Learning curve of femtosecond laser-assisted cataract surgery: Experience of surgeons new to femtosecond laser platform

Josephine Susai Christy, Manas Nath, Fredrick Mouttapa¹, Rengaraj Venkatesh²

Purpose: The purpose of this study is to assess the learning curve in the initial 100 cases of cataract surgery performed using femtosecond laser-assisted cataract surgery (FLACS) by experienced cataract surgeons without prior experience in femtosecond laser platform. Methods: This study was conducted at tertiary care eye hospital, South India. This was a prospective interventional study. The first 100 consecutive eyes undergoing FLACS were studied to understand docking time, number of docking attempts, problems encountered during docking, and complications attributable to docking. Phacoemulsification performed after femtosecond laser was also studied for complications, need for additional instrumentation, and total time required for surgery. Comparison was also made between two operating surgeons. Results: Successful docking was recorded in 70% eyes at the first attempt. Mean time taken for successful docking was 9.3 ± 6.4 min (median = 6 min, interquartile range (IQR) = 5–10 min, range = 4-35 min). When surgeries were divided into quartiles, docking time reduced significantly from 16.2 ± 7.9 min in the first quartile to 6.2 ± 2.7 min in the fourth quartile (P < 0.001). Phacoemulsification postdocking required 12.9 ± 6.2 min (median = 10 min, IQR = 9-17.5 min). Six eyes showed anterior capsular tags, one had radial extension of capsulorhexis, and two eyes showed pupillary miosis after femtosecond laser application. At 6 weeks, 79% eyes attained uncorrected vision of 20/20, and all eyes had best-corrected vision of 20/20. Conclusion: Approximately 25-30 cases were required before obtaining reproducible results with FLACS, irrespective of cataract surgical experience, suggesting that training programs must offer a minimum 25 surgeries. Very few complications occurred during the learning curve, making it patient friendly.



Key words: Cataract surgery, femtosecond laser docking, learning curve

Cataract surgery has undergone paradigm shifts in the past decade and is considered more of a refractive surgery these days. As the refractive expectation from the patient grew manifold, the need for safety, accuracy, and predictability of cataract surgery grew as well. The latest development in cataract surgery is the application of the femtosecond laser to create tailor-made corneal incisions,^[1,2] fashion perfectly centered and calibrated capsulorhexis,[1,3-6] and assist with fragmenting the nucleus.^[1,7,8] Additional benefits include reduced ultrasound energy^[9,10] during emulsification with resultant endothelial protection and creation of customized arcuate incisions^[11-13] to neutralize any astigmatism that may compromise visual quality. Femtosecond laser-assisted cataract surgery (FLACS) is being adopted widely for the precision, it offers compared to conventional techniques, which are surgeon dependent.

As with the adoption of any new surgical technique, FLACS is also bound to have a learning curve before the best results can be delivered to patients. In addition to financial investments, surgeons wanting to adopt new technology always consider the learning curve of a new technique. The previous authors have published the surgical learning curve

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and intraoperative complications following FLACS. Bali et al.[14] describe a clear learning curve in the first 200 eyes using the LenSx platform in a group of seven surgeons, many of whom were experienced with femto LASIK. Similarly, Chang et al.^[15] have studied the learning curve on the LensAR platform in three experienced femto LASIK surgeons. Technical learning curve, which deals with the usage of the Laser machine successfully on the patient's eye, by a process called "docking," is very crucial to perfect laser delivery and the final outcome. Documentation of the learning curves of docking in cohesion with phacoemulsification afterward would help in framing a structured prelaser training program for novice surgeons, which can go a long way to smoothening the initial learning curve. This study primarily aims to study the learning curve of an experienced cataract surgeon who is a novice to the femtosecond laser platform. We also attempted to learn the difference in the learning curve of two surgeons with varying experience in phacoemulsification and to report the visual outcome of the first 100 patients done in a tertiary care eye hospital in South India.

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Department of Cataract, ¹Department of Pediatric Ophthalmology and Squint, ²Department of Glaucoma, Aravind Eye Hospital and Post Graduate Institute of Ophthalmology, Puducherry, India

Correspondence to: Dr. Manas Nath, Aravind Eye Hospital, Thavalakuppam, Puducherry - 605 007, India. E-mail: drmanasnath@gmail.com

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Methods

The study was approved by the Institutional Ethics Committee and performed as per the tenets of the Declaration of Helsinki. This was a prospective study of the first consecutive 100 FLACS surgeries performed at a tertiary eye care hospital in South India from October 2014 to April 2015.

