Research Square

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Quantitative Evaluation of Metamorphopsia in Patients with Diabetic Macular Edema Using M-Charts™

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Research Article

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Abstract

Purpose

The aim of this study is to quantitatively evaluate and statistically analyze the vertical and horizontal metamorphopsia scores and Optical Coherence Tomography (OCT) data of diabetic macular edema (DME) patients who described metamorphopsia and had an indication for intravitreal bevacizumab injection, before and after intravitreal injection.

Methods

In this study, patients who applied to Ophthalmology outpatient clinic of Akdeniz University between December 2021 and December 2022 and were followed up for at least 6 months were retrospectively reviewed. Fifty-one eyes of 51 patients were included in the study. All patients received an intravitreal injection of 2 mg bevacizumab with four-week intervals. Age, gender, presence of systemic and ocular diseases, baseline visual acuity, best-corrected visual acuity (BCVA) 1, 3, and 6 months after injection, M-CHARTS parameters, and OCT parameters were evaluated for the patients.

Results

Findings of the study indicated BCVA increased in 35 of 51 eyes at the end of six months compared to pretreatment. The patients received an average of 4.5 injections, with a standard deviation of ± 1.3. At the end of six months, a statistically significant decrease was observed in central foveal thickness (CFT) ($p < 0.001$) and metamorphopsia scores (Mv; $p < 0.005$, Mh; $p < 0.05$). BCVA improved significantly at the end of six months ($p < 0.001$).

Conclusion

Diabetic macular edema is a vascular retinal disease that can impair visual acuity and cause metamorphopsia. M-CHARTS plays an important role in the quantitative evaluation of metamorphopsia complaints of patients with DME. The present study demonstrated the efficacy of intravitreal injections in addressing both DME and metamorphopsia complaints. Further research is needed to clarify the relationship between metamorphopsia and OCT parameters.

Introduction

Diabetes mellitus (DM) has become a growing public health problem worldwide.[1] Projections indicate that by the year 2040, the number of individuals aged 20 to 79 years affected by diabetes will reach

approximately 640 million.[2] Diabetic Retinopathy (DR) is the leading cause of vision loss in adults aged between 20–74 years.[3]

Approximately one-third of DM patients are affected by vision-threatening diabetic retinopathy, defined as the presence of non-proliferative DR(NPDR) or proliferative DR (PDR) or DME.[4] These estimates are expected to rise further as the prevalence of DM increases, the population ages and the life expectancy of people with diabetes increases.[5]

Treatment of DME involves the use of drugs that target inflammation and vascular endothelial growth factor (VEGF). Bevacizumab, a humanized monoclonal antibody that inhibits VEGF, was originally developed for use in combination with existing metastatic colorectal cancer regimens.[6] Intravitreal bevacizumab (IVB) injections have been widely used as off-label treatment for neovascular age-related macular degeneration and DME.[7, 8]

Metamorphopsia impairs quality of life of patients with DME. Although recent anti-VEGF therapy can relieve DME and improve visual acuity, many patients with DME continue to complain of metamorphopsia after successful treatment. Metamorphopsia is an important subjective symptom associated with vision-related quality of life in various ocular diseases.[9–12] Understanding the mechanisms that cause metamorphopsia in DME will allow to take metamorphopsia under control in patients with DME in the future. In the future, metamorphopsia score may play a key role in determining patient treatment. The aim of the present study is to quantitatively evaluate the vertical and horizontal metamorphopsia scores and OCT data of diabetic macular edema(DME) patients who described metamorphopsia and had an indication for intravitreal bevacizumab injection, and to analyze their response to treatment before the injection and 1 month, 3 months and 6 months after the injection.

Method

DME patients who applied to Ophthalmology outpatient clinic of Akdeniz University between December 2021 and December 2022 and were followed up for at least 6 months, were included in this study. For this study, ethics committee approval was obtained from Clinical Trials Ethics Committee of Akdeniz University Faculty of Medicine. The study adhered to the principles of the Declaration of Helsinki. All the participants gave their consent by signing the informed consent form.

