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Original Article

Clinical observation of femtosecond laser-assisted cataract surgery for diabetic cataract

Jianli Ma*, Xin Kao*, Xiaoxiang Sun, Min Zhang, Yuqiang Liu

*Department of Ophthalmology, Zhengdaguangming Eye Group, Weifang Eye Hospital, Weifang 261000, Shandong, People's Republic of China. *Equal contributors.*

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Abstract: Objective: To observe the clinical efficacy of femtosecond laser-assisted cataract surgery (FLACS) for diabetic cataract (DC). Methods: One hundred and seven cases of DC admitted between August 2018 and August 2021 were enrolled, and their clinical data were retrospectively analyzed. Of them, 53 cases treated with conventional phacoemulsification (Phaco) cataract surgery (CPS) were set as the control group (the Con) and 54 cases receiving FLACS were set as the observation group (the Obs). Clinical data such as effective phaco time (EPT), color doppler energy (CDE), best corrected visual acuity (BCVA), visual quality, corneal endothelial cell (CEC) count (CECC), and complication rate were compared and analyzed. Finally, multivariate Cox regression analysis was performed to analyze the prognostic factors based on the incidence of complications in DC patients. Results: The Obs had significantly lower EPT and CDE compared to the Con, as well as markedly elevated BCVA and visual quality at one month after operation compared to the preoperative levels and the Con. The CECC of the Obs differed insignificantly from that before surgery and was higher versus the Con. Moreover, the incidence of postoperative complications (corneal edema, fibrin exudation, pigment dispersion, and posterior synechia of the iris) was lower in the Obs. Moreover, the treatment method was an independent prognostic factor affecting the prognosis of DC patients. Conclusions: The above analysis suggests the superior efficacy of FLACS to CPS for DC, as it can more significantly reduce EPT, CDE, CEC loss, and the incidence of postoperative complications with a positive effect on improving BCVA, visual quality, and patient prognosis.

Keywords: Femtosecond laser, cataract surgery, diabetic cataract, clinical effect observation

Introduction

Diabetes mellitus (DM) is a metabolic disease derived from chronic hyperglycemia due to insufficient insulin production by the patient's own pancreas or an incorrect response of the body's cells to the insulin produced [1]. DM has now become a major global health problem, with a constantly rising prevalence ranging from 1% to 11% [2, 3]. A common consequence of uncontrolled DM is elevated blood sugar, in addition to which, there will be serious damage to the patient's heart, blood vessels, eyes, kidneys, and nerves over time [4]. It has been reported that DM patients are 2-5 times more likely to develop cataracts than normal people, with a much earlier age of onset [5]. Due to the high incidence and rapid progression of cataract, cataract has been identified as the major cause of visual impairment in DM patients [6].

Currently, cataract surgery is commonly used for the treatment of diabetic cataract (DC), but some reports suggest that this procedure may accelerate the progression of diabetic retinopathy in DC patients and eventually lead to decreased or lost vision [7, 8]. Thus, an effective surgical plan is urgently needed to minimize the harm from DC. This study takes femtosecond laser (FSL) as the breakthrough method to investigate whether this treatment modality has a better clinical effect on patients.

Cataract surgery is considered one of the safest and most effective surgical procedures in ophthalmology [9]. But for DC patients, the resulting adverse effects are still a major clinical focus [10]. Manual phacoemulsification (Phaco) is a common treatment plan, but in recent years, femtosecond laser-assisted cataract surgery (FLACS) has gained usage gradually [11]. For cataract patients, FLACS has many demonstrated advantages, such as better incision quality and higher accuracy [12]. However, there are still reports suggesting that FLACS is less effective than Phaco in improving patients' visual quality, warranting further investigation regarding its clinical effects in DC patients [13]. Therefore, in this study, we compared the application value of FLACS and conventional Phaco cataract surgery (CPS) in DC patients to verify the application advantages of the former in this medical setting, so as to make a contribution to the clinical promotion of FLACS for optimization of DC patients.

Data and methods

Patient data

This is a retrospective study that had been approved by the Hospital Ethics Committee of the Weifang Eye Hospital, Shandong, China. We selected 107 cases (120 affected eyes) of DC treated between August 2018 and August 2021. The control group (the Con; 53 cases with 57 affected eyes) received CPS, and the observation group (the Obs; 54 cases with 63 affected eyes) underwent FLACS. The two cohorts were similar in baseline data, showing clinical comparability ($P>0.05$).

