

Postoperative curative effect and safety analysis of combined femtosecond laser and phacoemulsification for cataract patients.

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Abstract

Objective: The objective of this study is to explore the influence of combined femtosecond laser and phacoemulsification on postoperative curative effect and safety on cataract patients.

Method: One hundred forty-five cataract patients (148 eyes) needing operation were selected and grouped by difference in operation method: control group, 72 patients (74 eyes) were treated with traditional phacoemulsification; observation group, 73 patients (74 eyes) were treated with femtosecond laser assisted by phacoemulsification. Through detailed ophthalmic examinations of all patients, intra-operative Cumulative Dissipated Energy (CDE) value, pre-operative corneal endothelial cell counting and LogMAR vision examination, as well as intra-operative CDE value and pre-operative corneal endothelial cell counting were used to evaluate safety of combined femtosecond laser and phacoemulsification in treating cataract. Vision difference was used to evaluate the influence of operative treatment on visual functions.

Results: The mean CDE value of grade II nucleus in the observation group was 6.41 ± 3.12 , and the mean CDE value of grade III nucleus was 17.48 ± 4.72 , which had significant differences from those of the control group ($P < 0.001$). In the observation group, accumulative energy release of grade II nucleus reduced by 28.43% and that of grade III nucleus reduced by 22.61%. Corneal endothelial cell counts of patients in the control group 3 months after the operation were within $2,091.3 \pm 492.81$ (ea/mm²), which were significantly lower than those ($2,317.8 \pm 512.77$ (ea/mm²)) of the observation group ($P < 0.05$). In the aspect of operation effect, vision examination results at different time points before and after the operation did not have statistical significance ($P > 0.05$), and combined femtosecond laser and phacoemulsification had the same curative effect on the restoration of visual functions of senile cataract as traditional phacoemulsification did.

Conclusion: When curative effects were consistent, combined femtosecond laser and phacoemulsification could reduce intra-operative accumulative energy release, avoid intra-operative additional damage of corneal endothelial cells, and significantly improve safety in comparison with traditional phacoemulsification technique.

Keywords: Femtosecond laser, Phacoemulsification, Cataract, Curative effect, Safety.

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Introduction

Cataract, a kind of progressive eye lens opacity caused by eye aging or injury, affects vision at an early stage. Phacoemulsification is a standard operation method of cataract, but it has cracking and leakage phenomena of inner opening [1,2]. Moreover, excessive use of intra-operative ultrasonic energy and release of ineffective ultrasonic energy will still damage corneal tissues and affect postoperative effect. Femtosecond laser, a technical means by which humans can obtain the shortest pulse under lab conditions so far, automates three critical manual steps in traditional phacoemulsification-incision cutting, capsulorhexis, and nucleus fragmentation, which has significantly improved postoperative visual effect

[3,4]. However, domestically imported femtosecond laser equipment and common clinically set parameters refer to foreign mature research; hence, safety and effectiveness of application of this technology to domestic cataract patients still need clinical investigation.

Data and Method

General data

One hundred and forty-five cataract patients (148 eyes) accepting operative treatment in the Ophthalmology Department in our hospital in January to December 2016 were selected. Inclusion and exclusion were conducted according to

operation method and intra-operative incision size. Moreover, these patients were grouped by difference in operation method: control group, 72 patients (74 eyes) were treated with traditional phacoemulsification (keratome was used to make primary incision of cornea, diameters of both outer opening and inner opening were 2.2 mm); observation group, 73 patients (74 eyes) were treated with combined femtosecond laser and phacoemulsification (femtosecond laser made primary operative incision, diameter of outer opening was 2.2 mm and diameter of inner opening was 2.4 mm).

Exclusion standard are as follows: corneal endothelial cell count was lower than 2,000/mm²; patients with corneal lesion and subluxation of crystalline lens or whose pupils could not be expanded to 6 mm; patients in the progressive stage of glaucoma; patients with serious cornea aging and optic atrophy; patients with operative history and medical history of eye ground. Differences between the two groups in general situation, state of illness, medical history, and cornea were not of statistical significance ($P > 0.05$) with comparability.

Operation method

All operations were completed by one proficient surgeon and the operation process was smooth without any complication. LenSx femtosecond laser system and INFINITI ultrasonic emulsification meter from US Alcon Corporation were used; energy, negative pressure, and flow parameters were set before the operation.