Inclusion criteria for the patients were determined as follows: (1) being aged > 18 years; (2) having a CFT ≥ 300 μm on OCT; (3) having a BCVA of 20/320 or better on Snellen chart; (4) lacking proliferative findings; (5) having no retinal pathology other than DRP; and (6) having compliance with M-charts metamorphopsia test. Exclusion criteria were determined as follows: (1) suffering from cataract other than mild cataract; (2) having a prolonged injection interval more than 2 weeks; (3) suffering from ophthalmic disease in both eyes before; (4) undergoing any intraocular surgery other than uncomplicated cataract surgery before treatment; (5) having an increased number of complaints due to

trauma or additional pathologies during follow-up, (6) not having undergone any eye surgery during the follow-up period.

Age, gender, presence of systemic and ocular diseases, baseline visual acuity and BCVA 1, 3, and 6 months after injection, M-CHARTS parameters, lens status, intraocular pressure (IOP), anterior segment and fundus examination findings, and OCT parameters were evaluated. BCVA was measured with Snellen threshold in all patients. For statistical analysis, the negative logarithm of the decimal representation of the BCVA value obtained according to the Snellen threshold was converted to logMAR. However, axial length and spherical equivalent were not measured.

M-CHARTS is a notebook designed by Inomi Co. in Tokyo, Japan to quantitatively assess metamorphopsia. The M-CHARTS test is performed in a brightly lighted room, with the best corrected visual acuity (wearing reading glasses) measured at a distance of 30 centimeters from the notebook, while the non-testing eye is kept closed. M-CHARTS consists of 19 dotted lines with dot intervals ranging from 0.2°–2.0° in visual angle. The M-CHARTS notebook has three testing methodologies: Type 1, Type 2 and a type specifically designed for patients with reduced visual acuity. Type 1 consists of a single vertical straight line containing 19 points with a central fixation point. Type 2 consists of two parallel 19-dot lines with a central fixation point placed between the lines. If the patient does not report experiencing metamorphopsia on the first image, the patient has a metamorphopsia score of 0. When the metamorphopsia score is assessed vertically, it is documented as a vertical metamorphopsia (Mv) score. If the patient characterizes the line as bent or irregular, the patient is shown progressively coarser dotted lines until the patient perceives that the dotted line appears in a straight configuration. The same test is performed after the M-CHARTS notebook is rotated 90° and the resulting score is documented as a horizontal metamorphopsia (Mh) score. Three repetitions of the test described above are performed and the mean M-CHARTS score is calculated. The test was performed by the same ophthalmologist in all patients. It took approximately 5–10 minutes to complete the test.

The distance between the internal limiting membrane (ILM) and retinal pigment epithelium (RPE) layer was measured by OCT using Topcon DRI Triton Swept Source OCT (Topcon FastMap, Version 10.15.003.01, Topcon Medical Systems) and automatic built-in software. The status of the external limiting membrane (ELM) and ellipsoid zone (EZ) and the presence of serous retinal detachment (SRD) were evaluated based on OCT images. ELM and EZ were divided into 2 groups as regular and irregular/intermittent. ETDRS (Early treatment diabetic retinopathy study) Grid was used to create 9 quadrants by automatically aligning the fovea centered zone map independently of the user. A 1-mm diameter ring centered on the fovea was considered as the central area and a 3-mm diameter ring surrounding this ring was considered as the parafoveal area. The parafoveal area was divided into 4 quadrants: superior, temporal, inferior, and nasal. If the automatic position was not smooth and central in the fovea, the relevant B-scan image was used as a reference and repositioned to the zone map with the “GRID/REPOSITION” option. Thickness of retinal nerve fiber layer (RNFL) was measured automatically from the zone map by selecting “RNFL (ILM RNFL/GCL)” and ganglion cell layer (GCL) thickness was measured automatically from the zone map by selecting “GCL + (RNFL/GCL - IPL/INL)”. The central

measurement, parafoveal measurements in 4 quadrants and the average of these measurements were evaluated. A single physician performed all evaluations. All the eyes received 3 consecutive doses of bevacizumab (2 mg) at 4-week intervals. The injection was administered from the superotemporal region to the pars plana region with a 27-gauge (G) needle at a distance of 3.5 mm from the limbus in phakic eyes and 3.00 mm from the limbus in pseudophakic eyes. The patients were routinely examined between all injections. The interval was shortened (minimum 4 weeks) in the presence of subretinal fluid, new intraretinal cyst, and CFT of 350 μm or more. Otherwise, the interval was extended to a maximum of 16 weeks.