Inclusion criteria: All the included cases met the diagnostic criteria for DM and cataract [14], with their blood glucose controlled within the reference range (2 h postprandial blood glucose ≤7.8 mmol/L, glycosylated hemoglobin ≤7%); cases with complete case records, and no surgical contraindications, inflammation such as conjunctivitis, keratitis or dacryocystitis that increased the risk of surgical infection; and cases without mental illness or mental disorders.

Exclusion criteria: Those with strabismus, amblyopia, glaucoma and other ocular organic lesions; multiple corneal conjunctival operations; lens dislocation or subluxation; fundus diseases, blepharoptosis, and deep eye sockets were excluded.

Surgical methods

The Con received CPS. All patients underwent sufficient preoperative pupil dilation. Following surface anesthesia and conventional disinfection, the bulbar conjunctiva was cut with a 2.2-mm puncture knife. Corneoscleral margin incision and lateral incision were then made, through which the viscoelastic agent was injected to maintain the anterior chamber. Next, the capsule on the superficial surface of the lens was torn off, and the lens nucleus and the cortex, as well as the cortex and the capsule, were thoroughly decomposed. After sucking out the turbid crystal with an ultrasonic emulsification probe, the transparent intraocular lens was implanted with the position well adjusted. Finally, the viscoelastic agent used to protect the corneal endothelium was aspirated, and the incision was closed to complete the procedure.

The Obs was treated with FLACS. The pupil was fully dilated and anesthetized before surgery. The LenSx FSL operating platform was used to set the main corneal incision, lateral incision, anterior capsular orifice and pre-chopping nucleus parameters and modes according to the reference images provided by the Verion digital navigation system. The patient was then instructed to gaze at the indicator light of the device, and the negative pressure suction device was adjusted to contact with the patient's eyeball surface. This was followed by the initiation of the negative pressure suction to fix the eyeball for eye structure scanning, parameter calibration, and laser firing. The main and lateral incisions were created with a special FSL opener, and the viscoelastic agent was injected into the anterior chamber to tear off the superficial capsule of the lens. The capsule was then separated from the lens nucleus with saline, and the lens nucleus was broken up by Phaco apparatus to aspirate it out of the eyeball in the shape of milk mud. After intraocular lens implantation into the capsular bag according to intraoperative navigation, watertight closure of the incision was carried out. The operated eye was bandaged after applying Tobramycin and dexamethasone Eye Ointment to the conjunctival sac.

Analysis indexes

The effective phaco time (EPT), color Doppler energy (CDE), best corrected visual acuity (BCVA), visual quality, and corneal endothelial cell (CEC) count (CECC) before and one month after surgery, as well as the postoperative com-

Table 1. Comparison of general data between two cohorts of diabetic cataract patients [n (%), mean ± SD]

Factor	n	Control group (n=53)	Observation group (n=54)	χ^2/t	P
Sex				0.080	0.777
Male	58	28 (52.83)	30 (55.56)		
Female	49	25 (47.17)	24 (44.44)		
Average age (years old)	107	64.70±10.00	63.59±11.62	0.529	0.598
Course of DM (years)	107	5.96±1.30	6.26±1.67	1.036	0.303
axial length (mm)	107	22.96±0.68	23.04±0.93	0.507	0.613
Astigmatism (D)	107	2.79±1.04	2.65±1.12	0.670	0.505
Emery-Little classification				0.077	0.781
Grade I-II	62	30 (56.60)	32 (59.26)		
Grade III-IV	45	23 (43.40)	22 (40.74)		
Hypertension				0.106	0.745
Without	67	34 (64.15)	33 (61.11)		
With	40	19 (35.85)	21 (38.89)		
Smoking history				0.086	0.770
Without	55	28 (52.83)	27 (50.00)		
With	52	25 (47.17)	27 (50.00)		
Family history of cataract				0.236	0.627
Without	75	36 (67.92)	39 (72.22)		
With	32	17 (32.08)	15 (27.78)		

plication rate, were observed and recorded. Among them, EPT and CDE were determined using a phaco-emusifier, and BCVA was measured by international standard visual acuity chart. Visual quality was mainly measured by the QOA-STMII visual quality analyzer to compare the modulation transfer function (MTF) cut-off before and 1 month after surgery. The CECC was measured using a non-contact corneal endothelial microscope, and the density of CECs in the central cornea of the two groups was compared before and one month after surgery. Finally, the incidence of postoperative complications (corneal edema, fibrin exudation, pigment dispersion, and posterior synechia of the iris) were recorded and compared.

