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Original Article

Studying the Effect of Different Treatment Modalities on Color Vision in Patients with diabetic Macular Edema

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ABSTRACT

Background: Diabetic macular edema [DME] is a significant contributor to vision loss globally, arising as a part of diabetic retinopathy [DR], which is the most prevalent ocular issue associated with diabetes mellitus [DM].

Aim: This study aimed to evaluate changes in color vision in patients with diabetic macular edema using Roth 28 hue color test before and after using of different modalities of treatment, either macular laser treatment or the intravitreal injection of anti- vascular endothelial growth factor [Anti-VEGF].

Patients and Methods: In a randomized cross-sectional study done on 30 eyes of 20 patients with diabetic macular edema of both types insulin dependent and non-insulin dependent of both genders at different age groups, presented to the ophthalmology outpatient clinic at New Najran General Hospital. For every patient; full history was taken, full ophthalmic examination was done [including; measuring the best corrected visual acuity [BCVA], color vision using Roth 28 hue test]. Ophthalmic investigation by the Heidelberg spectral domain optical coherence tomography [SD-OCT] at baseline. Color vision testing was repeated one month after using macular laser photocoagulation in group 1 and intra-vitreal injection of Anti-VEGF in group 2.

Results: The current study reveals there was no statistically significant improvement in BCVA, the percentage of change was 0%, and there was no statistically significant change of color global error among the studied patients in group 1. There was statistically significant improvement in BCVA, the percentage of change was 28% and improvement of color global error among the studied patients in the Anti-VEGF group.

Conclusion: Improvement of color vision is noticed after one month among the patients treated with intra-vitreal injection of Anti-VEGF, whereas it does not show such improvement in patients treated with macular laser photocoagulation.

Keywords: Color vision; Visual acuity; Diabetes Mellitus; Diabetic Macular Edema.



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INTRODUCTION

Diabetic macular edema [DME] is a significant contributor to vision loss globally, arising as a complication of DR, which is the most prevalent ocular issue associated with DM. The prevalence of DR is notably higher in patients with type I diabetes compared to those with type II diabetes [1]. This condition is characterized by variable correlations between OCT-measured macular thickness and visual acuity, leading to instances where visual acuity paradoxically changes despite alterations in macular thickness. Notably, the longer duration of diabetes the more severe forms of retinopathy, indicating the importance of early diagnosis and management [2].

Many risk factors are associated with the development and progression of DR. The most important are duration of DM, control of DM, associated hypertension [HTN], associated renal disease and pregnancy [3]. Central vision can be affected either due to macular edema or capillary non-perfusion. Proliferative diabetic retinopathy [PDR] may lead to severe visual loss through retinal distortion or hemorrhage. The classification of DR into nonproliferative and proliferative stages underscores the structural damage to retinal blood vessels that may occur [4]. The Early Treatment Diabetic Retinopathy Study [ETDRS] defined clinically significant macular edema [CSME] [figure 1] as 1 or more of the following: retinal thickening at or within 500µm of the center of the macula; hard exudates at or within 500µm of the center of the macula if associated with adjacent retinal thickening; or a zone or zones of retinal thickening 1-disc diameter [DD] in size, at least part of which is within 1 DD of the center of the macula [5].

Therefore, different treatment modalities such as intra-vitreal injection of Anti-VEGF or laser photocoagulation may be preferable over conservative management ^[5,6]. An increased extent of macular edema is a risk factor for visual impairment. The color discrimination defect is deteriorated in diabetic patients with macular edema. The aim of this study was to evaluate changes in color vision in patients with DME using Roth 28-hue color test before and after using of different methods of treatment, either macular laser treatment or the intra-vitreal injection of Anti-VEGF.

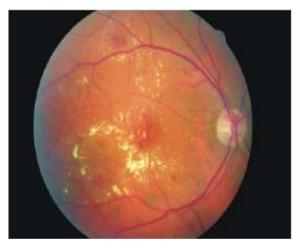


Figure [1]: CSME.

