

# Femtosecond laser-assisted cataract surgery with bimanual technique: learning curve for an experienced cataract surgeon

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## Abstract

**Purpose** To describe the intraoperative complications and the learning curve of microincision cataract surgery assisted by femtosecond laser (FLACS) with bimanual technique performed by an experienced surgeon.

**Methods** It is a prospective, observational, comparative case series. A total of 120 eyes which underwent bimanual FLACS by the same experienced surgeon during his first experience were included in the study; we considered the first 60 cases as Group A and the second 60 cases as Group B. In both groups, only

nuclear sclerosis of grade 2 or 3 was included; an intraocular lens was implanted through a 1.4-mm incision. Best-corrected visual acuity (BCVA), surgically induced astigmatism (SIA), central corneal thickness and endothelial cell loss (ECL) were evaluated before and at 1 and 3 months after surgery. Intraoperative parameters, and intra- and post-operative complications were recorded.

**Results** In Group A, we had femtosecond laser-related minor complications in 11 cases (18.3%) and post-operative complications in 2 cases (3.3%); in Group B, we recorded 2 cases (3.3%) of femtosecond laser-related minor complications with no post-operative complications. Mean effective phaco time (EPT) was  $5.32 \pm 3.68$  s in Group A and  $4.34 \pm 2.39$  s in Group B with a significant difference ( $p = 0.046$ ). We recorded a significant mean BCVA improvement at 3 months in both groups ( $p < 0.05$ ) and no significant SIA nor corneal pachymetry changes in the two groups during the follow-up ( $p > 0.05$ ). Finally, we found significant ECL in both groups with a significant difference between the two groups ( $p = 0.042$ ).

**Conclusions** FLACS with bimanual technique and low-energy LDV Z8 is associated with a necessary initial learning curve. After the first adjustments in the surgical technique, this technology seems to be safe and effective with rapid visual recovery and it helps surgeons to standardize the crucial steps of cataract surgery.

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## Introduction

Femtosecond laser-assisted cataract surgery (FLACS) has recently been introduced in clinical practice for cataract surgery. This new technology offers advantages in comparison with the standard technique in terms of reproducibility and safety when carrying out microincisions, capsulotomies and nucleus fragmentation [1–3].

Bimanual microincision cataract surgery (B-MICS) is a microinvasive variant of traditional coaxial phacoemulsification [4] characterized by the separation of the aspiration and the infusion probe enabling clear corneal incisions (CCIs) of 1.4 mm [4–6]. We believe that this technique could be associated with FLACS very successfully due to an increased stability of the anterior chamber, the use of both hands for the procedures and a greater visibility of the surgical field due to the small size of the instruments.

Many recent studies have reported on the advantages of FLACS in comparison with the standard technique [7–12] even though, as for the use of any new technology, a learning curve is needed for the surgeon using FLACS for the first time [12–14].

Up to date, there are no studies investigating the learning curve for FLACS with the bimanual technique with intraocular lens (IOL) implantation through a 1.4-mm incision.

The purpose of our study was to evaluate an experienced cataract surgeon's first approach to the FLACS with bimanual technique, taking into consideration the main intra- and post-operative complications which occurred during the learning curve of this surgeon and the post-operative results that were evaluated in terms of visual acuity, astigmatism, corneal thickness and endothelial cell count.

## Patients and methods

We evaluated 120 eyes which underwent FLACS cataract extraction with bimanual technique

performed by an expert surgeon (GMC) during his first experience with Ziemer LDV Z8 (Ziemer Ophthalmic Systems AG, Port, Switzerland) at the Institute of Ophthalmology, University of Modena & Reggio Emilia. The first 60 cases were considered as Group A, while the second 60 cases were considered as Group B. We compared the results obtained in the two groups. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee in September 2015. All patients provided informed consent before surgery.

