

Pupil Status with Low-Energy Femtosecond Laser-Assisted Cataract Surgery versus Conventional Phacoemulsification: An Intraindividual Comparative Study

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Purpose: To compare the pupil changes in low-energy femtosecond laser-assisted cataract surgery (FLACS) with conventional phacoemulsification (CP) intraindividually.

Patients and Methods: A retrospective review of registered surgical data from patients that undergone uncomplicated cataract surgery in a single centre, with randomly assigned femtosecond laser-assisted cataract surgery (FLACS) to one eye and conventional phacoemulsification (CP) to the other, was performed. The recorded pupil images were evaluated at pre and post laser treatment (after suction release) and at several surgical timepoints for both techniques (FLACS and CP). Pupil areas were calculated and compared in the same eye undergone FLACS (pre vs post laser treatment), between eyes (CP vs FLACS) in the same patient and between groups. Subgroups were built regarding age and ocular comorbidity.

Results: This study involved a total of 164 eyes of 82 patients (55 female, 27 male). No statistical differences regarding the total duration of surgery ($p=0.805$) between FLACS and CP. Pupil measurements between pre and post laser treatment in the FLACS group showed no statistically significant differences ($p=0.107$). The mean change in pupil area from the beginning until the end of surgery (total variation) was $6.59 \pm 2.08 \text{ mm}^2$ in the FLACS group and $6.67 \pm 2.13 \text{ mm}^2$ in the CP group, associated to less narrowing of pupil area with FLACS, although not statistically significant ($p=0.080$). Comorbidity group analysis revealed less, but not significant, pupil narrowing with the FLACS technique ($p=0.071$). No statistically significant differences between FLACS and CP concerning age subgroups were registered.

Conclusion: This study shows no significant pupil changes, namely myosis, after low-energy FLACS pre-treatment. Comparison between techniques showed less pupil variation in FLACS as compared to CP, more markedly in eyes with comorbidities (particularly with shallow anterior chamber), although non-statistically significant.

Keywords: low energy femtosecond laser, FLACS, myosis, pupil, phacoemulsification

Introduction

Femtosecond laser-assisted cataract surgery (FLACS) emerged as a novel technique in 2009.^{1,2} Since then, this technique has evolved considerably, covering several of the conventional surgical steps previously performed in a manual manner (incisions, lens fragmentation, and capsulotomy). The safety and effectiveness of FLACS is consensually established, with considerable evidence.³⁻⁵ However, intraoperative miosis has been associated with femtosecond laser-assisted cataract surgery,⁶⁻⁸ which renders inherent difficulties regarding nuclear fragmentation, cortex removal, intraocular implantation of the lens, and increases the risk of posterior capsule rupture.⁹ This undesired side effect is frequently reported in the vast majority of publications regarding FLACS, which, almost invariably, do not differentiate

femtosecond laser based on the pulse pattern, i.e., between low and energy pulse femtosecond lasers or do not contemplate low energy pulse at all.^{10,11}

As pointed out by Wu et al¹² there are different femtosecond laser devices, generating different pulse patterns, in terms of energy and frequency levels. Most commercially available devices produce high energy (μJ) and low frequency (KHz) pulses; this type of common, femtosecond emission, is driven by chirped pulse amplification (CPA). On the other hand, another type of device produces low energy (nJ) and high frequency (MHz) femtosecond pulses by means of increasing the laser focusing optics' aperture,¹³ therefore diminishing the laser spot diameter. The prevalence (in number and magnitude) of miosis with "high-energy" pulse femtosecond lasers has been shown to range between 9.5% and 32%.^{14,15} There is some evidence that the level of femtosecond laser cutting side effects are associated with prostaglandins release; these higher levels of prostaglandins (measured immediately after the laser pre-treatment), in turn, is accountable for the observed intraoperative myosis.^{16,17} Oppositely to the aforementioned "mainstream" reports, the few studies regarding pupillary changes with low energy pulse femtosecond lasers, show increasing evidence of minimal to absent narrowing of pupil size.^{18,19} This difference in behaviour may be related to the laser spots diameter and energy level, with smaller values achieved by "low-energy" devices, thus reducing an associate damage to the neighbour tissues. This fact is prone to reduce prostaglandins levels and, consequently, no significant intraoperative pupil narrowing.

