

Preliminary Clinical Investigation of Cataract Surgery With a Noncontact Femtosecond Laser System

A-Yong Yu, MD, PhD,* Li-Yang Ni, MD, Qin-Mei Wang, MD, Fang Huang, MD, Shuang-Qian Zhu, MD, Lin-Yan Zheng, MD, and Yan-Feng Su, MD

The Eye Hospital of Wenzhou Medical University, China, 270 Xueyuan West Road, Wenzhou 325000, Zhejiang, P.R. China

Background and Objective: Femtosecond laser-assisted cataract surgery (FLACS) is rapidly gaining popularity due to the improved consistency and predictability for capsulorhexis. This study aimed to investigate the preliminary clinical outcomes of FLACS with a noncontact femtosecond laser system.

Patients and Methods: This prospective study enrolled 25 eyes in the trial group underwent FLACS (LLS-fs 3D, LENSAR, USA), and 29 eyes in the control group underwent conventional cataract surgery (Stellaris, Bausch & Lomb, USA). The phacoemulsification time, energy, and complications during operation were recorded. Postoperative refraction at 1 day, 1 week, 1 and 3 months, the capsulorhexis size and corneal endothelial density at 1 and 3 months were also measured.

Results: Compared to the control group, reduction in phacoemulsification time was 51.5% ($P=0.02$), and in overall energy, 65.1% ($P=0.02$) in the trial group. In the trial group and the control group, total time of cataract procedure was 10.04 ± 1.37 minutes, 10.52 ± 1.92 minutes, respectively ($P=0.31$); the absolute difference between attempted and achieved capsulorhexis diameter at 1 month was $192.9 \pm 212.0 \mu\text{m}$, $626.9 \pm 656.6 \mu\text{m}$, respectively ($P=0.04$), and at 3 months, $256.6 \pm 181.9 \mu\text{m}$, $572.1 \pm 337.0 \mu\text{m}$, respectively ($P=0.03$); the absolute difference between attempted and achieved spherical equivalent at 3 months was 0.16 ± 0.16 D, 0.74 ± 0.65 D, respectively ($P < 0.01$); mean corneal endothelial cell loss at 1 month was 15.6% and 14.2%, respectively ($P=0.77$), and at 3 months, 2.9%, 4.2%, respectively ($P=0.50$).

Conclusions: With the noncontact femtosecond laser system, FLACS can significantly improve the accuracy and repeatability of capsulorhexis, reduce the phacoemulsification time and overall energy, and enhance the predictability and stability of postoperative refraction. *Lasers Surg. Med.* 47:698–703, 2015. © 2015 The Authors. *Lasers in Surgery and Medicine* Published by Wiley Periodicals, Inc.

Key words: cataract surgery; capsulorhexis; femtosecond laser; phacoemulsification

INTRODUCTION

Phacoemulsification is one of the main surgical procedures for cataract surgery owing to the advantages of small

incisions and rapid recovery. However, the surgical outcome of phacoemulsification can be negatively affected due to the potential issues of accuracy and repeatability for capsulorhexis [1], and the corneal endothelial cell damage by ultrasonic energy [2]. An eccentric or larger than intended capsulorhexis may cause tilt or axial shift of the intraocular lens (IOL) and impede achieving an accurate final postoperative refraction [3], and also increase the risks of posterior capsular opacification. To overcome those problems from the phacoemulsification, femtosecond laser-assisted cataract surgery (FLACS) had been used in the past few years and showed unique advantages [1,4,5].

However, previous studies focused primarily on the LenSx laser system (LenSx, ALCON, USA), the Catalys Precision laser system (Optimedica, AMO, USA), and the Victus laser system (Technolas, Bausch & Lomb, USA). These laser systems all employ optical coherence tomography (OCT) imaging technology, which will be limited and constrained by the depth of field within the anterior segment. The LENSAR laser system (LLS-fs 3D, LENSAR, USA) differs from the OCT technology in the other systems, that is, it uses 3-dimensional confocal structured illumination technology with a noncontact interface to image the intraocular structures from different positions. The technology is based on Scheimpflug imaging, which acquires anterior eye segment images with enhanced depth of field of ocular structures and superluminescent diode illumination,

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A.-Y. Yu had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis as well as the decision to submit for publication.

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*Correspondence to: A-Yong Yu, MD, PhD, 270 Xueyuan West Road, Wenzhou 325000, Zhejiang, P. R. China.