Preoperative assessment

Patients with senile cataract, good pupillary dilatation (mydriasis >6 mm) and with no other ocular pathology were carefully selected and counseled on FLACS and its advantages over existing phacoemulsification procedures. The preoperative evaluation included slit-lamp biomicroscopy and grading of cataract according to lens opacity classification system, horizontal pupillary diameter measurement, fundus examination by 90 D lens, manifest refraction, and noncontact tonometry for measurement of IOP. Axial length and keratometry were done using intraocular lens (IOL) master 500 (Carl Zeiss Meditec, Germany). Preoperative VERION vision planner (Alcon) registration was done, and IOL master K readings fed into it for IOL power calculation. According to standard cataract surgery protocol, patients were instilled ketorolac tromethamine four times/day, and antibiotic eye drops six times/day in the operated eye from the previous day of surgery.

Femtosecond laser application (docking)

Three surgeons who did not have prior experience with the femtosecond platform were trained for the laser docking procedure. Training was given in 10 eyes of 10 patients, for 1 week after obtaining their explicit consent. A pretraining video orientation was given. A technical assistant was trained simultaneously in preparing the laser machine before the procedure and for its maintenance.

Pupillary dilation was achieved before surgery with 1% tropicamide and 10% phenylephrine. All docking procedures and surgeries were performed under topical anesthesia with 0.4% proparacaine. The LenSx Laser System (Alcon Inc., USA) was used to perform the femtosecond laser procedure. The initial steps of the procedure involved programming the laser system for primary incision, secondary incision, lens fragmentation, and capsulotomy patterns. After all, pattern selections and parameter choices were complete; a predock image was taken with a limbal ring in the display just outside the limbus.

The LenSx laser was applied as described by Bali et al.^[14] The system uses a sterile disposable patient interface [Fig. 1] composed of an applanation soft contact lens, suction ring, and tubing, which are mounted onto the distal end of the laser-focusing objective. The objective lens is spring loaded to control the applanation force exerted by the objective. The delivery system (gantry) is lowered until the patient interface makes contact with the eye. Sensors in the delivery system detect the objective's position and applanation force, which is indicated on the delivery system touch screen. The surgeon observed applanation of the cornea using the video microscope and then applied suction when the cornea was properly applanated until the force indicator on screen was in the yellow or green zone. Once the patient interface and docking registration were successful, the control point settings displayed on the monitor were checked for limbal centration,



Figure 1: Lensx patient interface

primary and secondary corneal incision boundaries, pupil centration of the capsulotomy ring, and adjustment of the arcuate incisions, if enabled. Then, the optical coherence tomography (OCT scan) was performed wherein wave pattern of capsulotomy, lens offsets, lens fragmentation zone, corneal thickness, and wound tunnel length were reconfirmed. The laser treatment was then started by pressing the foot switch, and progress was monitored on the video screen through real-time OCT images of the anterior segment. The program delivered laser energy in a sequence of anterior capsulotomy, lens fragmentation, and primary and secondary corneal incisions similar to settings and protocols described by Grewal *et al.*^[16] Arcuate corneal incisions, if used, followed the secondary corneal incisions.

A coordinator then filled in the docking experience record, including the success of registration, number of docking attempts, presence of Descemet's folds, subconjunctival hemorrhage, and time required for the docking procedure, measured as the interval between insertion of speculum to completion of laser delivery. The patient was shifted from the femto laser suite to the main operation room (OR) on a gurney with the lasered eye patched.

Cataract surgical procedure

Among the three surgeons, two of the senior surgeons, one with 15 years of experience in phaco (Senior Medical Officer-SMO) and the other with 6 years of experience (Junior Medical Officer-JMO) operated on the patients randomly. For effective use of time, and to decrease the OR time for FLACS, one surgeon did the docking procedure and another performed phacoemulsification inside the theater.