Statistics

Mean, standard deviation, median, minimum, maximum, frequency and ratio values were used in descriptive statistics of the data. The distribution of variables was assessed by running Kolmogorov-Smirnov and Shapiro-Wilk tests. Wilcoxon test was used to analyze dependent quantitative data. McNemar test was run to analyze dependent quantitative data. Spearman correlation analysis was used to determine correlation between the variables. SPSS 28.0 software was used to analyze the data. As a result of the power analysis, the power of the study was calculated to be 87.9%, with an effect size of 0.40 and an alpha level of 0.05, considering a sample size of 51.

Results

Fifty-one eyes of 51 patients were included in the study. The mean age of the patients was 69.28 ± 5.75 years (between 59–88). Patients received an average of 4.5 ± 1.3 injections during the follow-up period. The characteristics of the patients are detailed in Table 1.

Table 1
Characteristics of the patients

Number of eyes	**51**
Side(Right/Left)	29/22
Side(Right/Left)	57/43%
Gender(Female/Male)	16/35
Gender(Female/Male)	31/69%
Age(year), Mdn(min-max)	64(41–83)
Number of injections	4.5 ± 1.3
BCVA(logMAR), Mdn(min-max)	0.40(0.00-1.30)
Mv, Mdn(min-max)	0.40(0.00–2.00)
Mh, Mdn(min-max)	0.30(0.00–2.00)
Mean CFT(μm), Mdn(min-max)	394.0(260–629)

BCVA of the patients was 0.47 ± 0.3 before the treatment. After treatment, BCVA was 0.41 ± 0.28, 0.35 ± 0.3 and 0.31 ± 0.27 in 1, 3, and 6 months, respectively. A statistically significant difference was found in 3 and 6 months after treatment compared to pretreatment ($p < 0.001$). (Fig. 1) No statistically significant increase was observed at post-treatment 1 month.($p > 0.05$)

Prior to the initiation of treatment, metamorphopsia was detected in 45 patients(88%). The six patients(12%) who did not report metamorphopsia prior to treatment did not report any metamorphopsia during subsequent follow-up. In 35 of 45 patients(78%), a metamorphopsia mean score decreased. In three cases (7%), the metamorphopsia score remained unchanged. The metamorphopsia score demonstrated an increase in seven patients (16%). The BCVA demonstrated an increase in all but one patient who exhibited elevated metamorphopsia scores. Conversely, the CFT decreased in all patients on OCT, and no patient subsequently developed SRD. Before treatment, 26 patients (51%) had SRD. SRD persisted in only 1 patient (2%) 6 months after treatment. SRD regressed in all other patients. The study revealed no correlation between EZ and ELM status and that the patients had elevated metamorphopsia scores.($p = 0.083$ $r = 0.245$, $p = 0.123$ $r = 0.219$)

The vertical metamorphopsia score (Mv) of the patients before treatment was 0.54 ± 0.43. Post-treatment Mv scores were 0.49 ± 0.41, 0.38 ± 0.24, and 0.36 ± 0.24 in the 1, 3, and 6 months, respectively. While Mv value did not show a significant ($p > 0.05$) change in the 1st month after treatment compared to pretreatment, it showed a significant ($p < 0.005$) decrease in the 3rd and 6th months compared to pretreatment.(Fig. 2) The horizontal metamorphopsia score (Mh) of the patients before the treatment was 0.49 ± 0.46. The Mh scores were 0.51 ± 0.43, 0.39 ± 0.29, and 0.36 ± 0.27 in the 1, 3, and 6 months, respectively. While the Mh value did not show a significant ($p > 0.05$) change in the 1st month after

treatment compared to pretreatment, it showed a significant ($p < 0.005$) decrease in the 3rd and 6th months compared to pretreatment.(Fig. 2)

When the OCT parameters of the patients were analyzed, it was determined that pretreatment SFT was 424 ± 104.4. SFT was 363.4 ± 79.1, 345 ± 91.5, and 319.0 ± 83.7 in post-treatment 1, 3, and 6 months, respectively. CFT value in these months showed a significant decrease ($p < 0.05$) compared to pretreatment. Parafoveal 4 quadrants, GCL and RNFL thickness showed a significant decrease in 1, 3, and 6 months after the treatment compared to pretreatment ($p < 0.05$).(Fig. 3)

