



# EFFECT OF UNCOMPLICATED ULTRASOUND PHACOEMULSIFICATION CATARACT SURGERY ON CENTRAL MACULAR THICKNESS CHANGES IN THE EARLY POSTOPERATIVE PERIOD IN DIABETIC PATIENTS

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**SUMMARY** – The aim of this prospective study was to determine changes in central macular thickness in the early postoperative period after uncomplicated phacoemulsification cataract surgery in diabetic patients using spectral domain optical coherence tomography (SD-OCT). Uncomplicated ultrasound phacoemulsification cataract surgery causes minimal changes of retinal layer thickness, which may result in subclinical cystoid macular edema development. This prospective study included 55 patients divided into two groups. Group 1 included diabetic patients with cataract, and group 2 included patients with cataract and without diabetes. All patients underwent uncomplicated ultrasound phacoemulsification cataract surgery at the Department of Ophthalmology, University Hospital Osijek in the period from November 2017 to January 2018. Patients were followed-up for one month after surgery. At each examination, OCT recording of the eye undergoing cataract surgery was performed. A statistically significant difference in central macular thickness in the diabetic group and control group ( $p=0.0005$  both) was confirmed preoperatively and one month after cataract surgery. A statistically significant difference in central macular thickness was confirmed in diabetic group ( $p=0.006$ ), as well as in the control group of patients ( $p=0.01$ ) seven days and one month after cataract surgery. There was no statistically significant difference in macular thickness changes between the diabetic and control group of patients preoperatively ( $p=0.618$ ), seven days ( $p=0.6848$ ) or one month after cataract surgery ( $p=1$ ). The effect of HbA1c on macular thickness change in diabetic patients was not statistically significant. The mean HbA1c in diabetic patients was  $7.24\pm 1.34\%$ . There was no statistically significant difference in the effect of cumulative dissipated energy on macular thickness change in either group. This study confirmed a statistically significant correlation of the effect of fluid volume consumption on macular thickness changes in diabetic patients. There was no statistically significant effect of fluid volume consumption on macular thickness change in the control group of patients. Uncomplicated ultrasound phacoemulsification cataract surgery caused changes in cen-

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Received September 2, 2022, accepted January 31, 2023

tral macular thickness in the early postoperative period in both patient groups. Changes in central macular thickness in the observed period were not manifested with clinically significant macular edema or by a more significant decrease in visual acuity. All patients had significant improvement in visual acuity seven days and one month after cataract surgery.

Keywords: *Cataract; Phacoemulsification; Diabetes; Central macular thickness; Spectral domain optical coherence tomography*

## Introduction

Ultrasound phacoemulsification cataract surgery is the most commonly performed surgery in developed countries. Improvement in the techniques of cataract surgery has significantly reduced the percentage of intraoperative and postoperative complications. Nevertheless, uncomplicated ultrasound phacoemulsification cataract surgery causes minimal changes at the retinal level, resulting in subclinical cystoid macular edema (CME) and leakage from retinal blood vessels<sup>1,2</sup>. Change in macular thickness after ultrasound phacoemulsification cataract surgery can be demonstrated by using noninvasive imaging diagnostic methods such as spectral domain optical coherence tomography (SD-OCT). The highest incidence of subclinical increase in macular thickness occurs 4–6 weeks after cataract surgery. Within 6 months of surgery, there is spontaneous withdrawal of macular edema and recovery of visual acuity<sup>3</sup>. The change in macular thickness after surgery is thought to be due to the release of proinflammatory elements (e.g., interleukin-1b) and disturbances at the level of the blood retina barrier<sup>4,5</sup>. The incidence of postoperative CME is still not fully known because the criteria for diagnosing pseudophakic CME differ<sup>6</sup>. Clinically significant macular edema (CSME) is defined as one or more of the following: retinal thickening at or within 500  $\mu\text{m}$  of the center of the macula; hard exudates at or within 500  $\mu\text{m}$  of the center of the macula, if associated with adjacent retinal thickening; or a zone or zones of retinal thickening one disc area in size, at least part of which is within one disc diameter of the center of the macula<sup>7</sup>. Risk factors influencing the incidence of pseudophakic CME are duration, severity and type of diabetes, HbA1c values, and cataract hardness<sup>8,9</sup>. Diabetic retinopathy (DR) encompasses a wide range of changes in the retina that occur as part of the underlying disease, i.e., diabetes mellitus. DR