PATIENTS AND METHODS

Study design: The current study is a cross-sectional study that was done on 30 eyes of 20 patients with DME of both types insulin dependent and non-insulin dependent of both genders at different age groups, presented to the ophthalmology outpatient clinic at New Najran General Hospital. Patients were selected to be participants in the current study according the following inclusion criteria:

- Slit lamp examination: media clarity, no infections [including conjunctivitis, meibomianitis, and significant blepharitis] and sufficient patient cooperation.
- Slit lamp fundus biomicroscopic examination by non-contact lens: Presence of diffuse CSME which is defined as an area, or areas of retinal thickening, 1 DD or larger, any part of which is within 1 DD of the center of the macula.
- OCT: presence of DME with the central macular thickness above 300 microns.

Exclusion criteria: Presence of any ocular condition that might cause macular edema or alter visual acuity during the course of study [other than diabetes]. e.g., media opacities, venous occlusion, epiretinal membrane, and/or vitreomacular traction, eyes with subretinal fluid, uveitis, neovascular glaucoma, vitreous hemorrhage, etc. and history of major ocular surgery e.g., vitrectomy, scleral buckling etc.

Sampling technique: A randomized convenient sample of all patients diagnosed with DME of both types insulin dependent and non-insulin dependent recruited from ophthalmology outpatient clinic at New Najran General Hospital during the study period and fulfilled the predetermined inclusion and exclusion criteria was included in the current study. Patients were classified into two groups: Group 1 treated with macular laser photocoagulation, and Group 2 treated with intra-vitreal injection of Ranibizumab.

Data collection: All patients were subjected to the following:

A. A detailed history taking including [Age, gender, type and duration of DM, type of control of DM, presence of any systemic disease e.g., HTN, renal impairment, anemia and previous eye surgery].

B. Full ophthalmological examination including [Anterior segment evaluation [Corneal opacity, Lenticular opacity, Presence or absence of rubeosis iridis], Fundus examination by [Non-contact slit lamp biomicroscopy; VA testing with and without correction using Snellen's chart [metric]. For statistical analysis, Snellen VA was converted to decimal fraction of vision to record the number of lines gained or lost after treatment].

C. Imaging:

• Optical coherence tomography [OCT]: OCT scanning using The Heidelberg ™ SD-OCT [Heidelberg Engineering,

Heidelberg, Germany, Figure 2] on the same session by the same operator was performed for central macular thickness in DME patients one week before usage of different modalities of treatment. poor OCT signal were excluded. Eyes with other conditions that might cause macular thickening such as venous occlusion, uveitis, and/or vitreomacular traction were also excluded.

• Optical Coherence Tomography scanning using the $Heidelberg^{TM}$ SD-OCT [Heidelberg Engineering, Heidelberg, Germany]. was performed using the 512×128 scan pattern where a 6mm × 6mm macular grid was scanned with 128 horizontal B-scan lines. Each eye involved in the study was pharmacologically dilated 30 minutes prior to the scanning. All scans were performed by the same certified OCT technician. A total of three "high-quality" scans were obtained; these were defined as scans with a signal strength ≥6 that exhibit correct delineation of the internal limiting membrane [ILM] and retinal pigment epithelium [RPE] as detected automatically by the intrinsic segmentation algorithm. The macular grid was centered on the intrinsic fixation target during OCT scanning. Hence, the center of the macular grid was maintained at the patients' point of fixation [8].



Figure [2]: Heidelberg OCT

D. Color vision testing: Using the Roth 28 hue color test [Luneau, Paris] [Figure 3] at first visit then one month after using of different modalities of treatment of DME, and evaluated by score sheet [Figure 4].



Figure [3]: The Roth 28 hue test.

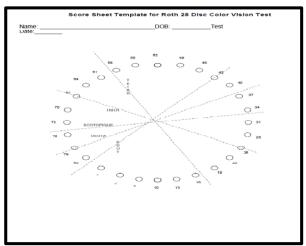


Figure [4]: Score sheet template for Roth 28 hue color vision test

Roth [1966] first described the cap-sorting test Roth 28 hue [Luneau, Paris]. A black cardboard was used as a background, and was illuminated by two fluorescent lamps. The subjects' visual acuity was corrected, if necessary, and gloves were used to protect the surface of the color caps. Each subject was tested monocularly. Subjects were instructed to select the cap most similar to the reference cap, then the cap most similar to the previously chosen one, and so on, and to place them in sequential order until all 27 caps were arranged in a circular sequence. The subject first viewed the test, which was explained to him. There was no time limit for the test, and the subject was allowed to correct each of his or her arrangements [9].

