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CLINICAL INVESTIGATION

Effect of uncomplicated phacoemulsification on the central retina in diabetic and non-diabetic subjects

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Abstract
Background The purpose of this study was to evaluate the subclinical influence of uncomplicated cataract surgery on foveal thickness and volume in the early postoperative period.
Methods In a prospective study, 108 eyes were assessed by optical coherence tomography preoperatively and 1 day, 1 week and 4 weeks after uncomplicated small incisional phacoemulsification with endocapsular intraocular lens (IOL) implantation under topical anesthesia. The study included 24 eyes of diabetic patients. Eyes with diseases predisposing them for postoperative macular edema, preexisting macular edema, and eyes that developed cystoid macular edema during follow-up were excluded. Main outcome measures were minimal foveal thickness (MFT) and foveal volume. Secondary outcome measure was VA.
Results Visual acuity (LogMAR) increased significantly ($p<0.001$) from 0.43±0.21 to 0.11±0.15 4 weeks after surgery, with a significantly ($p=0.001$) higher increase in VA for nondiabetic subjects. MFT increased from 183±27 µm preoperatively to 191±37 µm 4 weeks after surgery ($p=0.001$), with diabetic patients showing a tendency toward a more pronounced increase in minimal retinal thickness than nondiabetic subjects ($p=0.058$). One day and 1 week after surgery, MFT measurements were not significantly different from preoperative results. Foveal volume showed a significant increase at 1 week and 4 weeks after surgery ($p<0.001$), independent of the presence of diabetes ($p=0.565$). The proportion of patients exhibiting subclinical macular swelling was about 1/5 in the nondiabetic group and 1/3 in the diabetic group. Mean duration of surgery was 11.5±6.6 min.
Conclusion Foveal thickness and foveal volume demonstrate a subclinical increase within 4 weeks after uncomplicated cataract surgery in up to 1/3 of the patients. The amount and frequency of early postoperative subclinical retinal thickening was higher than expected.

Keywords Cystoid macular edema · Optical coherence tomography · Retinal thickness · Phacoemulsification · Complication · Foveal volume

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Introduction

Phacoemulsification with endocapsular intraocular lens (IOL) implantation is currently one of the most frequently performed surgical procedures. Cystoid macular edema (CME) may occur as a complication in the postoperative course and may reduce VA (VA) even if surgery is uncomplicated. Postoperative "clinical" CME, which is characterized by a thickening of the central retina and presence of cystoid intraretinal spaces, is detectable by biomicroscopy alone. Biomicroscopy, however, has the disadvantage that it is prone to a pronounced interobserver variability, and subtle subclinical changes might remain unrecognized [29]. Early studies on CME following cataract surgery, which in part did not utilize phacoemulsification but extracapsular or intracapsular cataract extraction, have shown that a significant number of eyes develop central leakage in fluorescein angiography after cataract 3surgery but do not develop clinical CME [1, 13, 20, 23, 32, 34]. Theoretically, this postoperative hyperfluorescence should find a morphological correlate in increased retinal thickness, which might not be detected by biomicrocopy but may be detected and quantified by optical coherence tomography (OCT). In contrast to fluorescein angiography, OCT is a noninvasive technology capable of measuring retinal thickness and producing pseudohistological images of the retina [2, 8–12, 21, 26, 27, 31, 33].

It was the purpose of the present study to investigate whether a subclinical increase in retinal thickness and volume can be found in the early postoperative course of 4 weeks after uncomplicated phacoemulsification with endocapsular IOL implantation in eyes that do not develop clinical CME.

Patients and methods

There were 116 eyes of 104 patients referred and scheduled for routine phacoemulsification and IOL implantation included into the prospective, observational study. All patients gave their informed consent prior to inclusion into the study. Exclusion criteria were any ocular diseases that might influence the study results, such as uveitis, macular edema due to diabetes, age-related macular degeneration, intraoperative complications, and/or inferior quality of OCT measurements due to pronounced media opacities. Since this study aimed to investigate particularly subclinical changes, eight eyes (four diabetic, four nondiabetic) that developed "clinical" CME detected by biomicroscopy during follow-up were excluded from analysis; 108 eyes (97 patients) remained in the study. Presence of mild or medium diabetic retinopathy or early nonexudative age-related macular degeneration showing drusen did not constitute exclusion criteria.