All the operated eyes had cataracts from grade 2 (NS2) to 3 (NS3) in the Lens Opacities Classification System III (LOCS III). Exclusion criteria were: eyes with previous surgery, complicated cataract (e.g. total cataract, traumatic cataract), hard cataracts, concomitant pathologies (uveitis, glaucoma, corneal opacities), insufficient mydriasis (< than 4 mm), low endothelial cell count (< 1500 cells/mm<sup>2</sup>) and patients with only one eye.

Prior to surgery all patients underwent a careful clinical history evaluation, BCVA examination, anterior segment biomicroscopy, fundus examination, biometry (performed with both IOL Master, Carl Zeiss, and US500 Echoscanner, Nidek), corneal microscopy (Noncon, Robo-CA, Konan), corneal pachymetry (IOPac, Heidelberg Engineering) and corneal topography (CT1000, Shin Nippon). The surgeon performed the operations using the same phaco machine (Faros, Oertli Instruments AG, Berneck, Switzerland).

## Surgical technique

A consistent mydriasis was obtained with the instillation of 10% phenylephrine and 1% cyclopentolate, and loco-regional anaesthesia was carried out with peribulbar block (1.5 ml of lidocaine 2% and 1.5 ml of bupivacaine 0.5%).

We carefully applied a disposable suction ring to the eye, centred over the limbus. The suction ring was filled with balanced salt solution in order to create a liquid interface, and the mobile arm of the laser system was docked over the corneal apex. The ocular structures were shown using integrated optical coherence tomography (OCT) system, and treatment parameters were determined in a customized manner using the laser platform wizard settings. The energy and frequency laser pulse setting was: 900 mW,

1 MHz for capsulotomy; 950–1000 mW, 2 MHz for phacofragmentation; and 1200–1300 mW, 2 MHz for corneal incisions. After the laser was successfully docked, laser treatment started with lens fragmentation with a sixteen pie-cut pattern. The fragmentation was then followed by an anterior capsulotomy of 5.2 mm diameter. Finally, the laser performed the two 1.4-mm biplanar corneal microincisions at 10 and 2 o'clock; the corneal incisions are shown in Fig. 1, and Table 1 shows the femtosecond laser machine setting used for all the CCIs. The suction ring was then removed from the eye surface to proceed with the phaco procedure. The surgeon checked the patency of the CCIs using a smooth spatula, initially with a perpendicular inclination to the limbus and then with gentle movements along the incision in order to open it completely.

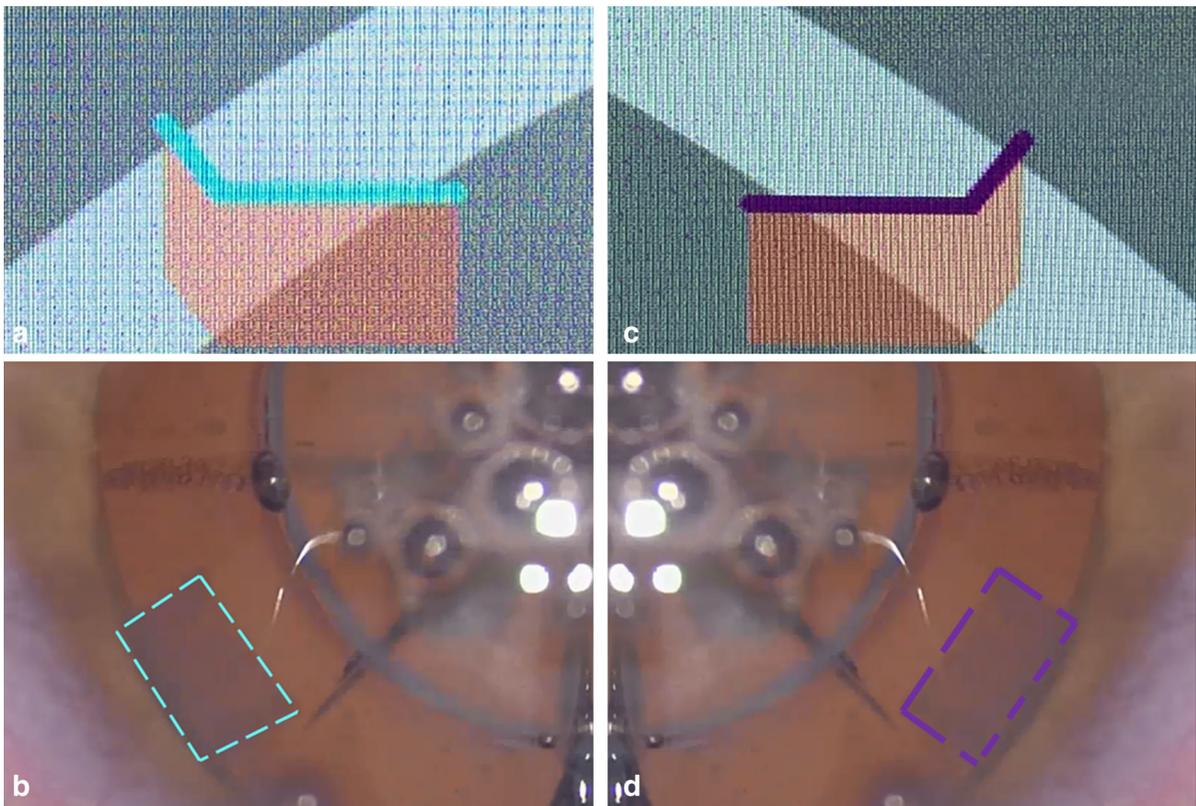
The anterior chamber was filled with ocular viscoelastic device (OVD) in order to proceed with the removal of the anterior capsule, paying attention to any tags or capsular bridges in order to avoid an