Statistics and methods

In this study, statistical software SPSS21.0 was used for data analysis. The number of cases/percentages (n/%) was used to represent the counted data; mean ± SEM was used to indicate the measured data. The inter-group difference of counted data was identified by the χ^2-test, and that of the measured data was determined by the independent sample t-test. Multivariate Cox regression analysis was used to analyze the independent factors affecting the prognosis of DC patients. Differences were significant when P<0.05.

Results

Comparison of general data between two cohorts of DC patients

There were no significant inter-group differences in sex, mean age, course of DM, axial length, corneal astigmatism, Emery-Little classification, hypertension, smoking history, or family history of cataract (P>0.05). See **Table 1** for details.

Impacts of two treatments on surgical indexes of DC patients

We detected two surgical indexes, namely EPT and CDE, in both cohorts (**Figure 1**); the results showed statistical significance in EPT and CDE between groups, with lower values in the Obs (P<0.05).

Influences of two treatments on BCVA and visual quality of DC patients

We evaluated pre- and post-operative BCVA and visual quality, with the latter evaluated by the MTF cut-off (**Figure 2**). The data showed similar preoperative BCVA and MTF cut-off values in the two groups (P>0.05); but the values of the two indexes were elevated after surgery (P<0.05), with higher postoperative BCVA and MTF cut-off values in the Obs (P<0.05).

Influences of the two treatments on CECC in DC patients

We measured the CECC in both groups (**Figure 3**). The CECC differed insignificantly between groups before surgery (P>0.05), but showed a downward trend in both cohorts postoperatively. Moreover, the postoperative CECC was notably higher in the Obs than in the Con (P<0.05).

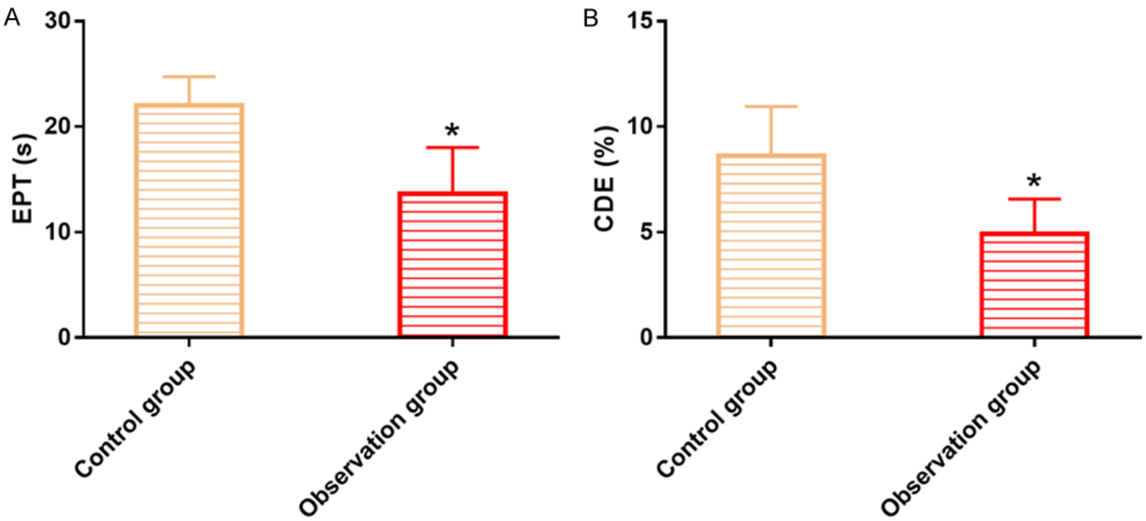

Figure 1. Impacts of two treatments on surgical indexes of diabetic cataract patients. A. The observation group had an obviously lower EPT than the control group. B. The observation group had an obviously lower CDE than the control group. Note: * represents P<0.05 compared with the control group. EPT, Effective Phaco Time; CDE, Color Doppler Energy.

