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Comparison of phacoemulsification parameters effect on macular thickness changes after uneventful phacoemulsification in diabetic and non - diabetic patients

Ayse Gul Kocak Altintas[1], Pinar Coban[1], Hasan Basri Arifoglu[2], Gultekin Koklu[1], Pehmen Yasin Ozcan[1], Kenan Sonmez[1]

[1]Department of Ophthalmology, S. B. Ulucanlar Eye Research and Education Hospital, Ankara 06240, Turkey
[2]Department of Ophthalmology, S. B. Kayseri Research and Education Hospital, Kayseri 38010, Turkey
Correspondence to: Hasan Basri Arifoglu. S. B. Kayseri Research and Education Hospital, Ophthalmology Department, Sanayi Mah Atatürk Boulevard Hastane Street No: 78, Kocasinan/Kayseri 38010, Turkey. habasa@yahoo.com
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比较糖尿病和非糖尿病患者超声乳化术超乳参数和黄斑厚度的变化

Ayse Gul Kocak Altintas[1], Pinar Coban[1], Hasan Basri Arifoglu[2], Gultekin Koklu[1], Pehmen Yasin Ozcan[1], Kenan Sonmez[1]
(作者单位:[1]土耳其,安卡拉 06240,Ulucanlar 眼科教育与研究医院眼科;[2]土耳其,开塞利 38010,开塞利教育与研究医院眼科)
通讯作者:Hasan Basri Arifoglu. habasa@yahoo.com

摘要

目的:调查无视网膜病变的糖尿病和非糖尿病患者接受普通白内障手术时,应用具有前房稳定环境(CASE)和加强控制和效率(ICE)的微脉冲超乳技术对患者超乳参数和黄斑中心凹厚度(CFT)变化的影响。

方法:前瞻性研究。研究包含 120 例患者,其中 60 例患者为 2 型糖尿病患者,设为糖尿病组(无视网膜病变),另 60 例设为对照组。所有患者均接受普通白内障超声乳化术。术中记录超乳参数,包括超乳时间和有效超乳时间。术前和术后 1、3mo 检测记录 CFT 并计算每次检测中 CFT 的差异。

结果:糖尿病组的平均超乳时间为 1.40±0.43min,而对照组为 1.44±0.32min,差异无统计学意义(P=0.85)。糖尿病组平均有效超乳时间为 20.12±8.82s,对照组为 19.24±9.02s,差异无统计学意义(P=0.964)。糖尿病组术前平均 CFT 为 218.4±12.0 μm,对照组为 222.1±16.6 μm,差异无统计学意义(P=0.168)。术后 1mo 糖尿病组 CFT 平均增加 30.3±37.2 μm,对照组平均增加 13.1±12.5 μm。术后 1mo 两组 CFT 明显增加,糖尿病组显著高于对照组(P=0.001)。术后 3mo 糖尿病组和对照组的平均 CFT 较术前分别增加 12.5±12.4 μm 与 4.6±9.7 μm。糖尿病组 CFT 的增加显著高于对照组(P=0.00)。但分别比较糖尿病组和对照组术后 1mo 至 3mo 平均 CFT 变化,会发现两组均显著减少(P=0.00,P=0.03)。

结论:普通超乳手术会使 CFT 显著增加。糖尿病组和对照组的超乳参数相似。糖尿病组 CFT 变化大于对照组,但这些症状大部分表现为亚临床,并且仅显示于光学相干断层扫描(OCT)的改变。术后 3mo 这种变化会恢复或消失,无需治疗。

关键词:白内障超声乳化术;糖尿病致黄斑水肿;超乳时间;有效超乳时间

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Abstract

• AIM: To evaluate the effect of phacoemulsification (phaco) parameters in micropulse phaco-tecnology with chamber stabilization environment (CASE) and increased control and efficiency (ICE) mode on central foveal thickness (CFT) changes after uneventful cataract surgery in normal and diabetic patients without retinopathy.