Under careful sterile surgical preparation, the horizontal pupillary diameter was measured with caliper. Sodium chondroitin sulfate-sodium hyaluronate was then injected into the anterior chamber through the side port. The laser-created corneal incisions were then dissected bluntly with a Slade spatula. Anterior capsulotomy flap was removed with Utrata forceps. The lens fragmentation was completed with a direct chop technique using the Centurion or Infiniti Vision System Unit (Alcon Laboratories). After the removal of the lens cortex, an IOL was implanted in the capsular bag. Wounds were hydrated, and intracameral moxifloxacin 0.1 ml was given at the end of surgery. The surgeon experience record, an extension of the docking record sheet, included difficulty with opening the corneal incision, use of keratome, presence of visible capsular tags and radial extensions of the capsulorhexis margin, and incomplete nuclear fragmentation. The duration of the phacoemulsification surgery was recorded from the time of incision opening to hydration of wounds. Finally, significant pupillary miosis was recorded if the pupillary diameter at the start of phacoemulsification was found to be <5 mm.

Postoperative regimen

The standard postoperative regimen included eye drops 0.3% ofloxacin qid for 2 weeks, ketorolac tromethamine qid for 2 weeks, and a combination of ofloxacin and prednisolone acetate eye drops eight times a day for 2 days. Steroid drops were tapered thereafter every week for 6 weeks. The patients were followed up with on day 1 and then 6 weeks after surgery.

Data such as preoperative visual acuity, grade of cataract, IOP, keratometry, axial length, and IOL power were retrieved from the patient case sheets. Docking and intraoperative surgeon experience details were taken from the data sheet attached to the patient case record. Postoperative details were recorded as per the Oxford Cataract Treatment and Evaluation Team protocol^[17] that is routinely used in our institution.

Statistical analysis

All continuous variables were presented as mean + standard deviation or median with interquartile range (IQR), and categorical variables were presented as percentages. To determine the learning curve, data from the 100 operated eyes were arranged in chronological order (1st to 100th case) and divided into quartiles (i.e., 4 equal parts) and deciles (i.e., 10 equal parts) for comparison. Comparison between continuous variables across quartiles as well as deciles was performed using the analysis of variance and the Kruskal-Wallis test for nonparametric variables. Comparisons between categorical variables across quartiles and deciles were performed using Chi-square or Fisher's exact test. Comparison of variables between the two surgeons was performed using the Student's t-test/Wilcoxon's rank sum test and Chi-squared test/Fisher's exact test for continuous and categorical variables, respectively.

All data were entered into Microsoft Excel and analyzed using STATA (I/c 12.0, Texas, USA). P < 0.05 was considered statistically significant.

Results

One hundred eyes of 91 participants were included in the analysis. The mean age of participants was 57.8 ± 8.2 years and 68% were men. Overall, the mean preoperative BCDVA was 0.5 ± 0.4 logMAR with >50% eyes having cataract of at least nuclear sclerosis Grade 2 or worse, and six eyes were classified as having mature cataracts. Surgery was performed by the SMO in 56 eyes and by the JMO in 44 eyes.

Successful docking of the femtosecond laser was recorded in 70% eyes at the first attempt. Most of the remaining eyes underwent successful docking at the second attempt. The mean time taken for successful docking was 9.3 ± 6.4 min (median = $6 \min$, IQR = $5-10 \min$, range = $4-35 \min$). The most common causes for failure of docking were inadequate suction, air bubble at the docking interface, failed patient registration, and eye movement postdocking. Seven patients had predock miscellaneous errors such as undetected patient interface, insufficient rise of the table height, and pretreatment error, which occurred due to inadequate tightness of the patient interface attachment. Only one patient experienced loss of suction during the laser delivery, and this occurred during lens fragmentation due to inadvertent movement of the eye. Laser delivery was aborted spontaneously. The docking procedure was repeated with a new patient interface with only primary and secondary incisions. Intraoperative period was uneventful. Lens chop was inadequate, and hence manual chop was required for fragmentation.

