

Safety and surgical outcomes of femtosecond laser-assisted cataract surgery

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Received: July 2019

Revised: July 2019

Accepted: August 2019

The Egyptian Journal of Cataract and Refractive Surgery 2019

Purpose

The aim of this study is to study the safety and surgical outcomes of femtosecond laser assisted cataract surgery FLACS according to our early experience with the procedure.

Patients and methods

This is a prospective study that included 50 consecutive FLACS cases of 40 patients. Cases have been performed by the same surgeon (A. E. Shama) between October 2015 and May 2016.

Results

In this study, we have reported no cases of programming errors, and only one (2%) eye had incomplete capsulotomy that necessitated completion using capsulorhexis forceps. Seven (14%) eyes had incomplete corneal incisions that were completed using a sharp keratome, and lens fragmentation was complete in all cases except only one (2%) case. Thirty four (68%) eyes showed postdocking conjunctival echymosis (Fig. 3), which is considered as a minor complication that necessitates only good counseling of the patients. Although miosis (pupil constriction ≥ 2 mm) was common in this study (70%), it did not create any intraoperative problems to the surgeon.

Conclusion

FLACS has a lower complication rate compared with standard phacoemulsification

Keywords:

FLACS, cataract, femtosecond laser

Introduction

Cataract surgery is the highest performed surgical procedure in the world [1]. The WHO estimates the number of cataract surgeries to be 32 million by the year 2020 [2].

Femtosecond laser was introduced to the ophthalmic practice initially as a tool to create flaps in laser in-situ keratomileusis, and then it was used in cataract surgery [3]. The femtosecond laser is commercially available to perform key steps in cataract surgery: capsulotomy, lens fragmentation, and wound construction as well as arcuate corneal incisions for astigmatic correction.

Although phacoemulsification is the most widely used procedure for cataract surgery, it still has some complications and concerns in challenging cases, for example, hard nuclei and weak zonules, which gave a potential advantage to the newer technology, femtosecond laser-assisted cataract surgery (FLACS), as it decreases the need to high ultrasonic power, thus decreasing the risk of endothelial cell damage and decreases intraoperative manual manipulation [4].

Despite the clear benefits of FLACS, it is still not widespread yet because of the high cost of adoption of this technology. When the surgeons are professional and confident about their outcomes of the conventional phacoemulsification, it is hard to ask them to try a new technology with its own drawbacks [5,6].

However, introduction of a new procedure to the clinical practice is associated with a learning curve. In this paper, we report the safety and surgical

outcomes of FLACS according to our early experience with the procedure.

Patients and methods

This is a prospective study that included 50 consecutive FLACS cases of 40 patients. Cases were performed at iCare Center, Alexandria, Egypt. All cases have been performed by the same surgeon (A. E. Shama) between October 2015 and May 2016.

The study conformed to the tenets of the Declaration of Helsinki. Ethical approval was obtained from Minia University Human Research Ethics Committee for the Evaluation of the Safety and Success of the LenSx laser system (Alcon Inc., Fort Worth, Texas, USA).

Eligible participants were examined before surgery to establish a baseline for their ocular condition. All cases had grade III nuclear cataract with otherwise normal ocular examination. Exclusion criteria included glaucoma, pseudoexfoliation, small pupils, corneal opacity, retinal pathology, narrow interpalpebral fissures, and uncooperative or overly anxious patients.

Follow-up visits were at 1 day, 1 week, 1 month, 6 months, and 12 months. Standard refractive and visual outcomes such as uncorrected and corrected distance visual acuity (UCDVA and BCDVA), slit-lamp

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examination results, and intraocular pressure were collected in all follow-up visits.

Statistical analysis was carried out using SPSS for windows Version 19 (IBM/SPSS Inc., Chicago, Illinois, USA).

