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Matthew Tukel fh1837@wayne.edu

Desiree Albert MD Henry Ford Health System

Sarah Syeda MD Kresge Eye Institute

Anita Vaishampayan *Wayne State University* 

Xihui Lin MD *Kresge Eye Institute* 

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## Focal Laser Photocoagulation for Diabetic Macular Edema Done by Resident Physicians: Predictors of Effective Treatment

Desiree Albert MD<sup>1</sup>, Kevin Bubel MD<sup>2</sup>, Sarah Syeda, MD<sup>3</sup>, Matthew R. Tukel BS<sup>3</sup>, Anita Vaishampayan, Kim Le MD<sup>1,2</sup>, Xihui Lin MD<sup>2,3</sup>

<sup>1</sup>Henry Ford Health System; Detroit, MI, USA <sup>2</sup>University of Texas Southwestern Medical Center, Dallas, TX, USA <sup>3</sup>Kresge Eye Institute; Detroit, MI, USA

Corresponding Author: Matthew R. Tukel 3150 Woodward Ave. 521 Detroit Mi, 48201 (248) 766-1619 Mtukel@med.wayne.edu

1	Abstract:
2	<b><u>Purpose</u></b> : To evaluate the effectiveness of focal laser for treatment of diabetic macular edema (DME)
3	performed by ophthalmology residents.
4	Methods: Chart review of DME patients treated in a resident clinic with focal laser. Visual acuity (VA),
5	OCT central subfield thickness (CST), and maximum subfield thickness (MST) at initial, 1 month, and 6
6	month visits were recorded.
7	<b><u>Results</u></b> : For 32 reviewed patients, average VA was 20/58 initially and 20/39 at 6 months (p=0.18). Mean
8	CST was 311 $\mu$ m initially and 305 $\mu$ m at 6 months (p=0.09). Mean MST was 413 $\mu$ m initially and 382
9	$\mu$ m at 6 months (p=0.007). Factors favoring success are: initial CST <400 $\mu$ m, treatment of localized
10	microaneurysms, and prior focal laser treatments.
11	Conclusion: Focal laser performed by residents was effective in decreasing MST and maintained visual
12	acuity. Initial CST, localized microaneurysms and repeat focal treatment predicted improved outcomes.
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#### 26 Introduction

27 Diabetic macular edema (DME) is the most common cause of vision loss in diabetic retinopathy.<sup>1</sup> It is a prevalent disease, affecting 7% of people with diabetes.<sup>2</sup> The mechanism for edema in diabetic 28 29 retinopathy is due to abnormal vascular permeability.<sup>3</sup> As in diabetic retinopathy, the greatest modifiable 30 risk factor for the development of DME is hyperglycemia.<sup>4</sup> DME is diagnosed by the presence of macular 31 thickening observed via slit lamp biomicroscopy, stereoscopic fundus photos, or on optical coherence 32 tomography (OCT) (figure 1). Other exam findings such as hard exudates in the presence of 33 microaneurysms and blot hemorrhages within one disc diameter of the fovea have been utilized for 34 diagnosis as well.<sup>4</sup> Fluorescein angiography (FA) can also aid in diagnosis. It will show vascular leakage in the setting of edema, which frequently correlates well with OCT findings.<sup>5</sup> 35 36 Treatment of DME, with goals of immediate and sustained visual improvement and prevention of 37 vision loss, has evolved through the years. The first available treatment option began in 1985 when the 38 Early Treatment Diabetic Retinopathy Study established the effectiveness of laser photocoagulation for 39 DME.<sup>6</sup> Laser can be performed in focal pattern, targeting specific leaking microaneurysms, or in a grid pattern to target areas of more diffuse leakage.<sup>6</sup> Our study concentrates on focal laser photocoagulation. 40 41 While laser was the only treatment option available for 20 years, there are now several other 42 modalities available. The advent of intravitreal anti-vascular endothelial growth factor (VEGF) 43 medications, beginning with pegaptanib in 2005 introduced a second treatment option, particularly useful 44 for center-involving DME that is not amenable to laser treatment.<sup>7</sup> Currently, ranibizumab, aflibercept, 45 and the off-label use of bevacizumab, are available anti-VEGF agents, and these agents have dramatically 46 changed the treatment of DME. The release of the Diabetic Retinopathy Clinical Research Network 47 (DRCR.net) Protocol I data, demonstrated the role of intravitreal anti-VEGF agents in combination with focal/grid laser treatment.8 48 49 There are additional treatment options that may be utilized, particularly in refractory cases. This 50 includes intravitreal triamcinolone, which was superior to laser alone in pseudophakic eyes when studied

51 in DRCR.net protocol I, as well as various other ocular steroid formulations.<sup>9</sup> Lastly, DME that is

associated with posterior hyaloid traction and/or epiretinal membrane may be amenable to improvement
with pars plana vitrectomy.<sup>10</sup>

Given the multitude of treatment options and various treatment algorithms that have been studied,
the decision for when focal laser is indicated is very practitioner-dependent and frequently based on
personal experience. Our study analyzes focal laser treatments performed by multiple physicians in an
inner-city population to identify patient selection factors and treatment parameters that correlated with
successful outcomes.