An analysis of the correlation between metamorphopsia scores and other findings revealed a significant correlation between Mv and BCVA in the 6 months ($p < 0.05$; $r = 0.347$) and between Mv and thickness of parafoveal temporal (PAT) quadrant ($p < 0.05$; $r = 0.299$). Parafoveal quadrant thickness other than ELM, EZ, SFT, PAT had no correlation with GCL or RNFL.

Discussion

In this study, metamorphopsia was not identified by the patients in the M-CHARTS test in 6 (11.7%) of 51 DME patients. The patients were not asked about subjective complaints of metamorphopsia outside the test. A number of factors, including educational and cultural status, showed significant differences between the patients. Therefore, only objective tests were performed. These patients had DM for more than 10 years. Patients did not have DME in the fellow eye and their metamorphopsia score was zero. For cases where patients did not report metamorphopsia in the affected eye, it was hypothesized that metamorphopsia in the fellow eye may have masked the symptoms or the patient had adapted to the visual changes.[13, 14] At the end of 6 months, metamorphopsia score increased in 35 patients. (68.6%)

Metamorphopsia is one of the most important factors related to visual function, along with visual acuity and visual field. There are multiple methods used for the diagnosis of metamorphopsia. The Amsler chart is one such method; however, its inherent qualitative nature is a disadvantage of this approach.[15, 16] Therefore, M-CHARTS is used to quantitatively test metamorphopsia.[17] A comparative analysis including both the M-CHARTS and Amsler tests was conducted on 64 eyes. The findings of the study revealed that metamorphopsia was detected in 37% of the Amsler test and 50% of the M-CHARTS test. In the analysis, it was concluded that the M-CHARTS test was more successful.[18] In a study that included 280 eyes with macular disease, both tests were compared and metamorphopsia was evaluated. The study revealed an agreement rate of 92.5% between the two tests. It was reported that the test for metamorphopsia may vary according to the disease.[19] M-CHARTS has been used to assess metamorphopsia in eyes with DME since 2015. In their study using M-CHARTS, Achiron et al., detected metamorphopsia in 46.6% of eyes with DME and found that 71.4% of the subjects showed an improvement in M-CHARTS scores after anti-VEGF treatment. However, the study did not evaluate the correlation between OCT parameters and metamorphopsia. [20] In the present study, 88.3% of the patients reported metamorphopsia. M-CHARTS scores increased in 78% of subjects who described metamorphopsia.