Procedure

A written consent was taken from all patients who underwent a detailed preoperative clinical assessment that included slit-lamp biomicroscopy, tonometry, measurement of UCDVA and BCDVA, and manifest refraction. Investigations included measurement of axial length and biometry (IOL Master Carl Zeiss Meditech Inc., Dublin, California, USA), pachymetry and corneal topography (Allegro Oculyzer; Wavelight Fort Worth, Texas, USA), and specular microscopy (Tomey, Nagoya, Japan).

Routine preoperative papillary dilation using 1% tropicamide and 10% phenylephrine followed by topical anesthesia using benoxinate hydrochloride 0.4% for all patients.

The LenSx system was programmed to perform capsulotomy, lens fragmentation pattern (Fig. 1), and primary and secondary incisions. Arcuate keratotomy was performed in selected cases of astigmatism (0.75–1.50 D). This is followed by docking the patient’s eye using a sterile disposable patient interface (Fig. 2), which is composed of a suction ring, an applanation lens, and tubing system. The process is monitored using video microscope, and when the cornea is properly applanated, the surgeon applies suction.

The system screen displays both live microscopic and optical coherence topography images of the anterior segment of the eye.

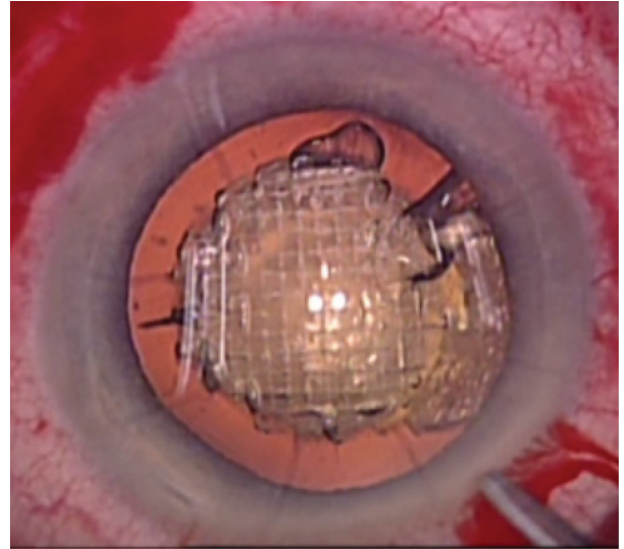
The patient is then moved to the operating room to complete the surgery under complete sterile conditions as a standard phacoemulsification using Infiniti unit (Alcon Inc.).

Postoperative regimen included 0.5% moxifloxacin (Vigamox; Alcon Inc.) four times a day for 2 weeks, 0.1% dexamethasone, and 0.3% tobramycin combination (Tobradex; Alcon Inc.) four times a day for 2 weeks then tapered to twice a day for another 2 weeks.

Results

A total of 50 eyes of 40 patients were included in the study. The mean age of the patients was 63.06±7.75

Figure 1



Nucleus cubes pattern.

Figure 2



LenSx SoftFit contact lens (container), disposable suction cone and tube with microfilter.

years. Table 1 lists the preoperative data of patients included in the study.

Mean femtosecond laser energy used was 12.92±0.72 mj (range: 11.00–14.00 mj) whereas mean docking

time was 3.00±0.83 min (range: 1.00–5.00 min). We have also estimated the mean laser treatment time as 92.00±25.01 s (range: 100–140 s).

The following data were measured preoperatively and during the postoperative follow-up period over 12 months, as presented in Table 2. Endothelial mean cell density, UCDVA and BCDVA in decimal, and both manifest sphere equivalent refraction (SER) and corneal astigmatism in diopters.

Attempted refraction in this study was -0.09±0.52 and achieved 12-month postoperative manifest SE was -0.19±1.11, which shows a very highly significant strong correlation ($r=0.8$ and $P<0.001$).

Mean error is the difference between postoperative manifest spherical equivalent and predicted postoperative target refraction. Calculated mean error for this study was -0.2±1.11 (range: -2.5 to 1.5).

Mean absolute error is the average of the absolute values of the deviation from predicted postoperative refraction. Calculated mean absolute error for this study was 0.97±0.57 (range: 0–2.5).