All eyes received a complete ophthalmological examination preoperatively. Postoperative examinations were performed 1 day, 1 week, and 4 weeks after surgery. Best-corrected VA (decimal) was measured 1 week and 4 weeks postoperatively; for statistical analysis, VA results were converted into LogMAR. OCT measurements were taken during each visit (Stratus OCT3, Carl Zeiss Ophthalmic Systems), and a macular thickness map was generated. This standard OCT protocol uses six radially oriented scan lines to produce a topographical map of the macula. From the associated tabular output, readings for the MFT (MFT) and central foveal volume (CFV) were taken. CFV was defined as retinal volume within a circle of 500-µm radius or 1 mm, respectively, around the center of the fovea. All OCT measurements were performed by the same examiner.

The study included 84 eyes from nondiabetic and 24 eyes from diabetic patients (blood glucose level controlled either by medication or by diet alone). Patients diagnosed with diabetes by their general practitioner as a consequence of laboratory findings were assigned to the diabetic group independent of the presence of diabetic retinopathy. Of the 24 eyes, 18 did not show signs of diabetic retinopathy in biomicroscopy, two had mild nonproliferative diabetic retinopathy, two had had panretinal laser photocoagulation, and two had had central and panretinal laser photocoagulation.

Mean patient age was 72.7±8.8 years, with no significant difference between diabetic and nondiabetic subjects (p=0.981). There were 58 eyes belonging to female patients; 51 procedures were performed on right eyes and 57 procedures on left eyes. Preoperatively, mean spherical correction was 0.01±2.7 (range −11.75 to 6.5) diopters, and cylindrical correction was 0.9±0.8 (range 0–3.5) diopters. All patients were treated with standard phacoemulsification (topical anesthesia, clear cornea incision 2.75- to 3.0-mm width, capsulorrhexis, hydrodissection and hydrodelineation, phacoemulsification, aspiration of the lens cortex, and endocapsular implantation of a hydrophobic acrylic IOL). Postoperative medication was a combination of an antibiotic and a steroid (Isopto-Max AT) given topically three times daily for 2–3 weeks according to the referring ophthalmologist's discretion. Pre- and postoperative measurements were analyzed by repeated measures ANOVA. Related p values shown in Tables 1, 2 and 4 are uncorrected; those p values that were still significant after

Table 1 Visual acuity

Visual acuity(LogMAR)	All eyes (n=108) mean±SD	Nondiabetics (n=84)	Diabetics (n=24)	Diabetics vs. nondiabetics
Preoperatively	0.43±0.21	0.42±0.21	0.45±0.24	p=0.550
1 week postoperatively	0.14±0.16 (p<0.001)*	0.13±0.12 (p<0.001)*	0.20±0.24 (p=0.007)*	p=0.070
4 weeks postoperatively	0.11±0.15 (p<0.001)*	0.09±0.11 (p<0.001)*	0.20±0.22(p=0.006) *	p=0.001

The p value gives the significance of difference of pre- and postoperative measurements. The last column shows the significance of difference between diabetic and nondiabetic subjects

*p values still significant after Bonferroni correction for multiple comparisons

Table 2 Minimal foveal thickness (MFT)

Minimal foveal thickness (µm)	All eyes (n=108) mean±SD (median)	Nondiabetics (n=84)	Diabetics (n=24)	Diabetics vs. nondiabetics
Preoperatively	183±27 (179)	182±27 (178)	187±28 (180)	p=0.478
1 day postoperatively	185±29 (183) (p=0.171)	186±28 (183) (p=0.061)	184±30 (182) (p=0.406)	p=0.826
1 week postoperatively	186±29 (183) (p=0.093)	186±27 (185) (p=0.078)	188±33 (180) (p=0.687)	p=0.698
4 weeks postoperatively	191±37 (186) (p=0.001)*	188 ± 30 (184) (p=0.002)*	204±54 (195) (p=0.057)	p=0.058