• METHODS: In this prospective study a total of 120 patients consist of 60 patients with type 2 diabetes mellitus as a diabetic group (DG) without retinopathy and 60 normal subjects as a control group (CG) who underwent uneventful phaco were evaluated. Intraoperative phacoemulsification parameters including phaco time (PT), and effective phaco time (EPT) were recorded. The CFT measurements were performed preoperatively, at 1 and 3mo postoperatively. The CFT differences were calculated in each exam.

• RESULTS: The mean PT in DG was 1.40±0.43min and it was 1.44±0.32min in CG, the difference was not significant (P=0.85). The mean EPT was 20.12±8.82s and

19.24±9.02s in DG and CG respectively which was statistically insignificant (P = 0.964). The mean preoperative CFT was 218.4±12.0 μm in DG and 222.1±16.6 μm in CG which was not statistically different (P=0.168). The mean increment of CFT in DG was 30.3±37.2 μm at 1mo postoperatively, while it was 13.1±12.5 μm in CG. Even the CFT increments were significant in both groups at 1mo postoperatively, it was statistically higher in DG than that of CG (P=0.001). The average CFT increment at 3mo postoperatively comparing to preoperative level was 12.5±12.4 μm and 4.6±9.7 μm in DG and CG respectively. The increment of CFT was significantly higher in DG than that of CG (P=0.00). But the comparison of the mean CFTs changes from postoperative 1mo and 3mo in both DG and CG, significant decrements were observed in each group (P=0.00 and P=0.03 respectively).

• CONCLUSION: The significant increment of CFT following uneventful phaco. With the similar phaco parameters were observed in both normal and diabetic subjects. The CFT changes were higher in DG than that of CG but fortunately these were mostly subclinical and optic coherence tomography (OCT) based changes and regressed or disappeared after 3mo postoperatively therefore not require immediate treatment in both group.

• KEYWORDS: phacoemulsification; diabetic macular edema; phacoemulsification time; effective phacoemulsification time

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INTRODUCTION

Cystoid macular edema (CME) following cataract surgery is known as Irvine-Gass syndrome in which intraretinal fluid accumulation is associated with retinal thickening and cyst formation[1-3]. CME observed by biomicroscopy is referred as clinical CME, on the other hand when it is documented by fluorescein angiography (FA) it is referred as subclinical CME. Although qualitative evaluation of various leakage patterns on FA is possible, quantification of the intravascular contents leakage from the dilated perifoveal capillaries is difficult[1-5]. On the contrary retinal thickness and other structural anomalies can be evaluated by optic coherence tomography (OCT) both quantitatively and qualitatively. Pseudophakic macular edema is one of the significant causes of delay in visual recovery after cataract surgery[5-9]. Surgical complications or traumas such as extended phaco time, increased phaco power, anterior chamber depth instability causes release of prostaglandins or other inflammatory mediators, which can diffuse through the vitreous and disrupts the blood retinal barrier to cause macular edema. It has been reported that diabetic patients with defective blood retinal barrier are at risk for acceleration of retinopathy and macular edema after cataract surgery[5-12].

The purpose of present study was to evaluate and compare the effect of phaco parameters in micropulse phacotecnology with chamber stabilization environment (CASE) and increased control and efficiency (ICE) mode on central foveal thickness (CFT) changes after uneventful cataract surgery in normal and diabetic patients without retinopathy.

SUBJECTS AND METHODS

The current study was conducted in accordance with the Declaration of Helsinki. The patients' protocol and associated informed-consent documents were reviewed and approved by Institutional Review Board of Ataturk Education and Training Hospital. All patients were informed about the nature of the procedure and written consent was obtained.

To evaluate effect of micropulse phaco parameters on CFT after uneventful cataract surgery in patients with both anatomically and histologically normal fovea, 120 patients in which 60 of them with type 2 diabetes mellitus without retinopathy and 60 healthy controls were enrolled in this prospective study. Each patient underwent a comprehensive assessment to obtain the following information, presence of other co-variants such as hypertension, nephropathy, neuropathy, and use of lipid lowering medications. Patient had any of these co-morbidity factor or both fasting serum lipids and glycaemia levels higher than upper normal limits, have HbA1c level of more than 6% were not included in this study.