In cases that had astigmatic keratotomy, we have noticed that although the mean laser treatment time

was longer among those patients with astigmatic keratotomy (89.47±13.43 s) compared with those without (87.7±18.97 s), the difference was nonsignificant ($P 0.73$). This may be explained by the limited number of cases and the relative wide SD compared with mean.

Predictability of the postoperative manifest SER on the first postoperative month was reasonable, as it showed that 80 and 92% of cases were within 1.0 and 1.5 D, respectively.

In this study, we have reported no cases of programming errors, and only one (2%) eye had incomplete capsulotomy that necessitated completion using capsulorhexis forceps. Seven (14%) eyes had incomplete corneal incisions that were completed using a sharp keratome, and lens fragmentation was complete in all cases except only one (2%) case.

Thirty four (68%) eyes showed postdocking conjunctival echymosis (Fig. 3), which is considered as a minor complication that necessitates only good counseling of the patients. Although miosis (pupil constriction ≥ 2 mm) was common in this study (70%), it did not create any intraoperative problems to the surgeon.

Table 1 Preoperative data of the patients included in the study

	Minimum	Maximum	Mean	SD
Axial length	19.33	32.76	23.4330	2.71572
AC depth	2.82	3.22	3.0414	0.10566
PC IOL power	3	29	19.22	5.933
UCVA	0.5	1.0	0.746	0.146
BCVA	0.1	1.0	0.808	0.164
Manifest SE	-6.50	4.50	-0.645	3.014
CCT	448	603	517.24	41.299
MCD	2003	2998	2558.82	344.953
Keratometric astigmatism	0.25	5.00	2.0150	1.03314

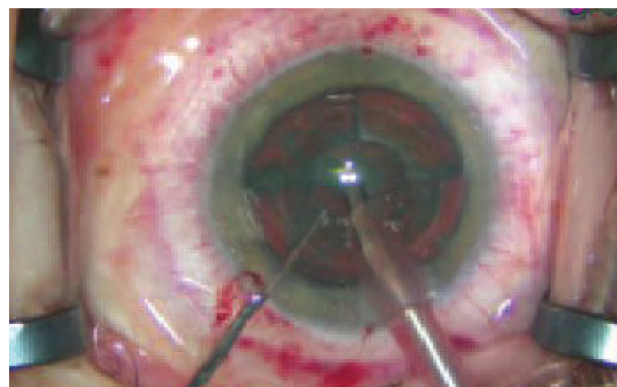
BCVA, best-corrected visual acuity; CCT, central corneal thickness; MCD, mean cell density; UCVA, uncorrected visual acuity.

Table 2 Patients' data preoperatively and over 12 month postoperative follow-up period

Parameters	Preoperative	1 m postoperative	6 m postoperative	12 m postoperative	P value (in the postoperative period)
MCD	2559	2456	2463	2461	0.001
UCDVA	0.81	0.15	0.17	0.14	0.02
BCDVA	0.75	0.08	0.11	0.07	0.03
SER	-0.65	-0.12	-0.17	-0.19	0.03
Corneal astigmatism	1.09	0.39	0.61	0.63	0.04

BCDVA, best corrected distance visual acuity; MCD, mean cell density; SER, sphere equivalent refraction; UCDVA, uncorrected distance visual acuity.

Figure 3



Postdocking conjunctival echymosis.

Other intraoperative and postoperative complications related to phacoemulsification were not reported in this study.

Discussion

Femtosecond lasers were initially developed for laser in-situ keratomileusis flap creation during corneal refractive surgery. Laser technology recently enabled surgeons to perform precise capsulotomy, lens fragmentation, and corneal incisions during cataract surgery [7].

The aim of this study was to evaluate the efficacy and safety of FLACS. Cases were performed by a single experienced surgeon, and this is important, as it eliminates the effect of learning curve as demonstrated in the literature [8].