E-mail: yaybetter@hotmail.com

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and helps to generate an in-focus image from the anterior cornea to the posterior lens capsule. LENSAR system employs biometric data measured in the x-, y-, and z-axes, enabling to achieve unique lens tilt detection and compensation to correct for lens tilt from the optical axis. We are the first hospital to use LENSAR system for its FLACS in the mainland of China [6]. This study aimed to investigate the preliminary clinical outcomes of FLACS, and compared with conventional cataract surgery.

PATIENTS AND METHODS

Patients

This prospective, single-center, comparative study recruited consecutive cataract cases from October to November 2013 at the Eye Hospital of Wenzhou Medical University, China. A comprehensive eye examination was performed on each patient. Inclusion criteria for the patients were: (i) Normal and transparent cornea; (ii) Pupillary diameter of at least 6 mm under dilation; (iii) Preoperative best corrected visual acuity worse than LogMAR 0.3; (iv) No local or systematic contraindications for cataract surgery. The surgical option of FLACS (trial group) or traditional phacoemulsification (control group) was randomly assigned after each patient was fully informed about the details and possible risks inherent to this study. The research followed the tenets of the Declaration of Helsinki, and was approved by the institutional review board (IRB) at the Eye Hospital of Wenzhou Medical University. Informed consent was obtained from all subjects after explanation of the nature and possible consequences of the study.

Surgical Technique

All surgeries were performed by the same surgeon (A-Y Y). Main steps below:

Conventional phacoemulsification for the control group: after pupillary dilation with compound tropicamide eye drops (Zhuobian, Sinqi Pharmaceutical, China) and instillation of topical anesthetics, a 2.75 mm clear corneal incision was created at temporal side, then the ophthalmic viscoelastic device (Iviz, Bausch & Lomb Freda, China) was injected into anterior chamber. Following side port, continuous curvilinear capsulorhexis (diameter: 0.25 mm smaller than the optical zone of implanted intraocular lens) was performed with capsulorhexis forceps. Following hydrodissection, phacoemulsification of the nucleus, aspiration of the residual cortex and capsular polishing were performed using a phacoemulsification machine (Stellaris, Bausch & Lomb Co. Ltd., USA) with setting of continuous ultrasonic energy 30% and vacuum 400 mmHg. After intraocular lens implantation into the capsular bag, the viscoelastic material was removed. The incision was closed by hydration without sutures.

FLACS for the trial group: after pupillary dilation and topical anesthesia, FLACS was performed using the LENSAR femtosecond laser platform. A suction ring of patient interface was placed on the eye and a low level suction pressure (up to 18 mmHg) was applied to stabilize the eye. The interface then filled with balanced saline

solution, used the joystick to move the laser's docking arm toward the patient interface until the 3D-CSI camera to focus directly above corneal apex, then locked the patient interface, activated automatic scanning and 3-dimension image reconstruction, selected automatic pupil center and lens tilt compensation, confirmed laser parameters, fired laser to perform capsulotomy (diameter: 0.25 mm smaller than the optical zone of implanted intraocular lens), divided the nucleus into 6 pieces. The laser wavelength was $1,030 \pm 2$ nm with a pulse repetition frequency of 80 ± 0.5 kHz. The laser parameters used for capsulotomy and lens fragmentation were different. For capsulotomy, the line spacing was set at 18 μ m and shot spacing at 5 μ m, with laser energy set at 8 μ J; whereas, for lens fragmentation, the shot spacing was set at a range of 6 μ m to 100 μ m, and Z-line spacing at a range of 20 μ m to 100 μ m, with laser energy set at 10 μ J. The patients were transferred to another operation room for phacoemulsification after the completion of laser procedure. The phacoemulsification procedure for the trial group was almost the same as that for the control group, except for the capsulotomy and pre-fragmentation of lens by femtosecond laser.

Measurements

The average phacoemulsification time (APT), effective phacoemulsification time (EPT, equaling to average ultrasonic energy multiplied by APT), total time of cataract procedure from the opening to closing of corneal incision, and complications during operation were recorded. Post-operative refraction at 1 day, 1 week, 1 and 3 months, the capsulorhexis size and corneal endothelial density at 1 and 3 months were also measured.

The capsulorhexis size was measured by a masked examiner using a digital slit lamp image analysis system (SLM-7E, Chongqing Kanghuaruiming, China) after pupillary dilation. The horizontal and vertical diameters of the optical body of IOLs and of the capsulorhexis were measured in μ m directly on the same monitor screen by the internal image analysis software (Eyestudio, Chongqing Kanghuaruiming, China). Since the actual diameter of the optical body of IOLs was provided by the manufactures, and the capsulorhexis and IOLs were almost at the same plane, the magnification was calculated as follows: measured horizontal or vertical diameter of the optical body of IOLs/the actual diameter of the optical body of IOLs. To compensate for the change in individual corneal magnification, the actual horizontal and vertical diameter of capsulorhexis were calculated as follows: measured horizontal or vertical diameter of capsulorhexis/horizontal or vertical magnification.