is retinal microangiopathy characterized by damage to small blood vessels, directly related to blood sugar levels or hyperglycemia. Hyperglycemia is a key factor in the development of DR because it leads to red blood cell damage, relative hypercoagulability, and increased protein glycosylation, consequently causing thickening of the basement membrane of retinal blood vessels and loss of pericyte<sup>10,11</sup>. The consequences of these events are occlusion of small retinal blood vessels and their increased permeability, which lead to changes characteristic of DR<sup>12,13</sup>. Macular edema is a major cause of postoperative decrease in visual acuity in patients with diabetes<sup>14–16</sup>.

The aim of this prospective study was to examine the effect of uncomplicated ultrasound phacoemulsification cataract surgery on the change in central macular thickness in diabetic and control groups of patients in the early postoperative period.

## Patients and Methods

All patients signed a written consent form to participate in this study. The research was approved by the Ethics Committee of the Osijek University Hospital Center, Osijek, Croatia. This prospective study included 55 patients divided into two groups. Study group consisted of 25 patients with diabetes and cataract, 7 (12.73%) men and 18 (32.73%) women. Control group included 30 patients with cataract, 11 (20.00%) men and 19 (34.55%) women, free from diabetes and any other ophthalmic disease. All patients underwent uncomplicated ultrasound phacoemulsification cataract surgery at the Department of Ophthalmology, University Hospital Osijek in the period from November 2017 to January 2018. Exclusion criteria for this study were previous intraocular surgery, previous uveitis, various retinal diseases, macular edema of any etiology,

vascular disease, moderate and severe nonproliferative diabetic retinopathy, proliferative diabetic retinopathy, and inability to perform OCT due to cataract, pupillary sequestration, or significant degenerative corneal changes. Patients were followed-up for one month after surgery. All patients underwent complete preoperative ophthalmologic examination with the best corrected visual acuity (BCVA) determined on Snellen chart, the degree of lens opacity using Lens Opacities Classification System III (LOCS III) was determined, and the SD-OCT macula of the eye intended for surgery was recorded. The measured macular area included central foveal area 1 mm in diameter. The first follow up examination was performed at one week, and the second one at one month after the surgery. At each follow up examination, BCVA was determined, complete ophthalmologic examination was performed, and SD-OCT of the macula of the operated eye was recorded. Total cumulative dissipated energy (CDE) and estimated fluid used *per ccm*<sup>3</sup> were measured as the most important parameters during surgery that might be associated with changes in macular thickness in the early postoperative period. None of the patients in either group was taking nonsteroidal anti-inflammatory drugs or corticosteroid eye medications prior to surgery. All patients took combined antibiotic and corticosteroid local therapy for one month postoperatively.

### Ethics

All the procedures followed in this research were in accordance with ethical standards of the institutional or regional responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983. The study protocol was approved by the Ethics Committees of the Josip Juraj Strossmayer University of Osijek and University Hospital Osijek.

### Statistical analysis

Categorical data were expressed as absolute frequencies. Numerical data were described by the median and interquartile range. Differences in categorical variables were tested by Fisher exact test. The normality of data distribution was tested by the Shapiro-Wilk test. Differences in numerical variables before and after surgery were tested by the Wilcoxon test. Differences in numerical variables between two independent

groups were tested by the Mann-Whitney U test. All p values were two-sided. The level of significance was set to  $\alpha=0.05$ . The MedCalc Statistical Software version 14.12.0 (MedCalc Software bvba, Ostend, Belgium; <http://www.medcalc.org>; 2014) was used on statistical analysis.