Different studies tried to investigate the clinical outcomes of FLACS as in a study of Bissen-Miyajima *et al.* [9], which assessed the safety and efficacy of FLACS in 529 eyes of 312 patients who underwent FLACS from 2013 to 2016 in a retrospective case series.

Preoperative UCDVA and BCDVA were 0.81 ± 0.16 and 0.75 ± 0.17 , respectively, which improved up to 0.15 ± 0.12 and 0.08 ± 0.11 , respectively, starting from the first postoperative day, and this effect was quiet stable during the follow-up period of 12 months.

These refractive results were supported by many studies, which showed significant improvement in visual parameters after FLACS. In a study of Lundström *et al.* [10], which described a large cohort of cataract cases in 18 cataract surgery clinics in nine European countries and Australia, and they found that the visual outcomes of FLACS were favorable especially when compared with manual phacoemulsification.

In a study of Ranjini *et al.* [11], on 55 eyes of 55 patients who compared the outcomes of FLACS with standard 2.2 mm clear corneal phacoemulsification, they found that no significant difference was found between the groups for UCDVA at 4 weeks postoperatively, whereas the FLACS group had better BCDVA ($P=0.0294$).

Regarding the manifest SER, the preoperative manifest SER was -0.65 ± 0.31 , which improved at the first postoperative month up to -0.12 ± 0.11 and the effect of improvement was stable during the

follow-up period, with little fluctuations until reached -0.2 ± 0.11 at the end of follow-up period of 12 months.

There is a very highly significant strong correlation between attempted refraction and achieved postoperative manifest SER ($r=0.8$ and $P<0.001$).

A total of 10 patients with corneal astigmatism were underwent astigmatic keratotomy. Our results showed that the mean preoperative corneal astigmatism was 1.1 ± 0.23 D, which improved to 0.4 ± 0.11 D at the first postoperative month. Results showed mild regression with stable final result at the 12th month follow-up, with mean of 0.63 ± 0.11 D.

The previous results coincides with Day *et al.* [12], who described the effect of femtosecond laser intrastromal astigmatic keratotomy performed during cataract surgery in a prospective case series study including 133 patients, who showed that the mean astigmatism correction was 63%.

Chan *et al.* [13] investigated the stability of corneal astigmatism after combined FLACS and arcuate keratotomy in retrospective, interventional case series study. The mean preoperative corneal astigmatism was 1.35 ± 0.48 D, which reduced to 0.67 ± 0.54 D at 2 months and 0.74 ± 0.53 D at 2 years postoperatively ($P<0.001$).

Injury reduction of corneal endothelial cells contributes to shortening the recovery period and improves visual outcomes [14]. Based on the advantages of FLACS over phacoemulsification, some researchers have even predicted that the femtosecond laser will become the standard method of cataract extraction within ten years [15].

In our study, the mean preoperative mean cell density which was 2558.82 ± 335 decreased to 2455.78 ± 335 on month 1 postoperative follow-up by specular microscopy. Follow-up after 6 and 12 months showed no statistically significant change during the follow-up period. Many studies support our results [5], whereas in a study of Abell and colleagues, they found no difference in endothelial cell loss between the FLACS and standard cataract surgery three weeks postoperatively [16].

Conclusion

FLACS has a lower complication rate compared with standard phacoemulsification [17]. In this study, we

have also reported few technical and intraoperative complications, which were not serious or vision threatening. This study demonstrates that although femtosecond laser made the surgical steps of cataract surgery more predictable, it still has to be further studied in large multicenter studies to justify the benefits against the high cost of the technology, as particularly many recent studies concluded that there was no statistically significant difference between FLACS and standard phacoemulsification in terms of visual outcomes and complications [18,19].

Acknowledgements

The authors thank Professor Dr Ahmed E. Shama for performing surgery and allowing us to access the patient's data to have this study.

Financial support and sponsorship

Nil.

Conflicts of interest

None declared.

The authors have no financial interest in any of devices or techniques used

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