**Table 1** Bimanual FLACS clear corneal incisions (CCIs): main characteristics

Clear corneal incisions	
Position (°)	143°, 32°
Entrance angle (°)	55
Bend angle (°)	– 55
Distance to limbus mm	0.30
Posterior safety distance (mm)	0.7
Anterior corneal offset (micron)	150
Posterior corneal offset (micron)	250
Corneal depth of bend point (%)	35

anterior capsule tear. Hydrodissection and hydrode-lination were performed using a 26-gauge cannula with a slow injection of BSS under the anterior capsule edge.

The bimanual phacoemulsification technique was used to aspirate the nucleus with a 20-gauge, 30-degree angled, sleeveless probe and a 19-gauge irrigating



**Fig. 1** Bimanual FLACS microincisions. **a, b** Left microincision **c, d** right microincision

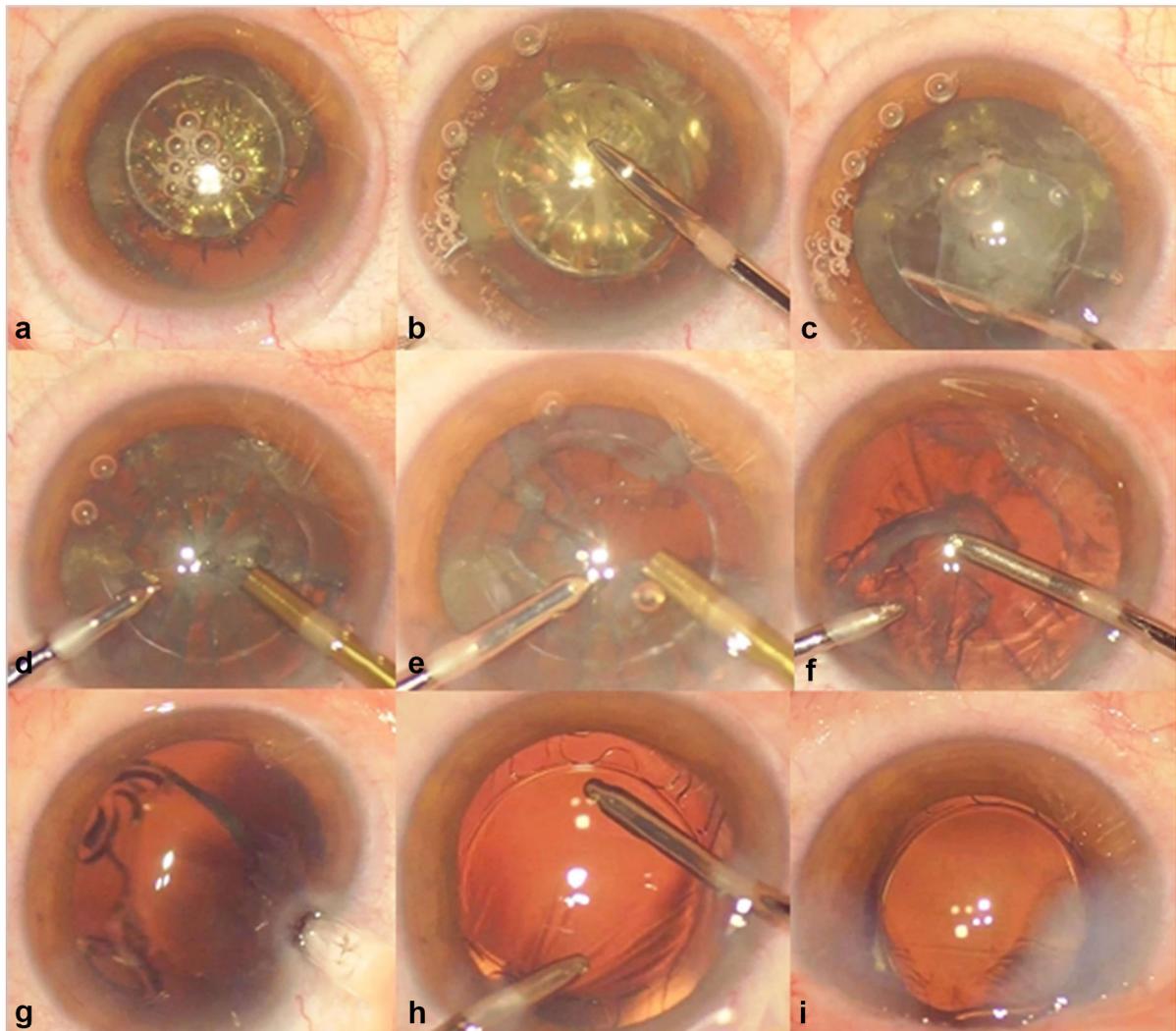
chopper (Oertli Instruments AG). Finally, bimanual irrigation/aspiration of the residual cortex was performed using two 21-gauge probes with an oval-shaped section (21-gauge smooth irrigation hand-piece, 21-gauge rough aspiration handpiece, Bausch & Lomb) followed by posterior capsule polishing. All intraocular lenses were placed in the capsular bag without complications. Figure 2 shows the main steps of the technique.

IOL was implanted without enlargement of the main incision; the incisions were hydro-sutured. BunnyLens AF IOL (Hanita Lenses, Israel) were

implanted through 1.4-mm microincisions using the wound-assisted technique with the ViscoJect™ BIO 1.5 injector. At the end of surgery, the OVD was removed and the incisions were hydrated for safety reasons.

Post-operative therapy consisted of tobramycin and dexamethasone eyedrops 4 times a day for 15 days, followed by flurbiprofen eyedrops 3 times a day for a further 15 days.

The intraoperative parameters recorded were total surgery time (from docking to hydrosuture) and effective phacoemulsification time (EPT).



**Fig. 2** Bimanual FLACS surgical technique. **a** Appearance of the lens after the FSL procedure with phaco-fragmentation, capsulotomy and clear corneal 1.4-mm microincisions performed; **b, c** removal of the capsulotomy with the dedicated

microforceps; **d, e** after hydrodissection, microphacoemulsification; **f** bimanual I/A; **g** intraocular lens implantation through 1.4-mm incision without enlarging; **h** removal of the OVD; **i** Microincision hydrosuture

Intraoperative complications were registered at the end of every operation and were divided into FLACS-related minor complications (loss of suction, incomplete capsulotomies, incomplete CCI, miosis, anterior capsule tags) and major complications (posterior or anterior capsule rupture, dropped nucleus).