Each patient underwent a complete preoperative examination that included corrected distance visual acuity and IOP measurements, both anterior and posterior segment evaluation by biomicroscopy, biometry. The OCT measurements were performed with spectral-domain OCT (Heidelberg Spectralis OCT, Heidelberg Engineering Inc., Heidelberg, Germany) in which an internal fixation target was used to focus the macular scans on the foveal pit and with the help of eye-tracking systems exact localization was achieved in each measurement. The quality of scans was enhanced by inhibition of artifacts by OCT. The scans were accepted when they were free of artifacts and decentration. To compare CFT changes measurements were done exactly the same area for repeating exam. Although the OCT machine could be used for measurement of the mean retinal thickness in various sectors, CFT was the only parameter evaluated in this comparative study. The CFT measurements were performed preoperatively,

Table 1 Demographic characteristics and phaco time values

Parameters	Diabetic Group (n=60)	Control Group (n=60)	P
Gender F/M	28/32	30/30	0.76
Age	66.5±8.5	66.1±10.5	0.92
Phaco time	1.40±0.43	1.44±0.32	0.85
Effective phaco time	20.12±8.82	19.24±9.02	0.96

at 1mo and 3mo post operatively; the differences were calculated in each exam.

All subjects underwent phacoemulsification with local anesthesia avoiding any intracameral drug injection. Surgery consisted of a clear cornea and two-side port incision, injection of visco elastic substance (VES) (Viscoat®, Alcon Laboratories, Inc., Fort Worth, Texas, USA) into the anterior chamber and a creation of continuous curvilinear capsulorhexis, hydrodissection and phacoemulsification. Phacoemulsification was performed using with ICE mode and CASE mode micropulse White Star Technology by Signature (Abbott Medical Optics, Santa Ana, CA, USA) unit as follows. All the patients underwent surgery by longitudinal cold phaco, with the same preoperative set-up parameters. In stage one performing groove on time/off time of duty cycle was 8/4 ms. Nucleus was removed with divide and conquer technique, in this stage to increase cavitation energy ICE mode with kick power of 8 in initial 1 millisecond was activated. In phacofragmentation on/off time interval was 6/6 ms in each duty cycle and CASE mode as an antisurge mechanism was activated. US power changed according to nucleus hardness with in the range of 30%-50%.

The cortex was aspirated with irrigation/aspiration mode. After injection of VES, a monobloc foldable acrylic IOL implanted into the capsular bag. VES was aspirated from the anterior chamber after which hydration was used to close the corneal incisions. Topical fluoroquinolone and prednisolone acetate eye drops were given 5 times a day for a week. Then topical steroids was slowly tapered and discontinued at 1mo postoperatively.

Intraoperative phacoemulsification parameters including phaco time (PT) and effective phaco time (EPT) were recorded.

Preoperative ophthalmic exclusion criteria was history of previous ocular surgery, glaucoma, uveitis, ocular trauma, retinal or choroidal disease, retinal laser procedures or any intravitreal injections that could effect macular morphology, media opacity such as dense cataract and vitreous hemorrhage that prevents OCT evaluation. Eyes with intraoperative complications such as posterior capsule rupture, iris trauma, presence of zonular instability, postoperative corneal edema persisting more than a week and increased anterior chamber inflammation that needed additional medication were also excluded.

All parameters were evaluated using statistical package for Social Science Version 15.0 (SPSS Inc., Chicago IL, USA). Nominal variables were analyzed with Chi-square test and aged difference between groups evaluated with Student t-test. Multivariate regression analysis was performed to evaluate PT, EPT and CFT. Pearson correlation test used for evaluation of EPT's effects on CFT. In order to evaluate the difference in CFT between patients with diabetes mellitus and normal groups, Student's t test was used. One-way ANOVA was used to compare CFT changes in different observational periods (baseline, 1mo and 3mo) for intragroup analyses. Levene's test was used to assess the homogeneity of the variances. An overall P value less than 0.05 were considered to show a statistically significant result. When an overall significance was observed, pairwise post-hoc test were performed using Tukey's test.

RESULTS

The study group comprises 120 eyes of 120 patients with cataract in whom 60 of them haddiabetes mellitus and 60 patients without any systemic problems as a control group (CG). No one had any surgical complication during the phacoemulsification. Therefore none of them was excluded due to surgical complication. None of the patient withdrew from the study for any reason.