## Results

The aim of this prospective study was to examine the effect of uncomplicated ultrasound phacoemulsification cataract surgery on the change in central macular thickness in diabetic and control groups of patients in the early postoperative period. A statistically significant difference in central macular thickness in the diabetic group ( $p=0.0005$ ) (Table 1) and control group ( $p=0.0005$ ) (Table 2) of patients was confirmed preoperatively and one month after the cataract surgery. A statistically significant difference in central macular thickness was confirmed in the diabetic group ( $p=0.006$ ) and control group of patients ( $p=0.01$ ) seven days and one month after the

Table 1. Central macular thickness changes in diabetic patients

	Central macular thickness ( $\mu\text{m}$ ) $\pm$ SD
SD-OCT <sub>0</sub>	248.24 $\pm$ 38.00
SD-OCT <sub>1</sub>	255.68 $\pm$ 45.69
SD-OCT <sub>2</sub>	263.36 $\pm$ 41.30

SD = standard deviation; SD-OCT = spectral domain optical coherence tomography; <sub>0</sub> = preoperatively; <sub>1</sub> = 7 days after surgery; <sub>2</sub> = 1 month after surgery

Table 2. Central macular thickness changes in control group

	Central macular thickness ( $\mu\text{m}$ ) $\pm$ SD
SD-OCT <sub>0</sub>	241.13 $\pm$ 29.78
SD-OCT <sub>1</sub>	247.77 $\pm$ 28.37
SD-OCT <sub>2</sub>	257.33 $\pm$ 31.99

SD = standard deviation; SD-OCT = spectral domain optical coherence tomography; <sub>0</sub> = preoperatively; <sub>1</sub> = 7 days after surgery; <sub>2</sub> = 1 month after surgery

cataract surgery. There was no statistically significant difference in macular thickness changes between the diabetic and control groups of patients preoperatively ( $p=0.618$ ), seven days ( $p=0.6848$ ) or one month after the cataract surgery ( $p=1$ ). The effect of HbA1c values on macular thickness change in diabetic patients was not statistically significant preoperatively ( $p=0.83$ ), seven days ( $p=0.48$ ) and one month after the surgery ( $p=0.74$ ). The mean HbA1c value in diabetic patients was  $7.24\% \pm 1.34$ . There was no statistically significant correlation in the effect of CDE on macular thickness changes in diabetic group of patients seven days ( $p=0.16149$ ; Spearman coefficient of correlation  $\rho=0.29$ ) and one month after the surgery ( $p=0.11737$ ; Spearman coefficient of correlation  $\rho=0.32$ ). There was no statistically significant effect of CDE on the change in macular thickness in the control group seven days after the surgery ( $p=0.883$ ), one month after the surgery ( $p=0.882$ ), and between the first and second follow up examination ( $p=0.478$ ).

This study confirmed a statistically significant correlation of the effect of fluid volume consumption and macular thickness changes in diabetic patients. The correlation between fluid volume consumption during surgery and central macular thickness changes seven days after the surgery was statistically significant ( $p=0.019164$ ). Positive coefficient indicates that the bigger amount of fluid used leads to bigger changes of macular thickness. As the value of Spearman coefficient of correlation was  $\rho \approx 0.5$ , it can be concluded that there is a moderately strong effect of fluid used during surgery on macular thickness (defining change in macular thickness as the difference in thickness preoperatively and on day 7 of the surgery). There was no statistically significant effect of fluid volume consumption on macular thickness change in the control group of patients. The correlation between central corneal thickness changes before and one month after the surgery and fluid consumed during the surgery was statistically significant ( $p=0.0016862$ ). As the value of Spearman coefficient of correlation was  $\rho=0.6$  it is clear that there was a high impact of the volume of fluid used on central macular thickness changes, which means that the greater volume of fluid is used, the higher is the chance of macular edema appearance.