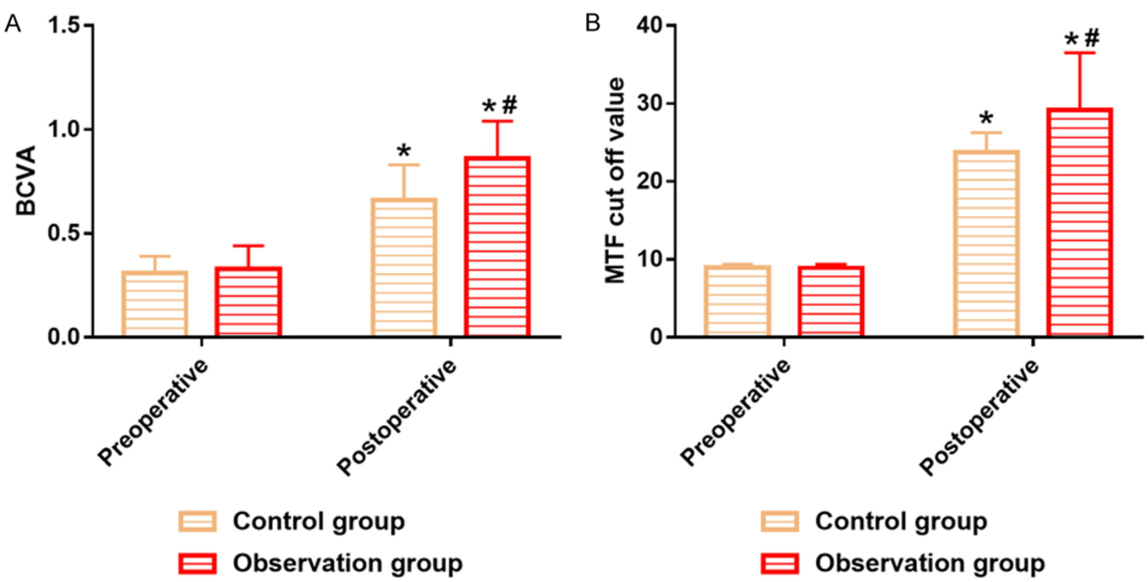

Figure 2. Impact of the two treatments on BCVA and visual quality of diabetic cataract patients. A. The BCVA of both groups increased markedly after surgery, showing a significant difference between groups. B. The postoperative MTF cut-off value of both groups increased markedly, with a significant difference between groups. Note: * means P<0.05 compared with preoperative, # means P<0.05 compared with control group. BCVA, Best Corrected Visual Acuity.

Influence of two treatments on the complication rate in DC patients

By recording the incidence of complications (corneal edema, fibrin exudation, pigment dispersion, and posterior synechia of the iris) in the two groups, we found that the overall complication rate in the Obs was 5.56%, significantly lower than that of 24.53% in the Con (P<0.05), as shown in **Table 2**.

Prognostic factors of DC patients

A 1-month follow-up was successfully completed. Patients with postoperative complications were included in the poor prognosis group

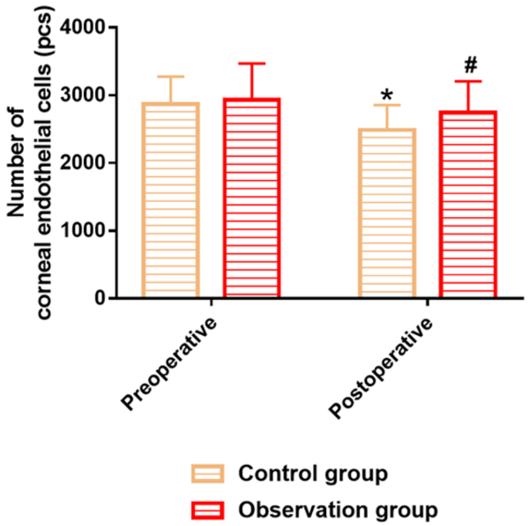

Figure 3. Impact of two types of treatment on the corneal endothelial cell count (CECC) in diabetic cataract patients. The CECC in the two groups decreased after operation, but the postoperative CECC was higher in the observation group compared to the control group. * means P<0.05 compared with preoperative, # means P<0.05 compared with control group. CECC, Corneal Endothelial Cell Count.

(n=16) and the rest were assigned to the good prognosis group (n=91). Multivariate Cox regression analysis of EPT, CDE, BCVA, MTF cut-off, CECC and treatment method showed that the treatment method (P=0.013) was an independent prognostic factor affecting poor prognosis of DC patients. DC patients who were treated with CPS within one month after treatment had an increased risk of poor prognosis. See **Table 3** for details.

Discussion

The health problems brought by cataract, one of the prime reasons for visual impairment and blindness worldwide, cannot be ignored [15]. A number of studies have reported DM as a risk factor for cataract. An approximately twofold increase in cataract detection was associated with DM in a study by Becker et al. on the incidence of DCs [16, 17]. Pollreisz et al. [18] reported that the induction of DC was a process of body fluid accumulation. This leads to extra output of potassium sorbate when the patient is in a hyperglycemic state, and the osmotic pressure generated during the accumulation will cause excessive fluid to flow into the lens and eventually lead to cataract [19]. In addition, DM can affect any ocular tissue, which also challenges the clinical treatment of DC [20]. Therefore, research on the clinical effect of FLACS on DC patients is needed for improving the safe treatment of DC.