Different results have been reported on the effects of anti-VEGF treatment on metamorphopsia. It is important to note that the detection of metamorphopsia is essentially a high-clarity condition based on visual discrimination. This means that people with low visual acuity may be less able to detect metamorphopsia, but it is important to consider that there may be a correlation between low visual acuity and metamorphopsia.[21] Okamoto et al., investigated vision-related quality of life and visual function in patients who received IVB injection for persistent DME after vitrectomy. The study included 20 consecutive patients (20 eyes) who had received 1.25 mg IVB for persistent macular edema after vitrectomy made for DME at least 3 months before. Measurements were made before the treatment and 1 and 3 months after IVB. The severity of metamorphopsia was assessed using M-CHARTS and significant improvements were observed in central retinal thickness and contrast sensitivity one month after IVB ($P < 0.05$). However, BCVA and metamorphopsia score did not show a significant improvement. No significant improvement was observed in the parameters examined three months after IVB. The mean score of M-CHARTS was 0.64 ± 0.58 before injection and 0.69 ± 0.53 3 months after the injection. The results of this study indicated that CFT improved in one month, but it returned to pretreatment levels in three months. There was no significant improvement in BCVA after treatment. They found no reason for the lack of improvement in metamorphopsia scores [22] A study of AMD patients receiving an injection of bevacizumab indicated that the degree of metamorphopsia assessed by M-CHARTS and Amsler Grid was not correlated with visual acuity or central retinal thickness. There was no correlation between vertical and horizontal metamorphopsia score and visual acuity ($R = -0.2$ and $R = -0.06$, respectively) or CRT ($R = -0.14$ and $R = -0.001$, respectively). [23] In their study examining 20 eyes with DME, Murakami et al., injected a loading dose of 2 mg aflibercept on all the eyes for 3 months, followed by a treat-and-extend regimen. OCT images were obtained by evaluating the severity of metamorphopsia and BCVA at each visit. The severity of metamorphopsia was assessed using M-CHARTS. The metamorphopsia scores before treatment and in 1, 2, 3, 6 and 12 months after the treatment were 0.25 ± 0.23, 0.21 ± 0.15, 0.19 ± 0.23, 0.14 ± 0.16, 0.17 ± 0.20, and 0.10 ± 0.17. Significant metamorphopsia (score ≥ 0.2) was detected in 10 of 20 eyes before the treatment and in 4 of 20 eyes 12 months after the treatment. The percentage of patients with significant metamorphopsia decreased significantly from pretreatment to 12 months after treatment ($p < 0.05$). The EZ and ELM layers, serous detachment, and retinal cyst status were analyzed from OCT images. The ELM and EZ status were then categorized into three grades: grade 0: continuous, grade 1: intermittent, and grade 2: absent. The status of ELM and EZ, as well as the presence of retinal cysts, SRD, and epiretinal membrane (ERM) in a 3-mm area centered on the fovea, were evaluated on OCT images. A subsequent analysis was performed to evaluate the correlation between metamorphopsia scores, visual acuity, and OCT findings. Among the OCT findings, only EZ ($p < 0.05$) and ELM ($p < 0.05$) were correlated with BCVA in the pre-treatment period. In the post-treatment period, only the presence of ERM was correlated with metamorphopsia ($p < 0.05$)[24] In a subsequent study that compared DME and OCT parameters, a retrospective review of 37 patients was conducted. The presence of metamorphopsia was detected in 54% of the patients. In the study, DRIL length was identified as the sole OCT parameter that demonstrated a correlation with the M-CHARTS score. The EZ and interdigitation zone (IZ) were not correlated with metamorphopsia.[25]

The precise anatomical abnormality that caused the metamorphopsia remains to be elucidated. The development of intraretinal cystoid structures and exudates in the outer nuclear layer is correlated with visual acuity and visual function measured by microperimetry before and after anti-VEGF treatment.[26] In another study, Murakami et al. suggested that deterioration of visual acuity was correlated with deterioration of the ELM and EZ, while the severity of metamorphopsia was correlated with increased CFT and the presence of inner retinal cysts.[27] In a prospective study of 42 patients with acute branch RVO, Manabe et al., demonstrated that the M-CHARTS score improved after treatment with intravitreal anti-VEFG. Post-treatment metamorphopsia scores demonstrated a correlation with baseline morphologic parameters, including serous retinal detachment height and maximum foveal thickness. However, no correlation was observed with post-treatment characteristics, such as inner, outer, and total retinal thickness. Moreover, there was no correlation between the severity of metamorphopsia and alterations in visual acuity.[28] Similar to many studies in the literature, the present study revealed no correlation between CFT and metamorphopsia. Except for the 6th month, BCVA was not correlated with metamorphopsia score. EZ, ELM and SRD had no correlation with metamorphopsia score. However, the correlation of BCVA and PAT quadrant thickness at 6 months with vertical metamorphopsia score was different from the studies in the literature.($p < 0.05$)

This study is an academic thesis, and patients were evaluated retrospectively due to unobtainable prospective ethics committee approval. Consequently, a 6-month follow-up period was feasible, and the sample size was moderate. A limitation of the study is the lack of a control or comparison group, which hinders the ability to draw definitive conclusions about the effectiveness of the treatment. This limitation is attributable to the mandatory treatment protocol in Turkiye. In our country, three consecutive doses of bevacizumab treatment are mandatory for aflibercept/ranibizumab treatment. Consequently, bevacizumab was used to administer a single treatment to the patients. Additionally, the effect of metamorphopsia on patients' quality of life and differences between treatment methods could have been investigated.