On one hand, the observation group had the following conditions: The patients underwent femtosecond laser assisted by phacoemulsification, and all patients accepted eye dropping with antibiotic 1 day before the operation. Sufficient mydriasis with compound tropicamide was conducted four times an hour before the operation and surface anesthesia of eyes was implemented with 0.4% Benoxil. Disinfection and draping were then conducted. Eyelids were opened with eye speculum and a 2.2 mm transparent-corneal-limbus incision above the temple or nose and a 1 mm side incision were made. Viscoelastic substance was injected into the anterior chamber to conduct continuous circular capsulorhexis, conventional phacoemulsification, and extraction of lens nucleus. Viscoelastic substance was injected into capsular bag then crystal was implanted. After which, viscoelastic substances in anterior chamber and in the rear of the crystal were removed. Tobradex was given to the patient four times per day, after 1-2 weeks. Levofloxacin and prednisolone acetate were used three times per day and decreased to once per day progressively week by week; this lasted 3-4 weeks.

On the other hand, the control group had the following conditions: The patients underwent traditional phacoemulsification and preoperative operations of all patients were the same as the control group. After surface anesthesia with 0.4% Benoxil, eyelids were opened with eye speculum and negative-pressure interface was used to attract and fix eyeballs. Conjunctiva was cut open along the upper corneal limbus for about 6 mm and peeled off backwards so as to

expose sclera for sufficient hemostasis. From the lace, 2 mm from the rear of the corneosclera, the sclera lamellar parallel with the ground edge was cut open; the depth was about 1/2 of full sclera thickness and the length depended on the size of crystalline lens to be implanted. Undermining dissection was made from the incision toward the direction of the corneal limbus to enter transparent cornea for 1 mm and form a sclera tunnel. A 3.2 mm stab knife was stabbed into the anterior chamber to form a valve-shaped internal opening with self-closing function. The outer opening of the sclera could also be made into a straight line so as to form reverse eyebrow shape; continuous circular capsulorhexis was made until anterior capsule with diameter at 6 mm was torn open. Under subvalvular water injection, the anterior capsule and subcapsular cortex were separated by virtue of pulsed impact of water. The inner incision was expanded to 3.2 mm, and the emulsification head was put into the incision so as to extract the nucleus. The postoperative drug used was the same as that of the observation group.

Evaluation indexes

Through detailed ophthalmic examinations of all patients, intra-operative Cumulative Dissipated Energy (CDE) value, pre-operative corneal endothelial cell counting, LogMAR vision examination, as well as intra-operative CDE value and pre-operative corneal endothelial cell counting were used to evaluate the safety of combined femtosecond laser and phacoemulsification in treating cataract. Vision difference was used to evaluate the influence of operative treatment on visual functions. Topcon SP-2000P corneal endothelial cell counting instrument was used to measure corneal endothelial cell density before and after the operation. LogMAR visual chart was used to measure distant vision of naked eyes from 5 m distance and do optimal correction of distant vision rightly before and after the operation as well as 1 week, 1 month, and 3 months after the operation.

Statistical method

SPSS16.0 software was used to analyse relevant data. Measured data were expressed by "mean value \pm standard deviation" ($\bar{x} \pm s$), and enumeration data were expressed by percentages. Inter-group comparison used χ^2 test; $P < 0.05$ meant that the difference had statistical significance.

Results

Comparison of intra-operative measured CDE values of patients

The mean CDE value of grade II nucleus in the observation group was 6.41 ± 3.12 and that of grade II nucleus was 17.48 ± 4.72 . In the control group, the two values were 8.54 ± 5.21 and 22.61 ± 4.97 , respectively, and significant differences existed ($P < 0.001$). For reduction of accumulative energy release in the observation group, accumulative energy release of grade II

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nucleus reduced by 28.43% and that of grade III nucleus reduced by 22.61%. Details are seen in Table 1.

Table 1. Intra-operative measured CDE values of patients.

Group	Number of cases	Intra-operative CDE value		CDE reduction rate	
		Grade II nucleus	Grade III nucleus	Grade III nucleus	Grade III nucleus
Control group	72 cases (74 eyes)	8.54 ± 5.21	22.61 ± 4.97	-	-
Observation group	73 cases (74 eyes)	6.41 ± 3.121	17.48 ± 4.722	28.43%	22.61%

Note: ¹In comparison with the control group, P<0.001; ²In comparison with the control group, P<0.05.

Comparison of corneal endothelial cell count

Difference between the two groups in corneal endothelial cell count did not have statistical significance (P>0.05). The same test was conducted 3 months after the operation. Corneal endothelial cell counts of both groups significantly decreased in comparison with those before the treatment (P<0.001). These were within 2,091.3 ± 492.81 (ea/mm²) in patients in the control group, which was significantly lower than those (317.8 ± 512.77 (ea/mm²)) in the observation group (P<0.05). Details are seen in Table 2.

Table 2. Corneal endothelial cell counting results of patients before and after the operation (ea/mm²).