Post-operative results have been evaluated at 30 days and 3 months after surgery in terms of BCVA, corneal pachymetry, corneal astigmatism and endothelial microscopy using the instruments previously described. All these examinations were performed by the same experienced physician.

All data have been recorded in an Excel database (Microsoft Excel 2010, Microsoft Office Professional Plus 2010), and for analysis, we used Stata 13.1 software (StataCorp LP, College Station, TX, USA) with Student's *t* test and Wilcoxon rank sum test. A *p* value < 0.05 indicated statistical significance.

## Results

For Group A, 60 eyes (32 right eyes and 28 left eyes) of 55 patients (23 males and 32 females) were included in the study; the average age was  $74.68 \pm 8.96$  years.

For Group B, 60 eyes (35 right eyes and 25 left eyes) of 57 patients (25 males and 32 females) were included in the study; the average age was  $75.50 \pm 7.77$  years.

Patients in both groups were similar for age ( $p > 0.05$ ) and cataract characteristics NS2/NS3. The Group A included 44 NS2 cataracts and 16 NS3 cataracts; the Group B included 41 cataracts NS2 and 19 cataracts NS3. BunnyLens AF IOL was implanted in all eyes. All IOLs were implanted in the bag.

### Intraoperative parameters

Regarding surgical times, in Group A we recorded a mean total surgical time of  $18.03 \pm 3.43$  min, while in Group B, it was  $17.86 \pm 3.05$  min. Mean EPT was  $5.32 \pm 3.68$  s in Group A and  $4.34 \pm 2.39$  s in Group B.

The difference for EPT between the two groups was statistically significant ( $p = 0.046$ ); the mean suction time during the femtosecond laser procedure in Group A was  $3.68 \pm 0.63$ , while in Group B, it was  $3.57 \pm 0.47$  with no significant difference between the two groups.

### Intraoperative complications

In Group A, we recorded intraoperative FLACS-related minor complications in 11 cases (18.33%). In particular, we had 4 cases of suction loss during the docking phase (6.67%) without any important major complications. We never had a suction loss when the laser was working. We recorded 3 cases of intraoperative miosis (5%), 3 cases of incomplete CCIs (5%), one case of incomplete capsulotomy (1.67%) and two cases of anterior capsule tags (3.33%).

In Group B, we only recorded one case of intraoperative miosis and 1 case of incomplete CCIs; no other complications were observed (Table 2).

### Post-operative complications

In Group A, we recorded 2 cases of post-operative complications: one case of iridocyclitis and one case of cystoid macular oedema at 30 days from surgery. In Group B, we did not find any post-operative complications (Table 2).

### Post-operative results

Regarding post-operative results, mean BCVA improvement in Group A was  $0.380 \pm 0.287$  logMar at 3 months, statistically significant from baseline

**Table 2** Intraoperative and post-operative complications in the two groups

	First 60 cases		Second 60 cases	
<b>Intraoperative complications</b>				
Loss of suction	2	3.33%	0	0
Miosis	3	5%	1	1.67%
Incomplete CCIs	3	5%	1	1.67%
Incomplete capsulotomy	1	1.67%	0	0
Anterior capsule tags	2	3.33%	0	0
Posterior capsule rupture	0	0	0	0
Anterior capsule rupture	0	0	0	0
Dropped nucleus	0	0	0	0
Total		18.33%		3.34%
<b>Post-operative complications</b>				
Microincision leakage	0	0	0	0
Cyclitis	1	1.67%	0	0
Cystoid macular oedema	1	1.67%	0	0
Total		3.34%		0%

( $p < 0.05$ ). In Group B, we found a mean BCVA improvement of  $0.432 \pm 0.295$  logMar at 3 months ( $p < 0.05$ ). The difference in the improvement of visual acuity between the two groups was not statistically significant ( $p > 0.05$ ).