Calculation and graphic demonstration of the Roth 28-hue color test [according to Erb et al. [10]: The Roth 28-hue test is a subset of the Farnsworth-Munsell 100-hue test [FM 100-hue] in which the color caps are numbered from 1 to 82, with only each third number used. The color chip number 82 is fixed and defined as the starting and end point. The error scores of this test are similar to those of the FM 100-hue, and calculated in the same way. For each of the 28 color chips, the differences of the chip number to both adjacent color chips were calculated [value X]. Values X and 84[=[82-1]+3]-X were then compared and the lower was chosen as the distance. The shortest distance between two caps within the circular arrangement was thus calculated. For example, the distance 82-1 is calculated as 3, which is the standard value for error-free arrangement. The values of distance on both sides were added, and the value 6 [2 x 3] was subtracted from this sum and the resulting value noted as a local error score. The sum of the local error scores of the 28 color chips was the resulting global error score. The graphic representation showed the 28 local error scores.

Procedure of intra-vitreal injection: [11] Topical anesthesia by Benoxinate HCL 0.4% eye drops.

Technique:

The intra-vitreal injection of Ranibizumab [LUCENTIS®; Genentech, Inc] was performed at the same day: 1]. Prior to the

intravitreal injection of ranibizumab, topical betadine [povidone iodine 5%] was applied, and washed out after 2-3 minutes, then the patient will be completely draped; 2] Lid speculum was inserted to open the palpebral fissure; 3] Injection of 0.5 mg of ranibizumab was performed through a 27- Gauge needle through the inferior pars plana, at 4 mm from the limbus; 4] Antibiotic eye drops were applied.

Post-operative evaluation:

The patients were evaluated 1 day after intra-vitreal injection for the intraocular pressure, inflammation and BCVA. Then the patients were evaluated after one month for BCVA, anterior Segment, intraocular pressure, fundus and color vision testing.

Procedure of macular laser photocoagulation treatment: [12] Topical anesthesia by Benoxinate HCL 0.4% eye drops was applied.

Technique of laser photocoagulation [modified ETDRS focal/grid treatment] using the MC-500ViXi laser system [Nidek Co., Gamagori, Japan]:

Pharmacologic dilatation of the pupil by Tropicamide 1% eye drops was done. The types of laser patterns used were

- 1- Focal: argon burns were applied to leaking microaneurysms 500–3000μm from the foveola; spot size 100μm, duration 50 milliseconds with sufficient power to obtain a greyish reaction beneath the microaneurysm.
- 2- Grid: Burns were applied to macular areas of diffuse retinal thickening, treating no closer than 500μm from the foveola and 500μm from the optic disc using a spot size of 100μm and duration 0.05 second, with power adjusted to give a mild reaction.

Finally, Antibiotic eye drops were used.

Post-operative evaluation: 1] The patients were evaluated 1 day after laser treatment for the intraocular pressure, inflammation and BCVA; 2] Then the patients were evaluated after one month for BCVA, anterior Segment, intraocular pressure, fundus and color vision testing.

Statistical analysis:

The collected data was revised, coded, and tabulated using the Statistical package for Social Science [IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.]. Data were presented and suitable analysis was done according to the type of data obtained for each parameter. Shapiro-Wilk test was done to test the normality of data distribution. The Kruskal-Wallis test was used to assess the statistical significance of the difference between more than two study group non-parametric variables. One-way ANOVA test was used to assess the statistical

significance of the difference between more than two study group parametric variables. Chi-Square test was used to examine the relationship between two qualitative variables. A p value is considered significant if <0.05 at confidence interval 95%.