Corneal endothelial density was measured from a central cluster of 50 cells from central corneal endothelial photographs with a specular microscope (SP-3000P, Topcon, Japan) by a masked examiner.

Statistical Analysis

All statistical analysis were performed using a commercial software (SPSS 18.0, Chicago, IL). Independent *T* test

and one-way ANOVA were used when compared the mean of each parameter. Chi-square test was used to analyze the difference in nucleus hardness of cataract between the two groups. The level of significance was $P < 0.05$.

RESULTS

There were 25 eyes of 17 patients in the trial group, and 29 eyes of 19 patients in the control group. The demographics of the patients before surgery were described as the Table 1, and there was no significant difference in the age, best corrected visual acuity, corneal endothelium density, nucleus hardness, or axial length between the two groups.

In the trial group, the mean laser energy required for capsulotomy was $8 \mu\text{J}$, and for lens fragmentation was $10 \mu\text{J}$. The mean duration for femtosecond laser operation was 95.43 ± 12.37 seconds, and no corneal edema, incomplete or breakage of capsulorhexis, or posterior capsule rupture occurred. Complications included pupil miosis occurred after femtosecond laser operation in 1 eye, which did not affect the phacoemulsification, and mild subconjunctival hemorrhage in 5 eyes, which disappeared within 1 week. Elevated intraocular pressure due to high sensitivity to glucocorticoid steroid in 1 eye, and returned back to normal after stop using of the glucocorticoid. There were no severe complications in the control group, except two patients with posterior capsular opacification occurred 1- and 3-month after surgery, respectively, and treated with YAG laser capsulotomy.

For nucleus hardness III and IV, the APT and EPT in the trial group were 51.5% and 65.1%, respectively, less than that in the control group (Table 2).

Mean corneal endothelium loss in the trial and control group 1 month after surgery was 15.6% and 14.2%

($P = 0.77$) respectively, and 3 months, 2.9% and 4.2% ($P = 0.50$), respectively. The capsulorhexis circles in the trial group were more circular and accurate compared with the control group (Table 2, Figs. 1 and 2).

Table 3 shows refractive outcomes in the two groups. The absolute deviation between the attempted and achieved spherical equivalent in the trial group was significantly less than that in the control group 3 months after surgery. There was no significant difference in the best corrected visual acuity between the two groups after surgery.

DISCUSSION

Cataract surgery has developed to the stage of refractive surgery with high demands in safety and visual quality, inspiring ever evolving philosophy and technology. In 2009, Nagy and co-authors [4] first introduced the application of using FLACS clinically, indicating such technology has successfully entered clinical stage, and become one of the hot topics for cataract surgery. In this study, FLACS saved the phacoemulsification energy up to 65.1% compared with the control group. This is consistent with other published results [4,5,7]. In the trial group, the nucleus was cut into 6 pieces using the femtosecond laser, enabling subsequently less phacoemulsification energy and time to be employed, thus reducing total energy of ultrasound during phacoemulsification. For those soft nucleus (lower than grade III), the nucleus can even be aspirated directly without applying any phacoemulsification energy. Different femtosecond laser systems had different reduction effects on the energy usage during phacoemulsification, according to current reports [5], at least 33% energy reduction can be achieved with the LenSx system. Nagy and co-authors [4] found that the ultrasonic energy used during phacoemulsification can be reduced by 43% after the use of the LenSx system. Robin and co-authors [7] reported that the mean EPT was reduced by 83.6% after using the LenSx system.

The greater the ultrasonic energy during phacoemulsification, the greater the damage will be for the surrounding ocular tissues. The reduction of ultrasonic energy used during phacoemulsification can reduce the damage on the surrounding tissues, including the damage of corneal endothelial cells and the probability of macular edema [2,8,9]. Takács and co-authors [10] compared FLACS with the LenSx system to conventional cataract surgery for 38 eyes in each group, and found corneal endothelial cell counts were slightly lower in the conventional group at all postoperative visits but differences were not statistically significant. In this study, there was no significant difference in the reduction of corneal endothelium loss between the two groups (15.6% and 14.2%, respectively), possibly due to the variable standard deviation of examining method of corneal endothelial cells, as well as the small sample size, which means the need of increased sample size for future studies. The calculated sample sizes is at least 275 eyes in each group to offer 90% statistical power at the 5% level to detect a 100 cells/mm^2 difference in corneal endothelial density between the two groups, when the standard deviation of the mean difference is 400 cells/mm^2 .