Total time for phacoemulsification surgery across the study period was $12.9 \pm 6.2 \text{ min}$ (median = 10 min, IQR = 9–17.5 min, range = 5–30 min). Keratome was required to open the corneal incision in 18% eyes. Similarly, 6% eyes showed anterior capsular tags [Fig. 2a] when the capsulorhexis was uncovered, and only one of these evolved into a radial capsular tear [Fig. 2b]. Two eyes with mature cataract had significant miosis after laser [Fig. 2c], and dilated well with intracameral adrenaline. Only one eye experienced zonular dialysis which was managed by capsular tension ring placement and in-the-bag intraocular lens implanatation without any vitreous disturbances. There were no other complications during surgery, including posterior capsular rupture, and vitreous loss. Six eyes had persistent subconjunctival hemorrhage in the 1st postoperative day, and 25 had corneal edema, all of which were resolved within 1 week of surgery. Eight patients had IOP



Figure 2: (a) Anterior capsular tag, (b) radial capsular tear, (c) pupillary miosis

Table 1: Quartile-wise comparison of variables						
Variable	Quartile 1 (n=25)	Quartile 2 (<i>n</i> =25)	Quartile 3 (<i>n</i> =25)	Quartile 4 (<i>n</i> =25)	Р	
Preoperative variables						
Age	58.1±9.4	57.3±6.9	58.1±10.0	56.6±6.2	0.72	
Gender (men), <i>n</i> (%)	19 (76)	15 (60)	16 (64)	18 (72)	0.60	
NS grade (>NS III), n (%)	19 (76)	12 (48)	14 (56)	15 (60)	0.78	
PSC (%)	18 (72)	16 (64)	18 (72)	20 (80)	0.69	
Axial length	23.6±1.2	23.1±0.7	23.1±0.8	23.3±0.8	0.16	
BCVA in logMAR	0.56±0.5	0.44±0.3	0.55±0.5	0.5±0.3	0.44	
IOP	16±2.1	16±2.2	16.5±2.6	14.4±3.0	0.06	
Mean cylinder preoperative	0.7±0.6	0.8±0.7	0.7±0.4	0.6±0.3	0.73	
Intraoperative variables						
Docking time (min)	16.2±7.9	6.6±2.2	7.9±5.1	6.2±2.7	0.001	
Docking success at first attempt (%)	9 (36)	23 (92)	18 (72)	20 (80)	<0.001	
Surgery time (min)	13.6±6.4	13.4±5.3	11.8±5.2	13.0±7.6	0.73	
Percentage cases by senior surgeon	14 (56)	13 (52)	17 (68)	12 (48)	0.52	
Intraoperative miosis (%)	1 (4)	1 (4)	0	0	0.56	
Posterior capsular rupture	0	0	0	0	-	
Zonular dialysis	0	0	1 (4)	0	0.39	
Keratome use (%)	9 (36)	4 (16)	3 (12)	2 (8)	0.049	
Anterior capsular tags (%)	2 (8)	1 (4)	2 (8)	1 (4)	0.87	
Radial tears in ALC (%)	0	0	1 (4)	0	-	
Outcome at 6 weeks						
IOP spikes postoperative	5 (20)	2 (8)	1 (4)	0	0.07	
UCVA in logMAR	0.01±0.04	0.04±0.09	0.07±0.08	0.03±0.08	0.06	
BCVA in logMAR	0	0	0	0	-	
Mean cylinder at weeks	0.4±0.8	0.9±1.0	0.5±0.5	0.5±0.4	0.06	

PSC: Posterior subcapsular cataract, BCVA: Best-corrected visual acuity, IOP: Intraocular pressure, UCVA: Uncorrected visual acuity, LogMAR: Logarithm of the minimum angle of resolution, ALC: Anterior lens capsule, NS: Nuclear sclerosis

spike (>21 mmHg) on the 1st postoperative day, out of which seven were resolved spontaneously, while one patient required topical timolol for a 1-month duration. At the 6 weeks follow up, 79% eyes attained UCDVA of 20/20, 19% had UCDVA of 20/30, and only two had 20/40. All eyes had BCDVA of 20/20.

When surgeries were divided into quartiles [Table 1], a significant reduction was seen in docking time between the first 25 eyes and the remaining 75. Similarly, successful first-docking attempts significantly improved from 36% in the first quartile to 80% in the fourth. Three attempts were required in two eyes (one in first and third quartile), and four attempts were required in one eye in the first quartile. In addition, the need to use a keratome to open the corneal incision showed time trends across quartiles [Table 1]. When surgeries were divided into deciles, docking time reduced significantly after the first 30 cases [Fig. 3]. Similarly, the proportion of successful docking at first attempt shows a trend of improvement. The average number of docking attempts per case was 1.44, which improved with learning from 1.6 in the first decile to 1.3 in the last decile. No other significant differences were observed between deciles.