In conclusion, metamorphopsia complaints of patients with DME are evaluated with Amsler cards in many clinics, but these cards give subjective results. The M-CHARTS metamorphopsia notebook used in the present study has an important place in quantitative evaluation. Intravitreal injections demonstrated efficacy in treating both DME and metamorphopsia complaints. However, further studies are needed to evaluate whether injections are superior to each other in the treatment of metamorphopsia.

Declarations

Conflicts of Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. This study is an academic thesis and has not been published elsewhere.

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Ethics approval and consent to participate

Ethical approval for this study was granted by the Ethics Committee of Akdeniz University Faculty of Medicine. The research was conducted in full compliance with the ethical principles outlined in the Declaration of Helsinki. Prior to enrollment, all participants were informed about the nature and purpose of the study, and written informed consent was obtained from each individual.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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Figures

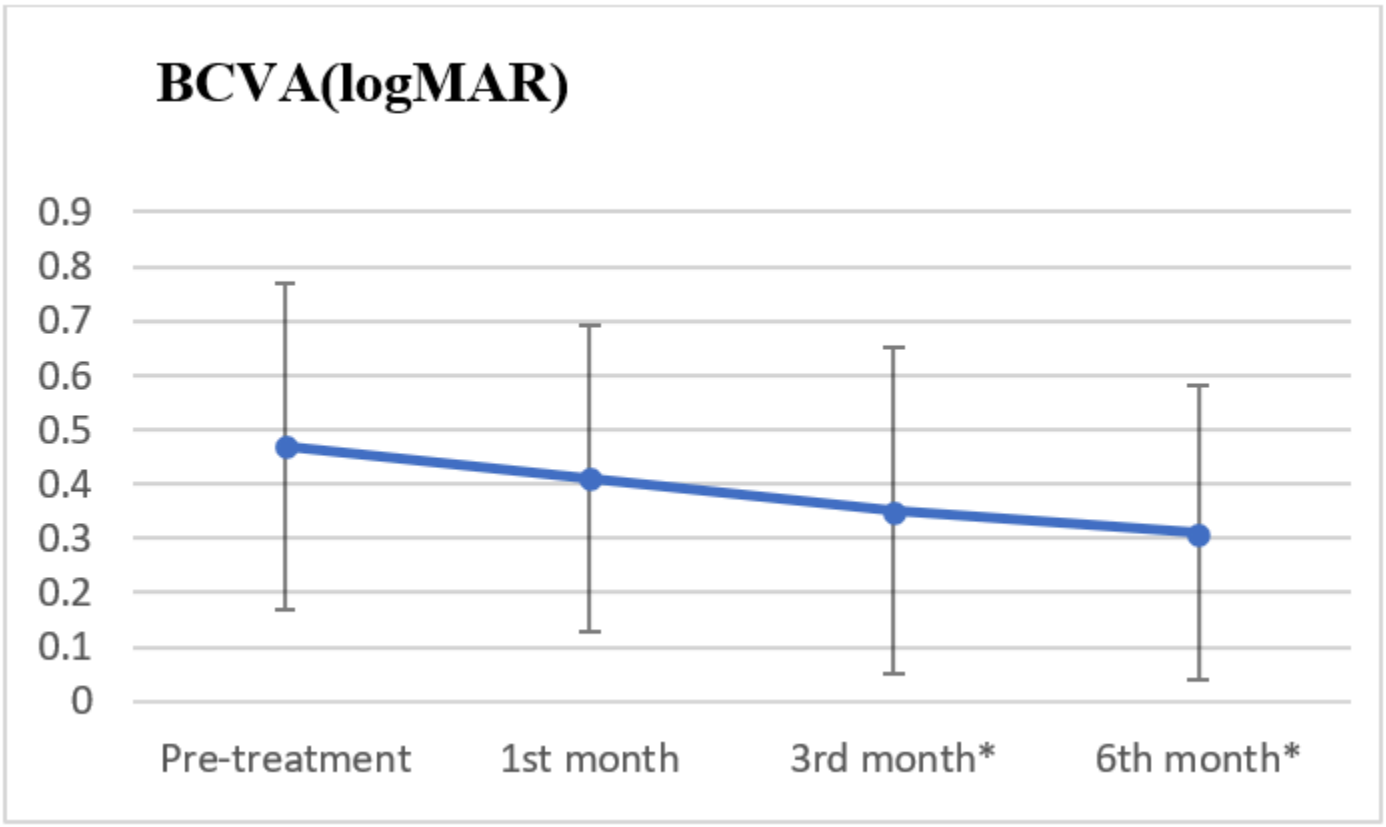


Figure 1

Changes in best-corrected visual acuity (BCVA) over the 6-month follow-up period. Statistically significant differences are indicated with an asterisk.