A total of 58 (48.3%) males and 62 (51.7%) females with the mean age of 66.44±9.53y were enrolled in this study. The diabetic group (DG) comprises 28 female (46.6%) and 32 male (53.4%) and the CG consists of 30 female (50%) and 30 male (50%) patients. The gender distribution was not statistically different in both groups (P=0.342). The mean age was 66.5±8.5y in diabetic group and 66.1±10.5y in CG, which was similar in both groups (P=0.827).

All patients underwent with same technique and with same phaco parameters in ICE mode, CASE mode, on/off time in each duty cycle, but PT and EPT were different in each patient. The mean PT in DG was 1.40±0.43 min (0.7-1.9 min) and it was 1.44±0.32 min (0.6-2.1 min) in control cases, the difference was not significant (P=0.85). The mean EPT in DG was 20.12±8.82s (range 9.2-48.7s) while it was 19.24±9.02s (range 8.1-52.4s) in control patients. The difference was statistically insignificant between groups in EPT (P=0.964) (Table 1).

Significant surge that cause floppy iris syndrome, significant miosis that need iris manipulation such as insertion of iris retractor hooks were not observed in any patient.

Table 2　Comparison of central foveal thickness at preoperative, 1mo and 3mo postoperatively

Parameters	Preoperative CFT	Postoperative 1mo CFT	Postoperative 3mo CFT	*P*
Diabetic Group	218.4±12.0	248.8±40.1	231.0±17.1	≤0.001[ab]
Control Group	222.1±16.6	235.3±19.4	226.7±18	≤0.005[ab]

CFT: Central foveal thickness; [a]Significant difference between preoperative CFT and postoperative 1mo CFT; [b]Significant difference between preoperative CFT and postoperative 3mo CFT.

The mean preoperative CFT was 220.29±14.59 μm (min 188 μm-max 262 μm) in all patients that was 218.4±12.0 μm in patients with diabetes mellitus and 222.1±16.6 μm in control subjects. Preoperative CFT was not statistically different between the diabetic patients and CG ($P=0.168$). The mean CFT was increased from 218.4±12.0 μm to 248.8±40.1 μm at 1mo postoperatively in DG, which was significantly higher than that of preoperative CFT ($P=0.001$). The mean CFT in CG was increased from 222.1±16.60 μm to 235.3±19.4 μm at 1mo postoperatively, which was statistically significant too ($P=0.001$).

The mean increment of CFT in DG was 30.3±37.2 μm in DG while it was 13.1±12.5 μm in CG μm at 1mo postoperatively. Even the CFT increasement at 1mo postoperatively was significant in both groups the amount of increasement was statistically higher in DG than CG ($P=0.001$).

The mean CFT was 231.0±17.1 μm at 3mo postoperatively in DG that was significantly higher than the mean preoperative value of CFT ($P=0.001$). The mean value of CG was (226.7±18 μm) significantly higher than preoperative thickness too ($P=0.005$) (Table 2). The average CFT increment at postop 3mo was 12.5±12.4 μm in DG, which was 4.6±9.7 μm in CG. The increment of CFT was significantly higher in DG than that of CG ($P=0.001$). But the comparison of the mean CFTs at 1 and 3mo postoperatively in both DG and CG, significant decrements were observed in each group ($P=0.001$ and $P=0.03$ respectively).

Comparison between the mean preoperative CFT of DG and CG shows that although it is not statistically significant, the preoperative CFT of DG was lower than that of CG but it increased to a significantly higher level than the corresponding mean CFT of CG at 1mo postoperatively ($P=0.021$). At 3mo postoperatively the mean CFT in DG was also higher than that of CG, but the difference was not statistically significant ($P=0.187$). According to our analyses after uneventful phacoemulsification although the CFT was still higher in DG than CG, the difference was not statistically significant any more at 3mo postoperatively.

CME observed with OCT in total of 8 cases (6.6%) one month after surgery, 6 of them in DG and 2 of them were in CG (Figure 1) Clinical macular edema occurred in 3 eyes out of 120 eyes all of them were in DG. The mean age of patient with CME was 72.1±12.2y, which was significantly higher than both DG and CG's mean age.