Comparison between the two operating surgeons showed that the senior surgeon performed phacoemulsification surgery significantly faster than the junior. However, he needed to use keratome in a significantly greater number of eyes [Table 2].

Discussion

We found that, over the first 100 FLACS surgeries performed by experienced cataract surgeons unfamiliar with the femto laser, it took approximately 25–30 femto docking procedures to obtain consistent results in terms of reducing docking time and successful first attempts at docking. In addition, we found that the need to use a keratome to open the corneal incisions significantly decreased after 25 cases. Only a handful of surgical complications were seen in our series, and none resulted in vision-threatening outcomes.

Docking is the procedure that "connects" the eye to the femtosecond laser system and is an important determinant of surgical performance. The time required for docking fell from 16 min in the first quartile to 6–7 min in the remaining quartiles. The previous authors such as Grewal et al. reported much shorter docking times (4.3-3.3 min) in Catalys laser system during their learning curve from the initial 166 cases of FLACS.^[16] Similarly, Chang et al. also reported shorter docking time of 6.72 ± 4.6 min (range 2-28 min) in Lensar laser system.^[15] Lubahn et al. reported on total surgical times, comparing FLACS to traditional phacoemulsification and noted that it took approximately 12-15 min longer for FLACS, presumably due to the docking procedure.[18] The wide range of differences in docking time between different studies could be due to surgeons' previous docking experience while performing femto-LASIK. The surgeons involved in our study

Table 2: Surgeon-wise comparison of variables across all quartiles						
Variable	Senior surgeon (<i>n</i> =56)	Junior surgeon (<i>n</i> =44)	Р			
Preoperative variables						
Age	57.8±8.4	57.3±7.9	0.73			
Gender (men), <i>n</i> (%)	39 (70)	29 (66)	0.69			
NS grade (>NS III), n (%)	32 (57)	26 (59)	0.90			
PSC, <i>n</i> (%)	41 (73)	31 (70)	0.76			
Axial length	23.3±0.8	23.3±1.1	0.92			
BCVA in logMAR	0.55±0.5	0.46±0.2	0.54			
IOP	15.7±2.7	15.7±2.6	0.84			
Mean cylinder preoperative	0.73±0.5	0.75±0.6	0.72			
Intraoperative variables						
Docking time (min)	8.9±5.2	9.7±7.8	0.62			
Docking success at first attempt (%)	40 (71)	30 (68)	0.73			
Surgery time (min)	9.0±2.9	17.9±5.5	<0.001			
Intraoperative miosis (%)	3 (3.6)	0	0.50			
Posterior capsular rupture	0	0	-			
Zonular dialysis	1 (2)	0	0.99			
Keratome use (%)	14 (25)	4 (9)	0.043			
Anterior capsular tags (%)	3 (5)	3 (7)	0.76			
Radial tears in ALC (%)	1 (2)	0	-			
Outcome at 6 weeks						
IOP spikes postoperative	5 (9)	3 (7)	0.69			
UCVA in logMAR	0.04±0.07	0.04±0.09	0.66			
BCVA in logMAR	0	0	-			
Mean cylinder at weeks	0.5±0.7	0.6±0.8	0.32			

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PSC: Posterior subcapsular cataract, BCVA: Best-corrected visual acuity, IOP: Intraocular pressure, UCVA: Uncorrected visual acuity, LogMAR: Logarithm of the minimum angle of resolution, ALC: Anterior lens capsule, NS: Nuclear sclerosis



Figure 3: Docking comparison across deciles

were naïve when it came to the femtosecond laser and hence required much more time for docking in the initial 25–30 cases. In addition, the number of docking attempts was also greater in the first 25–30 cases, with successful first docking in only one-third of the cases. Some patients needed to be docked up to four times. This could also be due to the surgeons' lack of experience with the femtosecond laser.