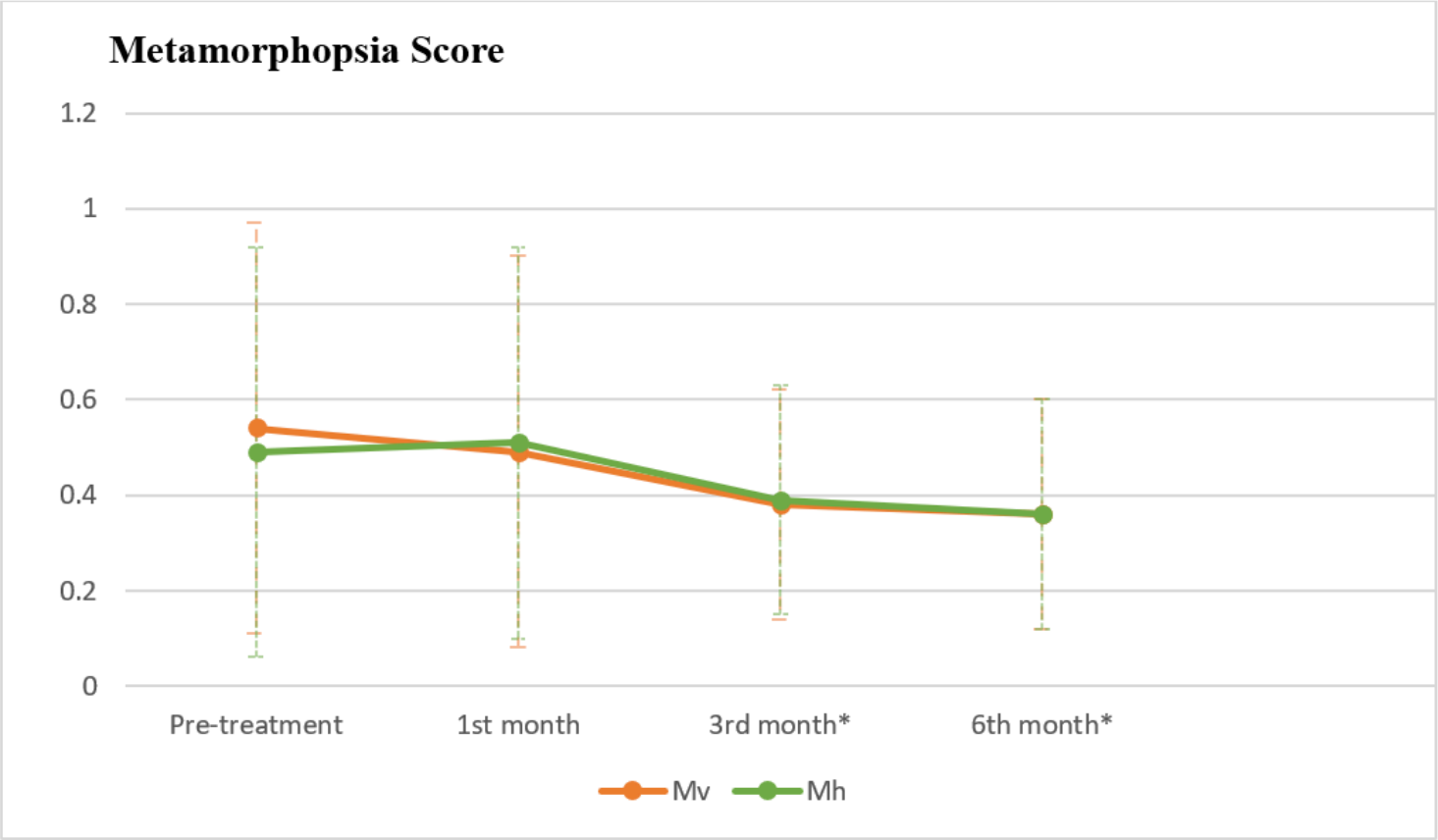


Figure 2

Changes in vertical (Mv) and horizontal (Mh) metamorphopsia scores during follow-up. Statistically significant differences are indicated with an asterisk.