## Discussion

Changes in central macular thickness after uncomplicated ultrasound phacoemulsification cataract surgery in the early postoperative period occur as a consequence of the breakdown of the blood retina barrier and consequent thickening of the retinal layers<sup>1</sup>. In diabetics, the integrity of the blood retina barrier is compromised<sup>18,19</sup>, and the aim was to compare whether there was a difference in the change in central macular thickness during the study period in the diabetic and control group of patients. Each subject underwent SD-OCT imaging of the eye scheduled for cataract surgery on the day of surgery, seven days after surgery, and one month after surgery. A statistically significant difference in macular thickness was confirmed in diabetics preoperatively and one month after the surgery ( $p=0.004$ ), and between day 7 and one month postoperatively ( $p=0.006$ ). There was also a statistically significant difference in macular thickness in the control group of patients preoperatively and one month postoperatively ( $p=0.005$ ), and between day 7 and one month postoperatively ( $p=0.012$ ). There was no statistically significant difference in the change in macular thickness between the study groups preoperatively ( $p=0.618$ ), at the first follow up visit ( $p=0.684$ ) or the second follow up visit ( $p=1$ ). The results may lead to a conclusion that cataract surgery influenced changes in macular thickness in the early postoperative period in both groups of patients, which fortunately are reversible. Since HbA1c is one of the more important parameters that alerts to good glycemic regulation in diabetics, the aim was to examine its effect on the change in central macular thickness in this group. Jin *et al.* demonstrated a positive correlation between HbA1c values and changes in macular thickness ( $p < 0.05$ )<sup>8</sup>. Our study did not confirm a statistically significant effect of HbA1c values on the change in central macular thickness in the early postoperative period in diabetics. In addition, Denier *et al.* did not demonstrate a statistically significant effect of HbA1c values on the change in central macular thickness<sup>17</sup>. OCT is a noninvasive diagnostic method that provides good insight into the structure and changes in macular thickness, and the use of OCT in monitoring changes in macular thickness in the postoperative period can be used to analyze and diagnose pseudophakic CME<sup>18,19</sup>. The incidence of

pseudophakic CME is unknown and varies from 1% to 70% because diagnostic criteria have not yet been established<sup>20-23</sup>. The prevalence of pseudophakic CME according to Jin *et al.* is 3.2%<sup>8</sup>, according to Denier *et al.* it is 7.4%<sup>17</sup>, while according to Dong *et al.*, the prevalence is 1.75%<sup>1</sup>. There were no patients with clinically significant pseudophakic CME in our study. Changes in central thickness of the macula in the early postoperative period are transient in nature and return to normal within 6 months of surgery<sup>3</sup>. Also, none of the patients in our study had a decrease in visual acuity as the result of change in macular thickness. In this study, the effects of fluid volume consumption and CDE on macular thickness changes were observed in both groups, as one of the parameters of ultrasound phacoemulsification that a surgeon can influence. There was a statistically significant correlation between the effect of fluid volume on change in macular thickness in diabetics at the first follow up visit ( $p=0.019$ ), as well as at the second follow up visit ( $p=0.001$ ). There was no statistically significant effect of fluid volume on change in macular thickness in the control group of subjects at the first ( $p=0.980$ ) or second follow up visit ( $p=0.836$ ). There was no statistically significant effect of CDE on change in macular thickness in diabetics and control group of patients at the first follow up visit, second follow up visit, or between the first and second follow up visit.

## Conclusion

Uncomplicated ultrasound phacoemulsification cataract surgery caused changes in macular thickness in the early postoperative period in both groups of patients. There was no statistically significant difference in the change in macular thickness between the study groups during the postoperative period examined. It was proven that HbA1c values in diabetics did not have a statistically significant effect on the change in macular thickness in the observed period. It was also found that the volume of fluid consumed, as one of the parameters that the surgeon can influence during the operation itself, influenced the change in macular thickness in the early postoperative period in diabetics. Although ultrasound phacoemulsification cataract surgery significantly reduced the proportion of

complications in the early postoperative period, this study proved that there was a statistically significant effect of surgery on the change in macular thickness in this period, as demonstrated by the use of SD-OCT. Changes in macular thickness in the observed period were not manifested by clinically significant macular edema or by a more pronounced decrease in visual acuity. All subjects had significant improvement in visual acuity after surgery on day 7 and at one month postoperatively. Although none of our study patients developed pseudophakic CME, general suggestion is to carefully follow-up all patients who underwent cataract surgery to avoid possible visual impairment due to unrecognizable macular edema.