The p value gives the significance of difference of pre- and postoperative measurements. The last column shows the significance of difference between diabetic and nondiabetic subjects

* p values still significant after Bonferroni correction for multiple comparisons

Bonferroni correction for multiple comparisons are indicated by an asterisk. The presence of a time effect within groups was assessed by the multivariate Wilks' lambda test statistic. The diabetic and the nondiabetic groups were compared using Student's t test for unpaired samples (SPSS 11.5.1, SPSS Inc., Chicago, IL, USA).

Results

VA (LogMAR) improved significantly from 0.43±0.21 preoperatively to 0.14±0.16 after 1 week and to 0.11±0.15 after 4 weeks (p<0.001 each). Preoperatively and 1 week postoperatively, VA did not differ significantly between diabetics and nondiabetics (p>0.05 each). Four weeks postoperatively, VA of diabetic subjects was significantly worse than of nondiabetic subjects (p=0.001; Table 1). VA increase over time was highly significant (p<0.001) and was different for the diabetic and the nondiabetic subgroups (p=0.012).

Preoperatively, MFT did not differ between the diabetic and the nondiabetic groups (p=0.478; Table 2). Up to 1 week after surgery, in neither of the subgroups nor in the total population, was a statistically significant increase in foveal thickness observed. Four weeks after surgery, however, a significant increase in MFT could be detected in the total population and in the nondiabetic subgroup. In diabetic patients MFT increased as well; however, this finding was not statistically significant (p=0.171; Table 2). The MFT increase over time was highly significant (p=0.001) and showed a difference for the diabetic and nondiabetic subgroups (p=0.028). The proportion of patients showing an increase in MFT ranged from 4.8% in the nondiabetic group on the first postoperative day to 33.3% in the diabetic group 4 weeks after surgery (Table 3).

CFV was similar in all groups preoperatively (Table 4). Postoperatively, CFV was higher at all times than preoperatively, with one exception: in the diabetic subgroup, CFV started to increase 1 week after surgery instead of the first postoperative day. The CFV increase over time was highly significant (p<0.001), with no significant difference between diabetics and nondiabetics (p=0.112).

The proportion of patients showing an increase in CFV ranged from 4.2% in the diabetic group on the first postoperative day up to 33.3% in the diabetic group 4 weeks after surgery (Table 5).

A comparison of the diabetic and the nondiabetic group revealed no statistically significant differences in MFT and CFV pre- and postoperatively. Solely MFT showed a tendency toward a higher postoperative increase in the diabetic group compared with the nondiabetic group 4 weeks after surgery (p=0.058). All other findings did not vary significantly (p>0.15) between the diabetic and the nondiabetic groups. Mean duration of the surgical procedure was 11.5±6.4 min. Operation time did not differ significantly between the diabetic and the nondiabetic groups (11.1±5.5 min. vs. 11.6±6.6 min; p=0.733).

Discussion

The aim of the study was to investigate the effect of uncomplicated standard phacoemulsification with endocapsular lens implantation on the central retina in diabetic and nondiabetic subjects in the early postoperative period of 4 weeks. Particular attention was paid to the question of whether subclinical retinal swelling without development of clinical CME occurs consistently. Older studies, particularly those predating the routine use of phacoemulsification, had shown that central exudation may occur in fluorescein angiography after surgery. "Angiographic" subclinical macula edema was reported in up to 75% of patients after intracapsular cataract extraction and in up to 30% of patients after extracapsular cataract surgery, each with a lower incidence of "clinical" macula edema [1, 5,

Table 3 Proportion of patients showing a postoperative increase in minimal foveal thickness (MFT) of at least 15 µm

Minimal foveal thickness: ≥15 µm increase	All eyes	Nondiabetics	Diabetics
1 day postoperatively	8.4%	4.8%	17.4%
1 week postoperatively	29.9%	32.1%	21.7%
4 weeks postoperatively	24.1%	21.4%	33.3%