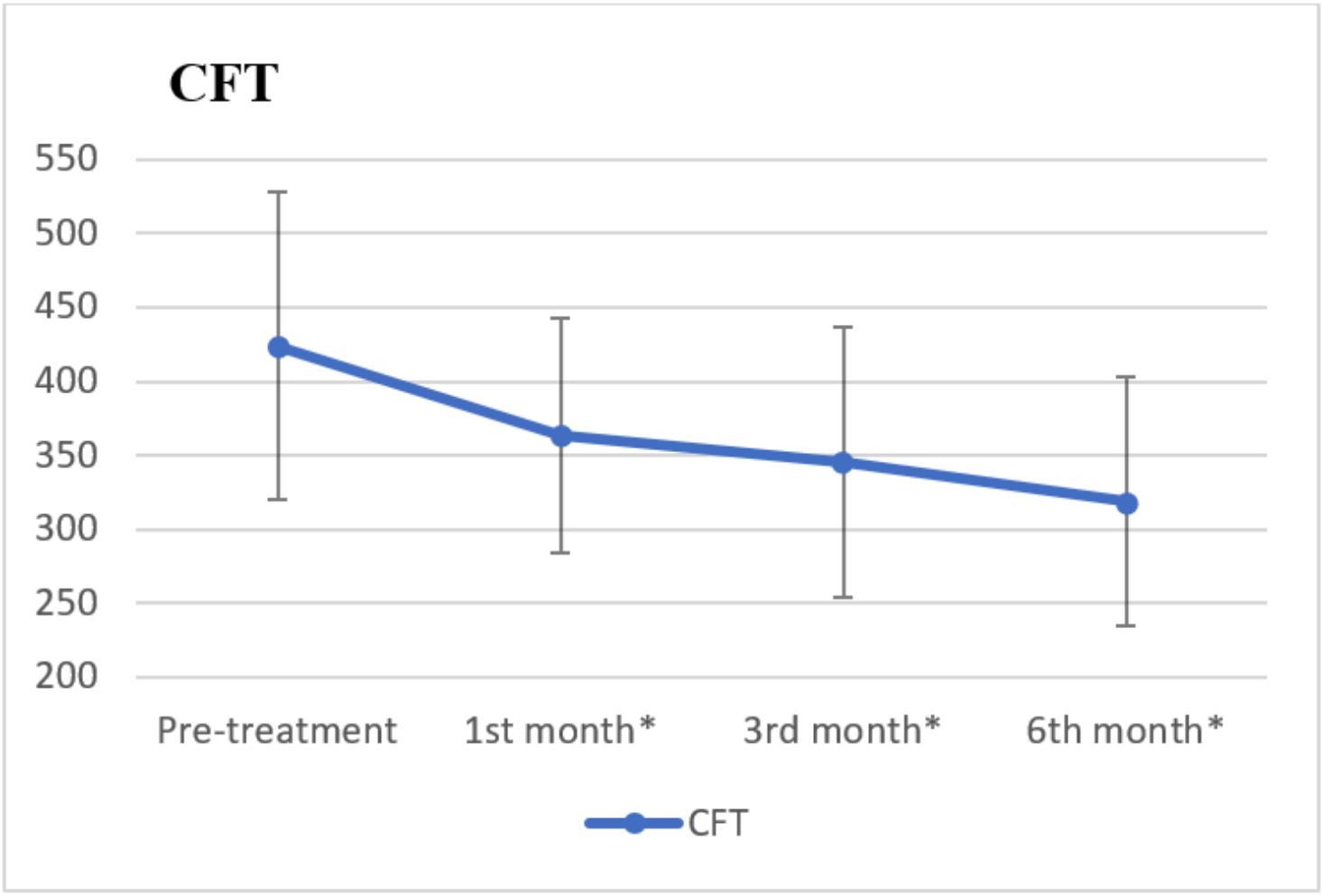


Figure 3

Changes in central foveal thickness (CFT) during follow-up. Statistically significant differences are indicated with an asterisk.