Our present study aims to further investigate on the pupil area changes with low energy pulse FLACS and compare it against the standard phacoemulsification. For this matter, an intraindividual study was performed.

Materials and Methods

This retrospective cohort study was approved by the Ethics Committee at Hospital da Luz Arrabida (HLA), Porto, and adhered to the ethical principles stated in the "Declaration of Helsinki", with each patient having signed an informed consent. Data were extracted from the charts of all patients who had cataract surgery in both eyes, with randomly assigned conventional phacoemulsification surgery in one eye and femtosecond laser-assisted surgery in the other eye. All patients had surgery between February 2015, and September 2020, at Hospital da Luz Arrabida (HLA). Two cataract and refractive surgeons performed all surgeries at HLA.

Inclusion and Exclusion Criteria

Patients were excluded from the study if they had previous corneal scarring, ocular surgery other than cataract surgery, or relevant axial anisometropia (defined as a ≥ 1 mm-difference in axial length between eyes of the same patient).

Chart Review and Data Collection

Charts were reviewed from surgeries performed between February 2015 and September 2020, and extraction was performed of demographic, clinical, and video recording data such as age, sex, date, type of surgery (conventional phacoemulsification versus femtosecond laser-assisted), procedure's duration, axial length, anterior chamber depth, cataract degree, ocular comorbidity, surgical videos, and adverse events. Optical interferometer Galilei G6 (Ziemer Ophthalmic systems AG) was used for biometry. Assessment of lens transparency was achieved by examination at the slit lamp followed by a grading procedure according to the Lens Opacities Classification System (LOCS) III. A Placido - dual Scheimpflug device (Galilei G6) was used for corneal tomography and topography assessment. Macular evaluation, by means of spectral-domain optical coherence tomography, was accomplished by a modular ophthalmic imaging platform (Carl Zeiss).

For pupil measuring purposes, recorded images from surgical videos were withdrawn at several time points: (1) at the beginning of both CP and FLACS (immediately before laser docking), (2) immediately after the vacuum suction release (end of femtosecond laser pre-treatment) in the FLACS group, (3) at 5 minutes intraoperatively, (4) at 10 minutes intraoperatively, and (5) at the end of the surgical procedure.

Surgical Technique

Two experienced surgeons (R.S., A.M.). performed all surgeries. The femtosecond laser-assisted lens surgery was performed with a LDV Z8 (Ziemer, Inc., Port, Switzerland) device. Capsulotomy, corneal incisions and lens fragmentation were accomplished by femtosecond laser, with the phacoemulsification device being used for the

subsequent steps, such as emulsification, irrigation and aspiration of lens material. FLACS was sequentially performed (femtosecond laser followed by the phacoemulsification) keeping the patient on the same operating bed and in the same operating theatre, as the FS platform employed is a portable one. The phacoemulsification device employed was the Active Fluidics™ torsional phacoemulsification machine (Centurion Vision, Alcon Laboratories, Inc., Fort Worth, USA). All surgeries were unilateral, with one eye at a time. Surgical protocol was the same for both surgeons.

Preparation protocol of was the same for both groups of patients, ie, tropicamide 0.28 mg in association with phenylephrine hydrochloride 5.4 mg contained in the form of an ophthalmic insert, with placement in the lower conjunctival sac and oxybuprocaine hydrochloride 4 mg/l eyedrops 20 minutes before procedure. No specific medication for myosis prevention was administered in the femtosecond group, nor additional steroid or non-steroid anti-inflammatory drugs (NSAID) were administered in the preoperative period to any of the patients. This specific protocol, without preoperative use of NSAID drugs (as this use is currently regarded as a standard practice) was explained to all patients, with given consent by each one of them. Although available as a backup measure, no intraoperative agents, like intracameral mydriatic mixtures, needed to be administered. Intracameral cefuroxime was injected in every patient at the end of each surgery.