TABLE 1. The Demographics of the Patients Before Surgery ($\bar{x} \pm s$)

	Trial group	Control group	P-value
Age (years)	62.3 ± 11.6 (43–80)	56.5 ± 16.6 (38–86)	0.14
Best corrected visual acuity (LogMAR)	0.94 ± 0.85	0.88 ± 0.83	0.82
Corneal endothelium density (cell/ mm^2)	2588.0 ± 345.0	2741.1 ± 285.4	0.15
Nucleus hardness			0.15*
I	1	4	
II	5	8	
III	9	11	
IV	8	6	
V	2	0	
Axial length (mm)	25.09 ± 2.85 (22.59–32.79)	26.94 ± 4.46 (20.69–36.59)	0.08

*Chi-square test.

TABLE 2. Comparison on Surgical Performance Between Two Groups ($\bar{x} \pm s$)

	Trial group	Control group	<i>P</i> -value
Average phacoemulsification time (second)*	8.41 ± 5.43	17.35 ± 14.11	0.02
Effective phacoemulsification time (second)*	85.04 ± 80.11	243.43 ± 244.05	0.02
Total time of cataract procedure (minute)	10.04 ± 1.37	10.52 ± 1.92	0.31
1 month postoperative CCD (cell/mm ²)	2120.0 ± 430.4	2192.1 ± 382.3	0.62
3 months postoperative CCD (cell/mm ²)	2044.1 ± 485.5	2166.6 ± 426.0	0.64
1 month postoperative ADCD (μm)	192.9 ± 212.0	626.9 ± 656.6	0.04
3 months postoperative ADCD (μm)	256.6 ± 181.9	572.1 ± 337.0	0.03

CCD, corneal endothelium density; ADCD, absolute deviation between the attempted and achieved capsulorhexis diameter.
 *For nucleus hardness III and IV.

All subjects in the trial group had a successful continuous curvilinear capsulorhexis, and there were no incomplete capsulorhexis or anterior capsule breakages. Compared with the control group, capsulorhexis by the femtosecond laser had better accuracy and repeatability. Friedman and co-authors [11] reported that the deviation between the attempted and achieved capsulorhexis diameter was $29 \pm 26 \mu\text{m}$ by the femtosecond laser, and $337 \pm 258 \mu\text{m}$ by conventional manual capsulorhexis. Continuous curvilinear capsulorhexis is one of the most important steps of cataract surgery with strong influence on the safety and accuracy of subsequent steps of surgery. A good capsulorhexis not only increases the safety of the

subsequent operation, but also helps in stabilizing the intraocular lens in the capsule bag, reducing its off-centering and tilting, lessening the capsule shrinkage, and improving the predictability of effective lens position, thus improved the predictability of postoperative refractive outcomes [5]. It was reported that the deviation between the attempted and achieved intraocular lens position was only a mere $77 \pm 47 \mu\text{m}$ after capsulorhexis by femtosecond laser [11]. In this study, after compensation for the change in individual magnification of cornea and anterior chamber depth, the mean absolute deviation between the attempted and achieved capsulorhexis diameter in the trial group was 1/3 of that in the control group 1 month after surgery, and

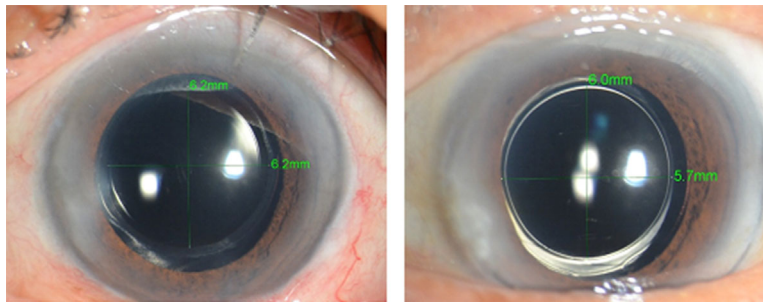


Fig. 1. Capsulorhexis shape under dilation 1 month after surgery. Left image is the trial group, right image is the control group. Numbers in the images are the original raw data, and the horizontal/vertical diameter after calibration is 5.5/5.5 mm, 5.5/5.8 mm, respectively.