RESULTS

The age range was between 42 and 70 years in group 1, with a mean age of 53.50 ± 8.77 years, and between 45 and 66 years in group 2, with a mean age of 54.90 ± 7.23 years as shown in Table [1]. Two [2] patients have type 1 DM [20%], 8 patients have type 2 DM [80%] in group 1, while 1 patient has type 1 DM [10%], 9 patients have type 2 DM in group 2 [90%]. The duration of DM ranged from 2 years to 27 years in group 1, and ranged from 3 years to 20 years as shown in Table [2].

According to BCVA, it ranged from [6/60] Snellen [0.1] decimal to 6/18 Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.11 in group 1, while in group 2 it ranged from [3/60] Snellen [0.05] decimal to 6/18 Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.12. One month after treatment of DME, the BCVA ranged from [3/60] Snellen [0.05] decimal to [6/18] Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.12 in group 1, the percentage of change was 0%. In group 2, the BCVA ranged from [6/60] Snellen [0.1] decimal to [6/7.5] Snellen [0.8] decimal with mean \pm SD 0.32 \pm 0.19, the percentage of improvement was 28% which was statistically significant at p \leq 0.05, as shown in Table [3].

According to OCT findings in the 2 groups, in macular laser group [group 1], the CMT ranged from $304\mu m$ to $498\mu m$ with mean \pm SD $377.40\pm63.44\mu m$. In group 2 [Anti-VEGF injection], the CMT ranged from $301\mu m$ to $575\mu m$ with mean \pm SD $398.60\pm94.14\mu m$ as shown in Table [4]. The range of color global [total] error in the studied eyes tested with the Roth 28 hue test was between 264 and 804 with a mean of 643.20 ± 142.55 in group 1. One month after treatment of DME with macular laser, the range of color global error was between 288 and 888 with a mean of 676.0 ± 167.98 . In group 2, the range of color global error was between 276 and 876 with a mean of 668.0 ± 177.04 . After one month, it ranged from 144 and 804 with a mean of 583.20 ± 180.90 ; there was statistically significant improvement of color vision [decrease of global error] in this group at $p \le 0.05$, as shown in Table [5].

Table [1]: Distribution of the patients in the two studied groups according to sex and age

	Macular Laser [n= 10]		Anti-VEGF Injection [n= 10]	
	No	%	No	%
Sex				
Male	4	40.0	4	40.0
Female	6	60.0	6	60.0
Age [years]				
Min. – Max.	42.0 -	- 70.0	45.0 -	- 66.0
Mean ± SD.	53.50	± 8.77	54.90	± 7.23
Median	51.0		54	.50

No: number; %: percentage; Min: minimum; Max: maximum; SD: standard deviation

Table [2]: Distribution of the patients in the two studied groups according to type of DM and duration

	Macular Laser [n= 10]		Anti-VEGF Injection [n= 10]	
	No	%	No	%
Type of DM				
Type I	2	20.0	1	10.0
Type II	8	80.0	9	90.0
Duration of DM				
Min. – Max.	2-27		3-20	
Mean \pm SD.	11.80 ± 8.36		12.0 ± 5.21	
Median	10		12	

No: number; %: percentage; Min: minimum; Max: maximum; SD: standard deviation

Table [3]:Comparison between the two studied groups according to BCVA

W DC VA				
Macular Laser [n=15]	Anti-VEGF injection [n=15]			
0.1 - 0.5	0.05 - 0.5			
0.18 ± 0.11	0.22 ± 0.15			
0.16	0.16			
0.05 - 0.5	0.1 - 0.8			
0.18 ± 0.12	0.32 ± 0.19			
0.16	0.32			
0.440	0.003*			
-80.0 - 60.0	0.0 - 400.0			
\uparrow 4.87 ± 41.97	↑74.02 ± 102.20			
0.0	28.0			
	Macular Laser [n=15] $0.1-0.5$ 0.18 ± 0.11 0.16 $0.05-0.5$ 0.18 ± 0.12 0.16 0.440 $-80.0-60.0$ $\uparrow 4.87 \pm 41.97$			

 p_l : p value for Wilcoxon signed ranks test for comparing between pre and post; *: Statistically significant at $p \le 0.05$.