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## 60 <u>Methods</u>

Patients with DME were selected from outpatient visits with multiple physicians at Parkland
Memorial Hospital (Dallas, TX). The study was conducted in accordance with the World Medical
Association Declaration of Helsinki.

64 The study consisted of 32 patients, 24 (75%) of which were male. The population was
65 predominantly Hispanic (59.4%), and the average age was 65 years old. Average hemoglobin A1c was
66 8.3%. See table 1 for additional demographic characteristics.

Patient selection for receiving focal laser treatment was physician dependent, and these selection
factors were analyzed in the study. Exclusion criteria included macula edema not secondary to diabetic
retinopathy (e.g. retinal vein occlusion, Irvine-Gass Syndrome, uveitic macular edema), lack of return for
the 1 month follow-up appointment, or if pre-treatment or post-treatment OCT's (Heidelberg Spectralis)
were not available.

For each selected patient, laser treatment was performed with an Iridex 532 nm green laser
through a slit-lamp delivery system in single spots without pattern scanning. The lens used for all
treatments was a Volk Area Centralis contact lens. Treatment parameters including laser power and
duration settings, spot size, number of shots, and pattern of treatment were analyzed.

Patients returned for 1-month follow-up, with the primary outcomes examined at that visit
including visual acuity change, OCT central subfield thickness (CST) change, and maximal subfield

thickness (MST) change as compared to pre-treatment values. MST was analyzed because the goal of
many focal laser treatments was to target a non-central area of leakage in order to prevent future central
involvement.

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#### 82 <u>Results</u>

83 Visual acuity was recorded on logMAR scale, with a pre-treatment average visual acuity of 0.42 84 (corresponding to 20/52) and 1-month post treatment average visual acuity of 0.34 (corresponding to 85 20/44). The average CST was 322.26 µm pre-treatment and 325.81 µm post-treatment, while the average 86 MST did improve marginally from 418.29  $\mu$ m to 407.74  $\mu$ m. Average laser parameters used were 87 96.78mW power, 0.1 second duration, 91.38 µm spot size, and shot count of 4.43. 88 When comparing patients with less than 400  $\mu$ m CST (n = 57) pre-treatment to patients with 89 greater than 400  $\mu$ m (n = 10), there was a statistically significant (p = 0.0001) difference in CST change 90 and MST change at 1 month, favoring those patients with thinner pre-treatment CST. This is attributable 91 to the fact that in eyes with CST greater than 400  $\mu$ m, significant amount of the leakage was centrally 92 located and was not amenable to focal laser. This OCT improvement did not, however, correlate with 93 statistically significant visual acuity improvement advantage for those with less than 400 µm pre-94 treatment. See Table 2 for detailed study results.

## 95 <u>Conclusions</u>

For patients who had less than 5 microaneurysms targeted with laser treatment, there was a
statistically significant difference in visual acuity, CST, and MST outcomes at 1 month as compared to
other targets of treatment. In those patients with fewer microaneurysms targeted, the source of leakage
was more focal and therefore responded better to laser treatment.

100 Due to limited resources at our county hospital, FA was only able to be obtained prior to laser

treatment in 1/3 of the cases where the source of leakage was uncertain (i.e. many candidate

102 microaneurysms), but there was no significant relationship found between visual acuity or OCT outcomes

at 1 month whether the patient had an FA conducted prior to treatment or not.

Laser parameters were evaluated, and patients were found to have worse outcomes when power settings outside the range of 80-100 mW were utilized, with worse visual acuity, CST, and MST outcomes at 1 month (p = 0.039, 0.022, and 0.014, respectively), as compared to those treatments conducted within the 80-100 mW range. This is likely due to laser power of less than 80 mW being inadequate to sufficiently coagulate microaneurysms or induce significant local photo-chemical changes, and power greater than 100 mW likely inducing more local inflammatory changes which temporarily worsened the swelling at 1 month.

111 Visual acuity outcomes at 1 month were worse for patients who had previous focal or grid laser 112 treatment prior to this study as compared to those who had no prior laser (p = 0.07).

There was no significant correlation found between hemoglobin A1c level and visual acuity,
CST, or MST outcomes at 1 month follow up. There was also no correlation found between number of
intravitreal bevacizumab (Avastin) injections received in the previous 6 months and post-laser
outcomes.

Overall, focal laser photocoagulation for DME in an inner-city county hospital population
improved visual acuity and stabilized macular swelling at 1 month post-treatment. Predictive factors for
favorable focal laser outcomes included pre-treatment CST of less than 400 µm, treatment targeting fewer
than 5 microaneurysms in a focal area of swelling, and using laser parameters of power between 80 mW
and 100 mW. Prior fluorescein angiography, prior macular laser treatments, and hemoglobin A1c
percentage did not correlate with improvement at 1 month.

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## 156 <u>Figure legends</u>

- **157** Figure 1 OCT images from a patient who received focal grid laser treatment. 1A pre-treatment image
- 158 with temporal macular edema. 1B 1 month post-treatment image with improved temporal macular
- 159 edema.