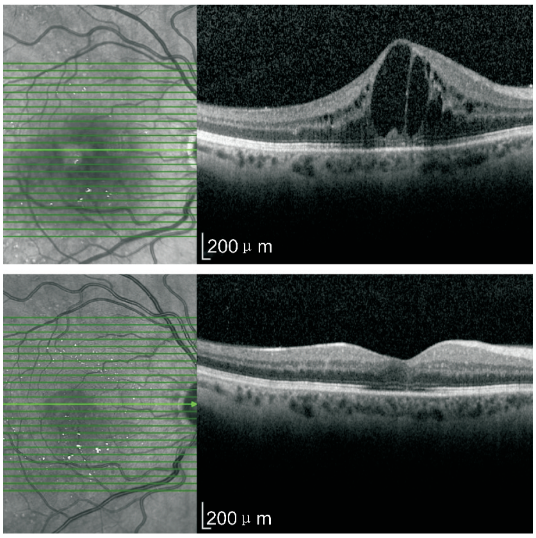

Figure 1　OCT findings of a patient at 1mo postoperatively (up) and 3mo postoperatively (down).

The best corrected visual acuity (BCVA) in DG was 0.70±0.11 in logMAR at preoperatively which was significantly increased to 0.05±0.22 and 0.03±0.13 in logMAR at 1 and 3mo postoperatively respectively. The increment of BCVA's was statistically significant at all time points ($P=0.001$, $P=0.001$).

Although the mean BCVA's of both group at 3mo postoperatively were higher than that of 1mo, the increment of BCVA was more prominent in CG than DG ($P=0.543$, $P=0.556$ respectively) and even not supported statistically the mean BCVA was higher in CG than DG in each postoperative observation period. According to correlation analysis between CFT and BCVA in each postoperative period a negative correlation was found in which BCVA increased while CFT decreased ($r=-0.631$ $P=0.001$ for 1mo postoperatively and $r=-0.557$ $P=0.001$ for 3mo postoperatively).

Even a minimal positive correlation was observed between EPT and CFT at 3mo postoperatively it was not supported statistically. Any other correlation was not observed between PT and EPT and CFT at any follow up period for each patient. According to this observation uneventful phacoemulsification without excessive phacotime and with stable anterior chamber were not related to CFT increment.

DISCUSSION

Several risk factors have been reported about foveal thickness increment after uneventful phacoemulsification including systemic disease such as diabetes mellitus and surgical factors such as intraoperative complications, increased surgical time or surgical parameters[12-15]. The incidence of clinical CME which is a significant cause of decreased in vision after cataract surgery is reported to be 0.1 – 2% while the subclinical CME is estimated to be 9 – 19% in healthy population after uneventful phacoemulsification[1, 5, 10-12]. In diabetic population, a wide range of CME incidence of 31% – 81% has been reported due to many different factors such diabetes type, pre – existing diabetic retinopathy or previous treatment with either laser or intraocular injections and type of evaluation technique[10-13].

In our study OCT was used to analyze CFT which is a non–invasive, non–contact, reproducible, reliable *in vivo* imaging technique that detected even minimal increment in central foveal area and evaluate the retina both qualitatively and quantitatively[5, 10, 13, 15].

In presented study CME detected by OCT in 8 cases out of 120 patients (6.6%) 6 of them in DG and 2 of them in CG. Clinical CME was observed in only 3 cases out of 8, all of them had DG. Katsimpris *et al*[12] observed CME 4.0% in control patients and 28.6% in diabetic group of 49 patients. Eriksson *et al*[1] reported the incidence of clinical CME in 6 out of 34 control eyes and 12 % in 35 diabetic eyes. Our results were similar to others' findings where all of them supported the general knowledge that postoperative CME frequency is higher in diabetic patient even in eyes without retinopathy.