Table [4]: Description of the two studied groups according to

CMT	Macular Laser [n= 15]	Anti-VEGF Injection [n= 15]
Min. – Max.	304.0 – 498.0	301.0 – 575.0
Mean ± SD.	377.40 ± 63.44	398.60 ± 94.14
Median	367.0	368.0

Table [5]: Comparison between the two studied groups according to color global [total] error

Colour Global Error	Macular Laser	Anti-VEGF
	[n=15]	injection [n=15]
Pre		
Min. – Max.	264.0 – 804.0	276.0 – 876.0
Mean ± SD.	643.20 ± 142.55	668.0 ± 177.04
Median	684.0	684.0
Post		
Min. – Max.	288.0 - 888.0	144.0 – 804.0
Mean ± SD.	676.0 ± 167.98	583.20 ± 180.90
Median	672.0	624.0
p 1	0.342	0.014*
% of change		
Min. – Max.	-20.34 – 52.08	-47.83 – 24.07
Mean ± SD.	↑6.44 ± 20.15	\downarrow 13.40 ± 19.12
Median	6.38	-13.21

 p_1 : p value for Paired t-test for comparing between pre and post; *: Statistically significant at $p \le 0.0$ %: percentage Max: maximum; SD: standard deviation

DISCUSSION

The aim of this study was to evaluate changes in color vision in patients with DME using Roth 28-hue color test before and after using of different methods of treatment, either macular laser treatment or the intra-vitreal injection of Anti-VEGF. The current study reveals there was no statistically significant improvement in BCVA, the percentage of change was 0%, and there was no statistically significant change of color global error among the studied patients in group 1. There was statistically significant improvement in BCVA, the percentage of change was 28% and improvement of color global error among the studied patients in the Anti-VEGF group. DME is a leading cause of visual loss in developed countries. Significant number of diabetic people with proliferative retinopathy are considered at risk of vision loss if they do not get suitable medical care [13]. OCT added a high-resolution cross-sectional scanning of the entire macular area. OCT is now considered essential in the diagnosis and follow up of DME as it could not only give an objective measurement of the macular thickness with a resolution of 10 microns, but also an image of intra-retinal structure like photoreceptors layer and epiretinal tractions [14]. The Heidelberg™ SD-OCT technology has offered higher axial resolution [≈5µm] compared to time domain instruments [≈10μm]. Several reports have recently described morphological characteristics in various macular diseases using Heidelberg[™] SD-OCT ^[15]. An increased extent of DME is a risk factor for visual impairment but, in the presence of focal macular edema, visual acuity may be normal. The color discrimination defect is deteriorated in diabetic patients with macular edema. Some authors in ETDRS reported that the tritan axis is more severely affected than the protan and deutran axes in patients with diabetic maculopathy, and that this tritan-like defect increases in magnitude with increasing severity of macular edema [16].

The blue-yellow defect or a combined blue-yellow and redgreen defect are the most frequently described color vision defects in diabetic patients. Therefore, the usual pseudoisochromatic plates, e.g., the Ishihara test, are not sufficient in screening because they screen only red-green defects [16,17]. Impaired color vision associated with DR was observed in ETDRS conducted by **Fong DS** *et al.* [18], who measured color vision function at baseline in 2,701 patients using FM 100-hue test, and found that approximately 50% of the ETDRS population had color vision scores worse than 95% of the normal population. The factors most strongly associated with impaired hue discrimination were macular edema severity, age, and presence of new vessels. However, many patients had color discrimination impairment without macular edema.

Changes in Best Corrected Visual Acuity: Regarding BCVA before treatment with either macular laser or Anti-VEGF injection, which ranged from [6/60] Snellen [0.1] decimal to 6/18 Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.11 in group 1 [Macular Laser] while in group 2 [Anti-VEGF injection] it ranged from [3/60] Snellen [0.05] decimal to 6/18 Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.12. One month after treatment of DME, the BCVA ranged from [3/60] Snellen [0.05] decimal to [6/18] Snellen [0.5] decimal with mean \pm SD 0.18 \pm 0.12 in group 1, the percentage of change was 0%. The study results are nearly similar to the results of **Aiello LP**, **et al study** [19] who evaluated the factors associated with improvement and worsening of visual acuity 2

years after focal or grid photocoagulation for DME. They found that visual acuity outcomes were similar in eyes with and without prior macular or panretinal photocoagulation.