With regard to astigmatism, in Group A SIA at 3 months after surgery was  $0.045 \pm 0.347$ , while in Group B it was  $0.033 \pm 0.277$  at 3 months after surgery; the difference between the two groups was not statistically significant ( $p > 0.05$ ).

Regarding corneal pachymetry, we did not record any significant differences in both groups as shown in Table 3 ( $p > 0.05$ ).

Finally, with regard to the endothelial cell count, at the 3-month follow-up we found a mean ECL of  $212.32 \pm 324.23$  cells/mm<sup>2</sup> for Group A and  $110.37 \pm 154.33$  cells/mm<sup>2</sup> for Group B, a reduction that is statistically significant ( $p < 0.05$ ) in both groups; interestingly, the cell loss was higher in Group A than in Group B, and this difference was statistically significant ( $p = 0.042$ ).

In Table 3, all the results are reported for both groups.

## Discussion

Femtosecond laser-assisted cataract surgery (FLACS) is the most recent innovation in cataract surgery and appears to be a safe, efficient and reproducible procedure [1–3]. It enables the creation of precise, perfectly centred anterior capsulotomies and effective lens fragmentation with reduced ultrasound power.

Like any new technique, FLACS needs a learning curve and this has already been described in the literature for coaxial cataract surgery [1, 12].

The femtosecond laser Ziemer LDV Z8 (Ziemer Ophthalmic Systems AG, Port, Switzerland) is a new high-frequency and low-energy femtosecond laser system, which is used to carry out both corneal and cataract surgery. The optics on the LDV Z8 system produce precise focused laser pulses that allow photodisruption of the tissue with low pulse energy (nJ range), adjustable according to the cataract grade, and very high pulse frequencies (MHz range) [15]. For cataract surgery, it uses a new non-applanation liquid interface on the patient that does not deform the cornea during the procedure thus preventing posterior corneal folds [16]. Moreover, the reduced dimensions of the Z8 allow the surgeon to perform the entire surgery in the same theatre [17].

This study investigated the initial difficulties and the complications encountered during the learning curve of an experienced surgeon at his first experience of FLACS using the low-energy Ziemer LDV Z8 combined with the microinvasive B-MICS technique. We consider B-MICS an ideal technique for FLACS as it combines the advantage offered by femtosecond laser assistance with that offered by the bimanual technique (a more stable anterior chamber, smaller instrumentations with a better visibility of the surgical field, the chance to use both hands during surgery).

Aliò et al. reported on bimanual versus coaxial MICS techniques both assisted by the femtosecond laser [18], showing that bimanual technique was surgically and statistically more efficient than the

**Table 3** Mean values of preoperative and post-operative parameters for Group A and Group B

	Preoperative	30 days	3 months
Group A (first 60 cases)			
BCVA	$0.399 \pm 0.279$	$0.009 \pm 0.028$	$0.010 \pm 0.056$
Astigmatism (D)	$0.73 \pm 0.46$	$0.71 \pm 0.40$	$0.70 \pm 0.51$
Corneal pachymetry	$543.39 \pm 44.51$	$553.83 \pm 47.67$	$545.72 \pm 49.46$
Endothelial cell density (cells/mm <sup>2</sup> )	$2401.83 \pm 284.30$	$2280.15 \pm 419.88$	$2179.15 \pm 387.57$
Group B (second 60 cases)			
BCVA	$0.448 \pm 0.289$	$0.025 \pm 0.037$	$0.012 \pm 0.053$
Astigmatism (D)	$0.94 \pm 0.57$	$0.86 \pm 0.059$	$0.91 \pm 0.65$
Corneal pachymetry	$539.53 \pm 49.42$	$539.86 \pm 62.05$	$540.80 \pm 63.76$
Endothelial cell density (cells/mm <sup>2</sup> )	$2384.07 \pm 367.19$	$2308.76 \pm 400.29$	$2265.94 \pm 351.10$

BCVA is expressed in logMar

coaxial one with excellent safety and efficient outcomes. However, in both groups IOL was implanted through enlarged 2.2-mm incisions.