The CFT increments were significantly higher in diabetic patients than control subjects in our study which were 30.3 μm versus 13.1 μm and 12.5 μm versus 4.6 μm at 1 and 3mo after surgery respectively. Our entire cases received topical steroids postoperatively only patient with CME received topical ketorolac combined with steroids as ourroutine procedure. Mathys and Cohen[16] reported the mean change in central macular thickness of 5.6 μm in the nepafenac treatment group and 2.78 μm in CG, none of them had diabetes. Wittpenn *et al*[17] observed 9.6 μm increment in macular thickness of in steroid treatment group and 3.9 μm in ketorolac/steroid combination group in that study no one had diabetes either. CFT increment after cataract surgery are more common in diabetic patients as reported in the literature which may caused by increased inflammatory mediators due to the breakdown of the blood–retinal barrier and compromised blood aqueous barrier[5, 11-13, 16, 18]. Surgical traumas such as excessive PT and EPT, iris traumas anterior chamber surge may be enhanced disruption of these barriers. With the help of CASE mode we did not observe surge and iris trauma in any of our patient. Phaco parameters such as PT and EPT were similar in DG and CG. According to our study we did not find any difference in term of both surgical parameters and risk factors for complication in diabetic patient. We did not observe any significant correlation between CFT changes and PT or EPT in both DG and CG. Von Jagow *et al*[19] did not observe any correlation between PT and central macular thickness (CMT) changes in their series of 33 patients either. Mathys and Cohen[16] reported that even phaco parameters may be associated with increased macular thickness (MT), the both PT and EPT were found not correlated with MT in their series either.

The peak incidence of CME is generally observed at 4–12wk after surgery. In several studies the maximum thickness increments evaluated by OCT reported to at 4 – 6wk postoperatively[5, 11-13, 16-20]. Ghosh *et al*[20] observed the maximum thickness on the 42d. Katsimpris *et al*[12] reported a statistically significant increment of the CFT; only at the 1mo compared to preoperative values in normal subjects, but at 3–6 and 12mo evaluations the mean CFT were not different comparing the preoperative value. They observed similar CFT in diabetic patient at 1mo but it did not regress to preoperative level like normal subject. In Katsimpris *et al*' s[12] study the preoperative CFT were the same in diabetic patients without diabetic retinopathy and non – diabetic groups. Even not supported statistically the mean preoperative CFT of DG was lower than the normal group's in our series. To minimize the effect of confounding factors related to stage of DR, our DG consist of patient with preexisting diabetic retinopathy, similar to Katsimpris *et al*' s[12] series, which includes diabetic patient without diabetic retinopathy. We observed a significant increment of CFT at 1mo postoperatively both DG and no diabetic control patients which were correlated with the literature. Even the mean the CFT of both group were also higher at 3mo comparing to the mean preoperative level, the CFT of both group showed a gradual decline through the time in which the mean CFT of both groups at 3mo were significantly lower than that of postoperative 1mo.

Comparison between DG and CG shows that even the mean CFT of DG was significantly higher than that of CG at 1mo postoperatively, the difference was not statistically significant any more at 3mo in our cases. Eriksson *et al*[1] found no significant difference between diabetic and non – diabetic patient in their 6wk follow up. But Katsimpris *et al*'s[12] reported the mean CFT of the diabetic group was significantly greater than corresponding mean CFT of the CG at each examination in their series with 12mo of follow–up period.

OCT provides quantitative analysis of macula that offers an opportunity to investigate a possible correlation between the CFT and BCVA. Several authors have reported a correlation between VA and CFT changes after phacoemulsification while others did not. In Mathys and Cohen's[16] study BCVA was not correlated with macular thickness. In Ghosh *et al*'s[20] study the increase in macular thickness was subclinical and did not affect final visual outcome. Although not statistically significant we found a negative correlation between postoperative CFT and BCVA at each observation period, in which the lower the CFT the higher BCVA was observed. And BCVA of normal subjects was not different than the DG similar to other authors' observations. But as far as we know ours is the first study that evaluates the effect of phaco parameters in CFT and comparison of diabetic and non-diabetic patient.

In conclusion phacoemulsification in term of phaco parameters and surgical risk factors for complication were not different in diabetic patient than non-diabetic control subjects. Our study highlights a high incidence of increase CFT following uneventful phacoemulsification similar to both normal and diabetic subjects. Fortunately these were mostly subclinical and OCT based changes regress or disappears after 1mo therefore not require immediate treatment.

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