The initial visual acuity outcome at one and 4 months was not generally predictive of the subsequent course. However, many eyes that worsened > or =10 letters from baseline to 4 months subsequently improved, and many eyes that initially improved, subsequently worsened. In group 2, the BCVA ranged from [6/60] Snellen [0.1] decimal to [6/7.5] Snellen [0.8] decimal with mean \pm SD 0.32 ± 0.19 , the percentage of improvement was 28% which was statistically significant at $p \le 0.05$. These results were in agreement with the study of Nowacka B, et al. [20] who assessed the macular function and structure in patients with DME before and after intra-vitreal injection of ranibizumab. Seventeen eyes of 17 patients with type 2 DM and DME were treated with intravitreal injections of 0.5 mg ranibizumab. Prior to the first injection, as well as after 3 and 6 months, the following examinations were performed: assessment of distance BCVA [log MAR], perception of metamorphopsia [M-Chart], slit lamp examination of the anterior and posterior segment of the eye [Volk 90 D lens], evaluation of the retinal and choroidal circulation [fluorescein angiography], assessment of the structure and thickness of the macula [OCT], as well as evaluation of the macular function. They observed that ranibizumab significantly improved visual acuity after 3 and 6 months from the beginning of the treatment, which was a consequence of reduced macular edema and vascular leakage. There was a statistically significant decrease in metamorphopsia frequency at month 3; however, at month 6, it was a statistically insignificant when compared to the baseline.

In the study of **Ghanchi F** *et al.* ^[21] the results were very much similar to our study, DME in 51 eyes of 41 South Asian patients was treated with ranibizumab 0.5 mg according to the modified DRCR.net protocol I. VA and central macular thickness [CMT] were recorded at baseline, 3, 6, and 12 months. Results were compared for eyes with different baseline visual acuities and different baseline macular thicknesses. Over the 12-month period, the mean ETDRS VA increased from 55.3±13.4 letters to 63.8±15.2 letters for all eyes. At 12 months, 70.6% eyes gained 5 or more letters acuity and 17.6% eyes gained 15 letters or more. During the same period, the mean CMT decreased from 532±129 to 318±136μm. They concluded that ranibizumab 0.5 mg is safe and effective at reversing vision loss due to DME in patients of South Asian origin at 12 months.

Changes in Color Global Error: The range of color global error in the studied eyes tested with the Roth 28-hue test was between 264 and 804 with a mean of 643.20 ± 142.55 in group 1. One month after treatment of DME with macular laser, the range of color global error was between 288 and 888 with a mean of 676.0 ± 167.98 . In this study, there was no statistically significant improvement in the color global error after using the macular laser for the treatment of DME. These results are against the study of **Birch J.** [22] who examined the effect of focal laser photocoagulation after one month on color vision using the FM

100-hue test in only 3 eyes with DME; this was a part of a large study examining the effect of panretinal photocoagulation on the color vision using the same test. In this study the subjects showed improvement of color vision with only one eye restored its tritan defect. He concluded that when only small amounts of focal photocoagulation are used, there is insufficient stray light to cause a problem, and the effect on color vision is always beneficial.

In group 2, the range of color global error was between 276 and 876 with a mean of 668.0 ± 177.04 , after one month, it ranged from 144 and 804 with a mean of 583.20 ± 180.90 ; The results of this study showed that there was statistically significant improvement of color vision [decrease of global error] in this group at $p \leq 0.05$. Unfortunately, there were no previous studies evaluating these changes.

Conclusion: DME is a major cause of vision loss worldwide. Over the past decade, several clinical trials have been done to assess the effect of various treatment options for DME. It occurs as a complication of DR, which is the most common ocular complication of DM, and its prevalence is higher in type I DM than in those with type II disease.

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