Table 4 Central foveal volume (CFV) within a circle of 500-μm radius around the center of the fovea

Foveal volume (μm^3)	All eyes (*n*=108) mean±SD (median)	Nondiabetics (*n*=84)	Diabetics (*n*=24)	Diabetics vs. nondiabetics
Preoperatively	263±29 (261)	263±28 (260)	262±33 (264)	*p*=0.952
1 day postoperatively	269±34 (264) (*p*=0.013)*	271±35 (267) (*p*=0.007)*	260±32 (261) (*p*=0.412)	*p*=0.182
1 week postoperatively	270±32 (265) (*p*<0.001)*	270±30 (265) (*p*=0.001)*	272±38 (267) (p=0.004)*	*p*=0.770
4 weeks postoperatively	279±38 (273) (*p*<0.001)*	278±34 (274) (*p*<0.001)*	283±52 (272) (*p*=0.009)*	*p*=0.565

The *p* value gives the significance of difference of pre- and postoperative measurements. The last column shows the significance of difference between diabetic and nondiabetic subjects

**p* values still significant after Bonferroni correction for multiple comparisons

13, 20, 23, 24, 32, 34]. Even with phacoemulsification, the rate of positive angiographic findings can still be as high as 9–19% [20, 32].

Diabetic patients may be prone to develop postoperative subclinical retinal swelling or clinical CME. Kodama and coworkers found a higher incidence of postoperative CME in diabetics than in nondiabetics after extracapsular cataract extraction (ECCE) [16]. Menchini et al. found an equally high rate of postoperative angiographic CME in nondiabetics and diabetic subjects without diabetic retinopathy 30 days after the procedure. Three to 12 months postoperatively, however, angiographic CME was significantly more frequent in the subgroup of patients suffering from diabetes without clinical retinopathy [19]. In a prospective study, Krepler et al. reported an incidence of 31% clinically significant macular edema in eyes of diabetic patients 1 year after phacoemulsification. This rate was higher, but not significantly higher, than in the nonoperated fellow eyes (13.5%) [17]. These findings may be related to impairment of the blood–retinal barrier or blood–aqueous barrier, respectively, in diabetics and an increased susceptibility to surgical trauma. Other factors that may contribute to the pathogenesis of diabetic retinopathy and possibly to an increased incidence of CME after phacoemulsification in diabetics may include chronic inflammatory mechanisms, as recently suggested by Joussen and coworkers [14, 15].

Hyperfluorescence in angiography is expected to be associated with an increased retinal thickness and possibly disturbed retinal architecture. In contrast to angiography, OCT is capable of quantifying retinal thickness changes, especially MFT and CFV, and give a pseudohistological insight into retinal structure. Furthermore, there are reports that VA may be correlated more closely to retinal thickness than to the amount of fluorescein extravasation [22]. Today, relatively few studies reporting on the influence of up-to-date phacoemulsification on the central retina are published, and they investigate relatively low numbers of patients. Grewing and Becker did not find retinal changes 30 min after phacoemulsification [9]. Sourdille and Santiago described a retinal thickness increase of 15 μm or more in 11 of 41 operated eyes but did not provide detailed information [31]. Lobo et al. studied 32 eyes after phacoemulsification, which developed retinal thickness increase in 41% of the cases 6 weeks after surgery, which still was present after 30 weeks in 22% [18].

To our best knowledge, the present study reports on the highest number of consecutive eyes regarding the questions above; additionally, the present study differentiates between diabetics and nondiabetics and gives detailed information on early postoperative retinal thickness development. As primary study parameters, we chose firstly MFT because the central depression of the fovea is the only retinal location that can be clearly identified in OCT due to its unique architecture and may thus be refound in control measurements. Secondly, the central retinal volume within a circle of 500-μm radius around the center of the fovea [similar to the Early Treatment Diabetic Retinopathy Study (ETDRS) definition], as this area is of high functional importance. Moreover, interpolation increases drastically with increasing distance to the fovea in OCT, measurements leading to reduced accuracy of the results.

