneurysms in clinical examination and fundus images within 24 weeks follow up. After threshold laser application on leaking microaneurysms, there was minimal scar formation to induce heat closure that didn’t extend beyond the original threshold laser burn. In addition, OCT shows that threshold laser burn destruction didn’t extend beyond outer retinal layers reduced in scar size within 24 weeks. |

| Table 1 | Characteristics of patients at presentation. According to the Hybrid threshold laser. In addition, there was no evidence of extending laser burn scar in the threshold treated area of leaking microaneurysms in clinical examination and fundus images within 24 weeks follow up. After threshold laser application on leaking microaneurysms, there was minimal scar formation to induce heat closure that didn’t extend beyond the original threshold laser burn. In addition, OCT shows that threshold laser burn destruction didn’t extend beyond outer retinal layers reduced in scar size within 24 weeks. |

| Age, Year (Mean ± SD) | 59.8 ± 9.86 |
| Sex, N (%) | 5 (50%) |
| Men | 5 (50%) |
| Women | 5 (50%) |
| Eyes: N (%) | 5 (41.66%) |
| Right | 7 (58.33%) |
| Left | 4 (40%) |
| Arabic | 6 (60%) |
| Caucasian | 7 (58.33%) |
| Lens N (% | 9 (75%) |
| Phakic | 3 (25%) |
| Pseudophakic | HbA1C (% (Mean ±SD) 7.4 ± 0.5 |
retinal pigment epithelium to accomplish a therapeutic effect, as the heat shock may disseminate into the inner retinal tissues [7-8-9].

In a randomized, prospective, single center study, comparing 810 nm laser vs 577 nm subthreshold laser using 5% duty cycle for six-months in 53 eyes with mild DME with central macular thickness less than 400 μm. The 577 nm subthreshold laser for diabetic macular edema, reduced central macular thickness from 357.8 ± 46.1 to 339.9 ± 55.7 μm and from 340.1 ± 35.7 μm to 335.3 ± 54.5 μm in the 810 nm subthreshold laser group. In contrast, in this study, hybrid threshold with 532 nm laser achieved thickness reduction from 336.58 ± 86.26 μm to 264.33 ± 61.41 μm in a 24 weeks follow up [10].

The subretinal scars induced by threshold laser to close the leaking microaneurysm were limited to outer retinal layers without expanding in size nor into inner retinal tissues. In 24 weeks follow-up, the scar size was reduced based on SD-OCT scans and funds images.

This study showed that a Hybrid threshold laser could stabilize the edema with the possibility of thickness reduction up to 20%. This can be beneficial in residual diabetic macular edema cases after injection to reduce injection frequency or in patients who refuse or are contraindicated for injection (Fig. 2). Which may reduce the cost burden for intravitreal injections and office visits especially for cases of DME with thickness less than 400 μm.

The limitation of this study includes the short time of follow-up which is only 24 weeks, that hinders the long-term results and durability of diabetic macular edemas with 532 nm Hybrid threshold laser.

Another limitation of this study is that it is a single-center study with a small number of eyes tested with 532 nm hybrid threshold laser. Which it is still not known the results of utilizing the hybrid threshold laser on larger sample of patients in a multicenter setting.

This study lacks both of a control arm and other comparison arms, such as with an intravitreal injection.

So it is imperative to have a long time follow up with a larger sample of patients with multicenter randomized clinical trial comparing hybrid threshold laser with control and other treatment modalities such as intravitreal injections.

5. Conclusion

This study showed that a 532 nm hybrid threshold laser effectively stabilizes diabetic macular edema with minimal subretinal scars limited to outer retinal layers.

However, long-term and larger studies are required to evaluate the actual efficacy and durability of the 532 nm Hybrid threshold laser.

Ethical approval

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Sources of funding

There is no source of funding for this paper.

Author contribution

Ameen Marashi designed and drafted the research manuscript and approved final version to be submitted. Aya Zazo analyzed and interpreted the research manuscript and approved final version to be submitted.

Registration of research studies

You can register any type of research at http://www.researchregistry.com to obtain your UIN if you have not already registered. This is mandatory for human studies only. Trials and certain observational research can also be registered elsewhere such as: ClinicalTrials.gov or ISRCTN or numerous other registries.

Consent

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The patients have given their written informed consent on admission to use their data base and files for research work.
Declaration of competing interest

The authors declare that there is no conflict of interest.

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None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104222.

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