In our study, the most common causes for more than two attempts at docking were failed patient registration, inadequate suction, air bubble at the docking interface, and eye movement postdocking, resulting in loss of suction. In addition, docking on a tilted eye leading to inadequate laser delivery can provide an inferior outcome compared to that obtained from a routine phacoemulsification. Tilting can be identified from the live OCT image. A very anterior incision, which commonly occurs due to eye tilt during docking, induces more astigmatism and postoperative dysphotopsias than usual. Intraoperatively, it also compromises the tight sealing nature of the corneal incision, making the eye vulnerable to endophthalmitis. An inadequately cut capsulotomy due to tilting, if not recognized early, can lead to a capsulorhexis tear and posterior capsular rent. We believe that preventing eye tilting is the single most important precaution that novice FLACS surgeons should take to prevent complications and yield reproducible and accurate results. In addition, we found docking to be difficult in anxious patients, those with narrow palpebral apertures, deep socket, flat, or steep corneas and patients with advanced cataract who have poor fixation of target light. Such patients may be at greater risk of docking-related complications.

During our learning curve, we found that one of the surgeons required the keratome, a relatively greater number of times to open up the corneal incision in the initial half of FLACS. This could be attributed to the difference in learning curve between SMO and JMO. We identified that the opening of primary incision with spade's spatula was comfortable in a visco-filled chamber. In addition, experience with the angle of entry and slight increase of energy setting in docking from 5 mJ to 6 mJ solved this issue. Both surgeons felt that the femtosecond-made corneal incisions, even when hydrated well, did not result in the formation of an anterior chamber as tight as that in blade-made ports. Although this was a concern for wound integrity, none of the cases had hypotony or a deformed wound postoperation.

Importantly, we did not find too many instances of the capsular tears and pupillary miosis that had been reported previously.^[14,15,19-21] There is a lot of debate regarding the integrity of the capsulotomy created by the femtosecond laser, predominantly initiated by electron microscopic studies showing ragged edges at the edge of the capsulorhexis.^[22] However, this did not translate into complications as we saw visible capsular tags in only six eyes and radial tear occurred in only one eye. Experiences from the previous studies, such as the expectation of a microadhesion in cases when there was no free floating capsulotomy cautioned us to use trypan blue in these patients and carefully scroll off the capsulorhexis from each quadrant. Following the circumferential pull method in cases of anterior capsule tags prevented tearing of the capsulorhexis. Since the cortical fibers are completely cut by the femtosecond laser, cortex aspiration by coaxial technique was more difficult. In the initial cases, the set laser energy for lens chop was inadequate, and hence the surgeons had difficulty in cracking the prechopped nucleus and needed to spend a longer time and more energy than necessary. As the laser energy became optimized with experience, postoperative corneal edema significantly decreased in the subsequent quartiles, clearly indicating the learning curve.

Finally, although the overall operating time was less for the senior surgeon when compared with the junior, he found that phacoemulsification after femtosecond laser consumed more time than usual, especially in incision opening and cortex aspiration. The necessity of unlearning and relearning certain long-learned techniques was clearly seen, even for an experienced surgeon.

We found that lessons learnt from the previous studies on the FLACS learning curve were really useful in improving the surgical outcome and avoiding major complications such as capsule block syndrome, posterior capsule rent, and nucleus drop in our first 100 cases, thus proving the need for experience-related studies. There were only a few studies that reported specifically on the learning curve of the femtosecond laser application, i.e. the docking procedure that is very crucial to a successful FLACS. An incorrect docking can make the whole surgery a substandard one. Using a prospective study, we report the learning curve from the point of view of an experienced cataract surgeon new to the femtosecond platform, and highlight the difficulties during docking, from registration issues with the patient interface, inadequate docking due to suction issues and problems encountered due to tilting of the eye postdocking. Dividing our cases into quartiles and deciles, we believe that it takes approximately 25-30 cases for an experienced cataract surgeon to understand the nuances of the femtosecond laser and deliver excellent results.

Although there was 100% attainment of BCDVA 20/20 at 6 weeks follow-up, an advanced laser procedure with added costs should ideally aim at UCDVA 20/20 for all eyes. In our first 100 cases, only 79% achieved UCDVA 20/20, probably due to the anterior incisions postdocking during the learning curve leading to induced astigmatism. Follow-up studies on visual outcome after the learning curve would provide a better picture of whether FLACS offers any advantage over routine phacoemulsification.

Conclusion

We found that it takes 25–30 cases to yield good results with FLACS. The docking time and attempts required for docking reduce significantly after 25–30 cases and intraoperative complications are rare with FLACS. We recommend a training course with a minimum of 25 cases for residents and femtosecond-novice surgeons to be able to independently perform FLACS in the real world and offer excellent outcomes to patients.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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