Group	Number of cases	Corneal Endothelial Cell Count (ea/mm ²)	
		Before operation	the 3 months after the operation
Control group	72 cases (74 eyes)	2,512.3 ± 472.63	2,091.3 ± 492.811

Table 3. LogMAR vision examination results of patients in the two groups before the operation and 1 day, 1 week, 1 month, and 3 months after the operation.

Group	Before operation	the 1 d after the operation	1 week after the operation	the 1 month after the operation	the 3 months after the operation
Control group	0.86 ± 0.29	0.20 ± 0.231	0.12 ± 0.52	0.06 ± 0.07	0.05 ± 0.07
Observation group	0.88 ± 0.41	0.19 ± 0.191	0.11 ± 0.17	0.06 ± 0.05	0.05 ± 0.05

Note: ¹In comparison with the result before the treatment, P<0.001.

Discussion

Cataract, a kind of progressive eye lens opacity caused by eye aging or injury, has the main clinical manifestations of progressive visual deterioration and it affects vision in the very early stage [5]. With accelerated living tempo and aggravated aging phenomenon, onset age, morbidity, and overall cardinal number of cataract have rapidly risen. Phacoemulsification, a standard operation method of cataract, treats cloudy crystalline lens [6]. However, it is very difficult for manually made corneal incision to guarantee size consistency and centering of capsulorhexis; in addition, there are cracking and leakage phenomena of inner opening, which results in non-ideal

Observation group	73 cases (74 eyes)	2,509.6 ± 417.28	2,317.8 ± 512.7712
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Note: ¹In comparison with the count before the operation, P<0.001; ²In comparison with the control group, P<0.05.

Vision distribution before and after the operation

LogMAR vision examination results of patients in the two groups had no statistical difference; the vision 1 day after the operation significantly reduced in comparison with that before the operation (P<0.001), but examination results of patients in the two groups did not have any difference (P>0.05). Vision examination of patients was conducted separately at different time points of 1 week, 1 month, and 3 months after the operation. All examination results presented descending trend without rebound and vision differences of patients in the two groups at different time points did not have statistical significance (P>0.05). Details are seen in Table 3.

occlusion. Moreover, excessive use of intra-operative ultrasonic energy and release of ineffective ultrasonic energy will still damage corneal tissues and affect postoperative effect [7]. With growth in the living standard, people are having higher and higher requirements for visual quality. Cataract patients have increasing requirements for post-operative visual quality, and they are not satisfied only by visible requirements as for the previous operations. Femtosecond laser, a technical means by which human can obtain the shortest pulse under lab conditions so far, automates three critical manual steps in traditional phacoemulsification-incision cutting, capsulorhexis, and nucleus fragmentation; no knife is needed for the incision, which reduces operative wounds [8,9]. More perfect visual

effect can be obtained after the operation with higher precision and strong penetrating power to make precise cutting of corneal tissues and crystalline lens become a reality. This research aims at evaluating safety of combined femtosecond laser and phacoemulsification and its influence of visual functions so as to provide reference for further clinical research [10].

Research results showed that in the aspect of operation effect, vision examination results at different time points before and after the operation did not have any statistical significance ($P > 0.05$), which indicated that combined femtosecond laser and phacoemulsification has the consistent curative effect on restoration of visual functions of senile cataract in comparison with traditional phacoemulsification; both had significant effect on restoring vision. In treatment safety evaluation, the mean CDE value of grade II nucleus in the observation group was 6.41 ± 3.12 , and the mean CDE value of grade III nucleus was 17.48 ± 4.72 , which had significant differences from those of the control group ($P < 0.001$). For reduction of accumulative energy release in the observation group, accumulative energy release of grade II nucleus reduced by 28.43% and that of grade III nucleus reduced by 22.61%. In terms of corneal endothelial cell count, cell counts of patients in the control group 3 months after the operation were within $2,091.3 \pm 492.81$ (ea/mm²), which were significantly lower than those ($2,317.8 \pm 512.77$ (ea/mm²)) of the observation group ($P < 0.05$). This showed that combined femtosecond laser and phacoemulsification could reduce intra-operative accumulative energy release, avoid intra-operative additional damage of corneal endothelial cells, and significantly improve safety in comparison with traditional phacoemulsification technique.

Conclusion

In conclusion, in comparison with traditional phacoemulsification in treating senile cataract, combined femtosecond laser and phacoemulsification can obtain the same effect in the aspect of restoring visual functions and can effectively avoid corneal injury caused by the operation; consequently, it is worthy of clinical popularization. Clinical research on femtosecond laser parameters was not conducted in this paper; thus, further research is still needed.

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