We evaluated intraoperative and post-operative complications as well as the visual outcomes in the first 3 months of follow-up after surgery with FLACS with IOL implanted through 1.4-mm incision, comparing the results obtained in the first 60 cases to those obtained in the second 60 cases.

### Intraoperative parameters

The recent literature showed that a FLACS learning curve is accompanied by significantly decreased phacoemulsification power over time [19]. In our study, EPT was significantly reduced in the second 60 cataract operations ( $p = 0.046$ ) suggesting an improved learning curve. In Group A, EPT records were higher in the first cases and then progressively reduced during the learning curve of the procedure; this was probably due to both the initial difficulties in the setting of the laser for the lens segmentation and fragmentation and the improved ability of the surgeon during the learning curve of the new technique.

As regards surgical time, in our case series we found a longer total surgical time in the first cases, as expected; duration of surgery decreased during the learning curve; however, the difference was not statistically significant. Grewal et al. showed that with the increase in a surgeon's experience, there is a significant reduction in surgical time with a plateau at around 100 cases [13]; however, FLACS procedure requires a longer overall procedure compared to phaco. This is probably due to the docking/suction phase that is a new procedure for cataract surgeons. The docking of the eye to the laser is one of the most important steps of the learning curve for FLACS, and it requires practice, especially if the surgeon has not used LASIK before. In our case series, despite the learning curve, the docking phase and laser delivery were successfully performed in almost all cases. Suction time decreased over time, but this change was not significant.

### Complications

As regards intraoperative complications, some recent publications suggested that FLACS can be safely

incorporated into routine practice with proper training [12–14].

Nagy et al. showed that all femtosecond laser-related complications only occurred during the learning curve in the first 100 cases [20]. In our study, we had 11 intraoperative FLACS-related complications in Group A, while only 2 in Group B (Table 2).

In the cases of a small pupil after femto procedure, mydriasis was re-obtained by the instillation of mydriatic drops.

CCIs created with FLACS in five cases were not completely open, and the surgeon had to enter the anterior chamber with a blade to complete the procedure.

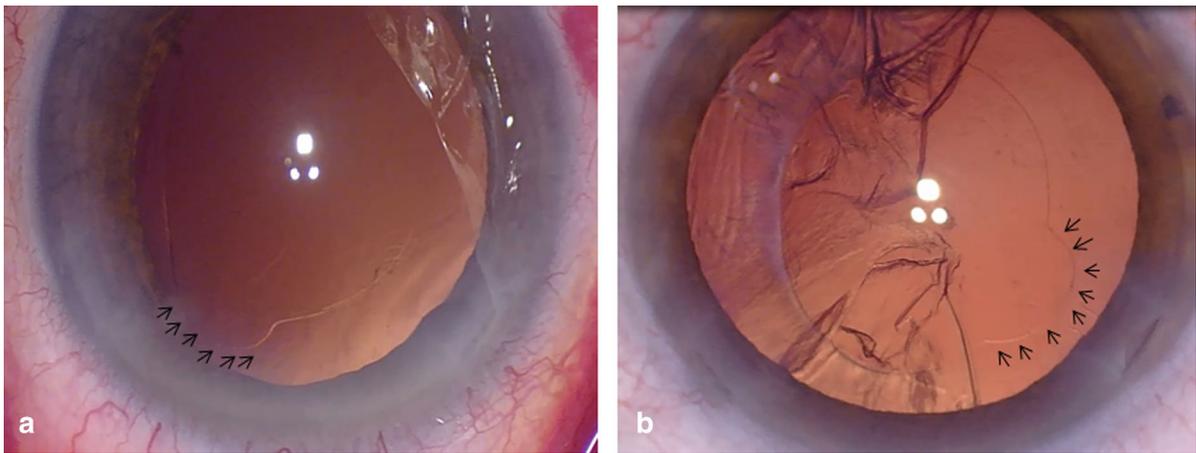
In our case series, we only found one case of incomplete capsulotomy in Group A. Apart from this case, capsule buttons were always perfectly centred and very easy to remove: the liquid interface did not lead to formation of any marked corneal folds and enabled precise and complete capsulotomies. It is proven that FLACS capsulotomies are more predictable and stable than manual ones [21], and we all know that a well-centred curvilinear anterior capsulorhexis is much safer during phacoemulsification than an irregular one.