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## Sažetak

UTJECAJ NEKOMPLICIRANE OPERACIJE MRENE METODOM ULTRAZVUČNE  
FAKOEMULZIFIKACIJE NA PROMJENU CENTRALNE DEBLJINE MAKULE U RANOM  
POSLIJEOPERACIJSKOM RAZDOBLJU U DIJABETIČARA

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Cilj ovoga prospektivnog istraživanja bio je utvrditi promjene centralne debljine makule u ranom poslijeoperacijskom razdoblju nakon nekomplikirane operacije mrene metodom ultrazvučne fakoemulzifikacije u dijabetičara primjenom optičke koherentne tomografije (SD-OCT). Nekomplikirana operacija mrene metodom ultrazvučne fakoemulzifikacije uzrokuje minimalne promjene debljine mrežnice, koje mogu rezultirati nastankom subklinikoga cistoidnog makularnog edema. Ovo prospektivno istraživanje uključilo je 55 bolesnika podijeljenih u dvije skupine. Ispitnu skupinu činili su bolesnici s mrenom i dijabetesom, a kontrolnu skupinu bolesnici s mrenom bez dijabetesa. Svi ispitanici podvrgnuti su nekomplikiranoj operaciji mrene metodom ultrazvučne fakoemulzifikacije na Klinici za očne bolesti KBC-a Osijek u razdoblju od studenoga 2017. do siječnja 2018. godine. Bolesnici su praćeni u razdoblju od mjesec dana nakon operativnog zahvata. Na svakom pregledu učinjeno je OCT snimanje oka predviđenoga za operaciju mrene. Dokazana je statistički značajna razlika u centralnoj debljini makule u dijabetičara ( $p=0,0005$ ) i kontrolnoj skupini pacijenata ( $p=0,0005$ ) prijeoperacijski i mjesec dana nakon operacije mrene. Također, statistički značajna razlika u centralnoj debljini makule dokazana je sedam dana i mjesec dana nakon operacije mrene u dijabetičara ( $p=0,006$ ) i kontrolnoj skupini ( $p=0,01$ ). Nije bilo statistički značajne razlike u promjeni centralne debljine makule između bolesnika s dijabetesom i kontrolne skupine prijeoperacijski ( $p=0,618$ ), sedam dana nakon operacije ( $p=0,6848$ ), kao ni mjesec dana nakon operacije ( $p=1$ ). Utjecaj vrijednosti HbA1c na promjenu debljine makule u dijabetičara nije bio statistički značajan. Prosječna vrijednost HbA1c u dijabetičara bila je  $7,24 \pm 1,34\%$ . Nije zabilježen statistički značajan utjecaj kumulativne utrošene energije na promjenu debljine makule ni u jednoj od dviju ispitivanih skupina. Dokazana je statistički značajna povezanost utjecaja volumena potrošene tekućine na promjenu debljine makule u dijabetičara. Nije utvrđen statistički značajan utjecaj volumena potrošene tekućine na promjenu debljine makule u kontrolnoj skupini. Nekomplikirana operacija mrene metodom ultrazvučne fakoemulzifikacije uzrokovala je promjene centralne debljine makule u ranom poslijeoperacijskom razdoblju u objema skupinama ispitanika. Promjene centralne debljine makule u promatranom razdoblju nisu se manifestirale klinički značajnim edemom makule, kao ni izraženijim padom vidne oštine. Svi ispitanici imali su značajno poboljšanje vidne oštine nakon operativnog zahvata sedam dana i mjesec dana nakon operacije mrene.

*Ključne riječi: Katarakta; Fakoemulzifikacija; Šećerna bolest; Centralna debljina makule; SD-OCT*