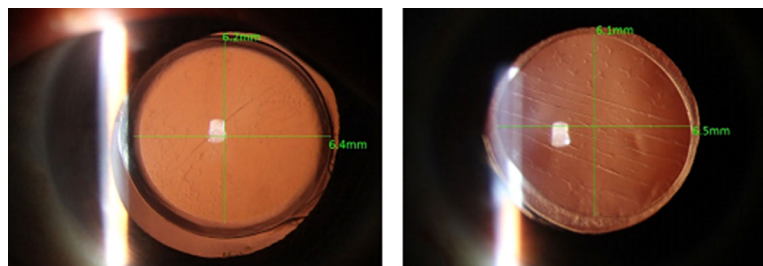


Fig. 2. Capsulorhexis shape under dilation 3 months after surgery. Left image is the trial group, right image is the control group. Numbers in the images are the original raw data, and the horizontal/vertical diameter after calibration is 5.6/5.4 mm, 5.7/5.3 mm, respectively.

TABLE 3. Comparison on Refractive Outcomes Between Two Groups ($\bar{x} \pm s$)

Post-op	ADSE			BCVA		
	Trial group	Control group	<i>P</i> -value	Trial group	Control group	<i>P</i> -value
1 day	0.54 ± 0.54	0.57 ± 0.57	0.87	0.16 ± 0.20	0.35 ± 0.45	0.07
1 week	0.41 ± 0.34	0.42 ± 0.41	0.95	0.06 ± 0.15	0.18 ± 0.21	0.10
1 month	0.48 ± 0.42	0.51 ± 0.47	0.82	0.09 ± 0.10	0.19 ± 0.44	0.37
3 months	0.16 ± 0.16	0.74 ± 0.65	0.00	0.12 ± 0.09	0.33 ± 0.56	0.18

ADSE, absolute deviation between the attempted and achieved spherical equivalent (D); BCVA, best corrected visual acuity (LogMAR).

the trial group still present higher accuracy and stability of capsulorhexis 3 months after surgery compared with the control group regardless the possible fibrosis of capsule. The achieved refraction in the trial group was more stable and much closer to the attempted compared with the control group. These indicated FLACS not only improved the predictability, accuracy, repeatability, and stability of capsulorhexis, but also improved the predictability and stability of postoperative refraction [12,13]. This is especially important on the visual quality for patients implanted with an aspheric IOL or a multifocal IOL.

The total time of cataract procedure was slightly shorter in the trial group, but the difference was not statistically significant. However, FLACS had short phacoemulsification time, providing improvements in safety, accuracy, and repeatability of surgery. Compared with the control group, phacoemulsification time was shortened by 51.5% in the trial group. Nagy and co-authors [4] reported phacoemulsification time was shortened by 51% after using femtosecond laser system. In this study, the femtosecond laser operation system had high automation and safety due to its features of noncontact to cornea, 3-dimension image reconstruction, automatic pupil center location and lens position tilting compensation. The pupil constriction (1 eye) and short-term mild subconjunctival hemorrhage (5 eyes) in the trial group were all from 10 earliest cases, and related to prolonged operational time. These complications did not occur latter when operation time was shortened. In the literature [14], the mean time for femtosecond laser operation was 3–5 minutes. But in this study, average femtosecond laser operation time was within 95 seconds. As the instrument improves, femtosecond laser operation time can be shortened even more, thus further reduces the possibility of complications, and improves the surgical performance.

FLACS also has great implication for the trainees of phacoemulsification. Capsulorhexis and fragment of nucleus are the two difficult techniques to grasp on phacoemulsification for beginners [15–18] Dooley and co-authors [14] reported for beginners the mean difficulty index for capsulorhexis was 3.30, ranked only second to fragment of nucleus. Other studies showed a high rate of posterior capsule rupture of 5.8–15% for beginners [19–21]. Beginners may have difficulties controlling the opening shape of capsule during continuous curvilinear capsulorhexis, sometimes even tear to the area of zonule or posterior capsule. They also have difficulties chopping

nuclear during management on nucleus, sometimes even cause posterior capsule rupture, resulting to vitreous loss. These may affects intraocular lens position and postoperative refraction, and increase the risk of complications of retina. The improvements in capsulorhexis and fragmentation of nucleus by FLACS facilitate learning and promotion of standardized phacoemulsification.

In conclusion, FLACS with the noncontact system can significantly improve the accuracy and repeatability of capsulorhexis, reduce the phacoemulsification time and overall energy, and enhance the predictability and stability of postoperative refraction.

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