In this study, a total of 107 patients with DC were enrolled and grouped according to different surgical schemes: the Con receiving CPS and the Obs receiving FLACS treatment. First, we compared differences in EPT and CDE between groups and found that there were significantly lower levels in the Obs. Lin et al. [21] reported that the lens fragmentation grid pattern in FLACS can reduce EPT and CDE, which is consistent with our observations. Excessive use of power during surgery will increase the production of heat and oxidative free radicals, resulting in endothelial cell injury and prolonged recovery time, which is not conducive to the treatment and recovery of DC patients [22]. Therefore, this study recorded the CECC before and after intervention. As a result, the post-treatment CECC showed a non-significant declining trend in both groups, with a markedly higher CECC in the Obs compared to the Con, suggesting a positive effect of FLACS in protecting the corneal endothelium and a better prognosis of patients treated with FLACS. In terms of safety, we compared and analyzed the incidence of corneal edema, fibrin exudation, pigment dispersion, and posterior synechia of the iris between the two groups. It was found that the total incidence of complications in the Obs was significantly lower than that of the Con (5.56% vs. 24.53%), indicating that FLACS is safer than CPS in the treatment of DC, similar to the results of Feldhaus et al. [23] who analyzed the safety of FLACS. After that, we evaluated patients' BCVA and visual quality. The two indexes were significantly increased in both groups after surgery, with notably higher BCVA and MTF cut-off values in the Obs, which indicates that FLACS has significant advantages in improving BCVA and visual quality of patients. Finally, multivariate Cox regression analysis identified that the treatment method was an independent prognostic factor affecting the poor prognosis of DC patients, suggesting that FLACS as a treatment is beneficial to reduce the risk of adverse prognosis of DC patients within one month after treatment.

Compared to similar studies, the innovation of this study was that we first confirmed that FLACS had a significant positive impact on the

Table 2. Impact of two types of treatment on the complication rate in diabetic cataract patients [n (%)]

Category	Control group (n=53)	Observation group (n=54)	χ^2 value	*P* value
Corneal edema	7 (13.21)	2 (3.70)	-	-
Fibrin exudation	2 (3.77)	1 (1.85)	-	-
Pigment dispersion	3 (5.66)	0 (0.00)	-	-
Posterior synechia of the iris	1 (1.89)	0 (0.00)	-	-
Total incidence	13 (24.53)	3 (5.56)	7.571	0.006

Table 3. Multivariate Cox regression analysis of factors influencing postoperative complications in patients with DC

Factor	B	SE	Wald	P	HR (95% CI)
EPT	-0.079	0.084	0.891	0.345	0.924 (0.784-1.089)
CDE	0.114	0.118	0.935	0.334	1.121 (0.890-1.412)
BCVA	-0.556	1.558	0.127	0.721	0.574 (0.027-12.159)
MTF cut-off	0.066	0.063	1.079	0.299	1.068 (0.943-1.209)
CECC	0.000	0.001	0.005	0.942	1.000 (0.999-1.001)
Treatment method	1.591	0.641	6.169	0.013	4.911 (1.399-17.239)

Note: EPT, Effective Phaco Time; CDE, Color Doppler Energy; BCVA, Best Corrected Visual Acuity; MTF, Modulation Transfer Function; CECC, Corneal Endothelial Cell Count.

surgical treatment of diabetic cataract patients from the aspects of surgical indicators, BCVA, visual quality, and CECC. Then we confirmed that FLACS had a significant inhibitory effect on postoperative complications based on the common negative status of patients. Finally, the factors affecting patient outcomes are analyzed, which makes the article more comprehensive. Still, this research still shows room for improvement. First of all, it is a single center study, which introduces some degree of information collection bias. This can be addressed by including multi-center data for analysis. Second, no follow-up was conducted. The fluctuation of blood sugar in DM patients always affects patients' health, and the long-term impact of surgical treatments on patients with DC can be more intuitively understood if a 6-24-month follow-up can be supplemented. This study can be constantly improved, taking the above two points into consideration.

Thus, FLACS has a significant effect on improving the curative effect of DC patients while ensuring patient safety. It also has a positive impact on patients' BCVA, visual quality, and prognosis, with promising clinical application potential.

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Disclosure of conflict of interest

None.

Address correspondence to: Yuqiang Liu, Department of Ophthalmology, Zhengdaguangming Eye Group, Weifang Eye Hospital, No. 139 Happiness Street, Weifang 261000, Shandong, People's Republic of China. Tel: +86-0536-2113699; E-mail: 18742979@qq.com

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