Visual acuity increased significantly after surgery in all groups. However, 4 weeks postoperatively, diabetic patients performed significantly worse than nondiabetic patients (Table 1). This finding corresponds with a relatively and absolutely higher increase in MFT in the diabetic group, which just failed to reach the level of statistical significance. As the present study included diabetic patients with or without presence of retinopathy, it is likely that this finding could have reached significance if solely diabetic patients with diabetic retinopathy had been included. Nondiabetic subjects and the total population developed a significant thickening of the fovea. CFV increased as early

Table 5 Proportion of patients showing a postoperative increase in central foveal volume (CFV) of 10% or more

Central foveal volume: ≥10% increase	All eyes	Nondiabetics	Diabetics
1 day postoperatively	16.8%	8.4%	4.2%
1 week postoperatively	11.4%	9.9%	16.7%
4 weeks postoperatively	23.1%	20.2%	33.3%

as the first day postoperatively in some groups. One week and 4 weeks after surgery, this finding was highly significant in all study groups. Other readings partially showed a tendency toward an increase in foveal thickness or volume but behaved nonuniformly. The proportion of patients showing a subclinical increase in MFT or CFV was higher than expected and reached 1/3 in diabetic patients. Eyes from nondiabetic subjects demonstrated retinal thickening in up to more than 1/5 of the group. However, as VA was highly significantly better after surgery than before surgery despite the induced macular swelling, the impact of this finding on VA seems to be less dramatic than one could fear.

Preoperative foveal thickness measurements as obtained in this study were higher than in previous investigations, in which the mean measurements ranged between 142±18 µm and 183±6 µm [2, 8, 10, 11, 26, 27, 30, 33]. Diabetic patients without diabetic retinopathy were reported to have a retinal thickness of 156±28 µm and patients with nonproliferative diabetic retinopathy without macular edema 169±33 µm [25]. Yang et al. measured 175±38 µm in diabetic patients without edema [35]. One possible explanation for the higher results in our study can be seen in the use of the new Stratus OCT III in contrast to the previous reports, which might have a reduced comparability with OCT I and II [26]. Furthermore, it has been shown that the highest variability of measurements occurs in the fovea [2, 21].

Reasons for the subclinical increase in central foveal thickness and volume may be the same as those that may lead to development of postoperative CME. Among the leading pathogenic factors, which are poorly understood, may be a combination of inflammation and vitreous traction, intraoperative hypotony, increased amounts of vascular endothelial growth factor and interleukin 6, amount of ultrasound energy applied during surgery, vitreous loss, diabetic retinopathy, and others [3, 4, 6, 7, 28]. It is not known why postoperative retinal thickening is merely subclinical in some patients and leads to clinical CME in others.

The present study has limitations. Firstly, follow-up is relatively short. Secondly, the post-hoc exclusion of eyes that developed clinical CME might be problematic. However, as we aimed to specifically study the subtle subclinical changes in the early postoperative phase rather than the well-known clinical CME, which can be diagnosed by biomicroscopy without any other technical help, both concerns can be regarded immanent to the objective of the study. Furthermore, after exclusion of cases of diabetic macular edema or proliferative diabetic retinopathy, we classified every patient diagnosed with diabetes by his or her general practitioner as a diabetic subject, irrespective of metabolic parameters such as blood glucose or presence of mild or medium diabetic retinopathy. The reason for this decision was that in most cataract cases scheduled for surgery in daily practice, these parameters are not systematically recorded either, and therefore, such information would have limited practical value. In the present study, we tried to collect data that can be transferred to everyday practice instead.

In summary, we found a subclinical increase in MFT and central retinal volume in diabetic and nondiabetic patients after uncomplicated phacoemulsification, which may be detected and quantified by OCT. A slightly more pronounced increase in MFT in diabetic than in nondiabetic patients corresponds with a worse VA outcome 4 weeks after surgery in diabetic patients. The effect of uncomplicated phacoemulsification on the central retina in patients without signs of clinical CME in the early postoperative course was more pronounced and frequent than clinically expected.

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