However, in our study we have reported two cases of anterior capsule tags which occurred during the I/A phase of the FLACS procedure in Group A as shown in Fig. 3.

This was probably due to the presence of anterior capsule tissue bridges accidentally aspirated with the aspiration probe. For this reason, we recommend great care during the removal of the capsulotomy, especially in the presence of any anomalous adherences between the free cap and the remaining capsular bag.

During lens fragmentation, especially in the first cases, we noticed the formation of some microbubbles that could confuse the surgeon and lead to a more delicate and slow hydrodissection. The surgeon initially had some difficulty separating the lens fragments due to the thick dimension of the chopper compared to the pre-cut lens. For this reason, the surgeon planned to develop a thinner but longer chopper with a spatula shape that could easily be inserted into the lens laser sulcus in order to more easily separate the lens fragments and safely continue the surgery using less ultrasound.

In Group A, in particular in the first cases, the surgeon had some difficulty with the aspiration of the lens fragments because the laser beam made an incomplete cut in the lens.



**Fig. 3** Anterior capsule tear. Two cases of anterior capsule tears occurred during the I/A phase of the FLACS procedure. The arrows indicate the edges of the anterior capsule's tag area

The safety level of FLACS procedure was very high according to the surgeon; we did not register any major complication as posterior capsule tears, nor dropped nuclei, indicating that the meticulous preparation of the femtosecond laser settings probably provides high levels of safety during the procedure.

As regards post-operative complications, these occurred only in Group A. We registered a case of iridocyclitis managed with the use of antibiotic/steroid drops and a case of cystoid macular oedema at 1 month of follow-up that was managed with bromfenac 0.9 mg/ml eyedrops. This is in line with the recent literature that states that FLACS procedure may cause higher prostaglandin concentration [22].

We did not find any IOL decentrations during the follow-up in both groups.

The femtosecond laser setting for the microincisions performed a perfect wound healing in all patients without any cases of CCI leakage. It is reported in the literature [18, 23] that CCIs created with FLACS have a lower risk of hypotony, iris prolapse and endophthalmitis and reduce the risk of wound slippage and induced astigmatism. Interestingly, the angle degree and width can be set permanently which may be useful when training young surgeons.

#### Post-operative results

With regard to post-operative results, we found a significant increase in BCVA in both groups as previously reported in the literature for FLACS [1–3].

We found no significant difference in SIA in the two groups as already shown for coaxial FLACS [23]; central corneal thickness (CCT) values showed no significant change between pre- and post-operative values for both groups, as expected [24–26].

Finally, our findings on ECL are statistically significant in both groups. The difference between the two groups was statistically significant in favour of Group B; this could be related to the reduced use of ultrasound energy in Group B, thus causing less trauma to corneal endothelial cells.

This study has a limitation: we analysed results of a single surgeon in order to try to remove any possible bias due to the presence of different surgeons and thus different surgical approaches; however, in order to obtain a more precise evaluation of the technique, the study could have examined the results of more surgeons, as the adaptability of each surgeon on a skill could change.

In conclusion, our case series shows that the use of femtosecond LDV Z8 laser system, even though it facilitates crucial steps of cataract surgery, is associated with a necessary learning curve. A significant difference was noted between the two sequential groups in terms of intraoperative parameters and minor complications. However, the use of FLACS in B-MICS with the low-energy LDV Z8 system appeared to be safe and effective even in the first cases performed by an experienced surgeon. Despite this, a learning curve is necessary to safely incorporate the femtosecond laser into a routine surgical

technique. Further improvements in instrumentation and technique will reduce the learning curve for this technique in future generations of surgeons allowing FLACS to become the first and safest approach for cataract surgery.

### Compliance with ethical standards

**Conflict of interest** None of the authors have conflict of interest with the submission.

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