Study Protocol and Statistical Analysis Plan

Evaluation of Retinal Microvascular Change That May Develop in After Open Globe Injury

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Objective: To evaluate the effect of open globe injury on anterior chamber, intraocular pressure measurements, retina and choroidal microvascular circulation in the unaffected eye; and to compare results among healthy age-matched individuals.

Methods: This prospective case-control study was approved by the local ethics committee of the Akdeniz University Faculty of Medicine (Approval Number: 2021-162) and the study was conducted in compliance with the ethical standards set out in the Declaration of Helsinki. Informed consent was obtained from the participants who agreed to participate in the study. All subjects underwent a comprehensive ophthalmologic examination, which included refractive error (Nidek ARK-700A, Nidek Co., Ltd, Gamagori, Japan), best corrected visual acuity (BCVA), IOP/Fully Automatic Tonometer, NIDEK NT-2000, Nidek Co., Ltd., Aichi, Japan), biometry and axial length (AL) (IOLMASTER 500, Carl Zeiss Meditec AG, Jena, Germany), slit-lamp examination of the anterior and posterior segments, Scheimflug Topography (Pentecam Oculus Optikgeräte GmbH, Wetzlar, Germany), and retinal and choroidal thickness and microvascular circulation of the retina and choroid were measured and recorded with Swept-Source Optical Coherence Tomography Angio™ (Topcon Corp, Japan). The BCVA was converted into the logarithm of minimal angle resolution (logMAR). Of the individuals included in the study, anterior chamber depth (ACD), anterior chamber volume (ACV), central corneal thickness (CCT), thinnest corneal thickness (TCT), astigmatism value (AST), corneal volume (CV), axial length (AL), spherical equivalent (SFEQ), intraocular lens power (ILP), VA (visual acuity), central retinal thicness (CRT), central choroidal thickness (CCT), superficial retinal circulation (SRC), deep retinal circulation (DRC) and choriocapillaris circulation (CC) data were recorded. The patients were followed for approximately six months, examined at one week, one month and three months after the trauma, and a total of three measurements were taken from the subjects. One measurement was taken from the control group.

Statistical Analysis Plan (SAP): Statistical analyzes were performed using the IBM SPSS package, version 23.0 (SPSS Inc., Chicago, IL, USA). The Shapiro-Wilk test was used to analyze the normality of sample distribution. To define the sample, normally distributed values are presented as means ± standard deviation, and non-normally distributed values are presented as median (minimum–maximum). The two-way repeated measures ANOVA test was used to examine the time-dependent change of the data. For the analysis of independent data, the independent-sample t-test and Mann-Whitney U test were used. For the analysis of

correlation, Spearman's correlation coefficient was used. The results were evaluated at a 95% CI. A level of $p<0.05$ was accepted as statistically significant.