In the FLACS group, vacuum suction was set at approximately 420 mbar and the following laser procedures were performed: lens fragmentation (in six pieces with a 6-mm diameter) at 105% laser energy, corneal incisions (main of 2.8 mm and secondary paracentesis of 1.2 mm) and capsulotomy (5.2-mm diameter) at 90% laser energy. Further surgical steps followed immediately after suction release (phacoemulsification device employed for emulsification, irrigation, and aspiration of lens material) and were performed in the same way for both groups (FLACS and CP).

All patients were prescribed with prednisolone, ibuprofen and ofloxacin eyedrops postoperatively for 3 weeks.

Pupil Area Measurement

Pupil area was measured at the established time points, after analysing images from the recorded surgical videos. For that purpose, we have adopted the Fiji image processing program from ImageJ (software version 2.0.0-rc-49/1.51a) as suggested by Mirshahi et al,¹⁸ which enables direct area measurements by tracing pupil margin. Calibration was accomplished by using the constant limbus horizontal size as a reference, allowing pixel measurements conversion into millimetres for each eye.

Statistical Analysis

The analysis involved the examination of possible differences in pupil area from the baseline preoperative measurement and along the different timepoints, comparing both techniques intraindividually (within subjects) and interindividually (between subjects). Subgroup analysis was also performed to evaluate pupil area changes with respect to age and comorbidity.

Regarding pupil change pre-laser versus post-laser treatment in the FLACS group of eyes, a paired *t*-test was applied. Comparison of pupil size between the FLACS and CP in the same patient (within-subject) at each time point was accomplished by a paired *t*-test.

Differences in pupil size between groups at different times were compared using analysis of variance (ANOVA). A mixed-design ANOVA was applied, considering pathology (yes or no) and type of pathology (when associated) as a between-subjects factor. Regarding the within-subjects' factors, type of surgery (FLACS or CP) and time were used. Before the analysis, the sphericity assumption was tested using the Mauchly's Test, and when the assumption was not accomplished, the Greenhouse-Geisser correction results were reported.

A statistical significance level of $\alpha=0.05$ and a power of 95% were chosen, with P-values < 0.05 being considered statistically significant. All statistical analyses were performed using SPSS (Statistical Package for the Social Sciences, version 28, Chicago, Illinois).

Results

Preoperative Patient Data

The study population consisted of 164 eyes of 82 patients, with 55 female (67%) and 27 male (33%), and a mean age of 73.4 ± 8.5 years (median: 74, range: 55–95). For each patient, one of the eyes underwent FLACS and the other was operated with CP; therefore, in the total population, 82 eyes (50%) had femtosecond laser-assisted surgery and 82 eyes (50%) underwent conventional phacoemulsification.

Table 1 shows the patients' preoperative characteristics by technique group. There was no statistically significant difference between the 2 groups preoperatively.

Preoperatively, the pupil area after dilation presented no statistically significant difference between the techniques, with $45.01 \pm 7.60 \text{ mm}^2$ in the FLACS group and $45.00 \pm 7.60 \text{ mm}^2$ in the CP group ($p=0.748$). Comorbidity, as shown in Table 2, was present in 47 eyes (28.7%) of 23 patients and distributed as follows: glaucoma and pseudo exfoliation in 22 eyes (13.4%); shallow (<2.5 mm depth) anterior chamber in 10 eyes (6%), mild non-proliferative diabetic retinopathy in 8 eyes (4.8%), Fuchs dystrophy in 4 eyes (2.4%), high myopia in 2 eyes (1.2%), and post-retinal central venous thrombosis in one eye (0.6%). No adverse events were registered.

Postoperative Data

In the FLACS group, pupil area comparison between pre and post laser treatment showed no statistically significant differences ($p=0.107$, 95% CI (Confidence Interval): -0.01 to 0.05), with a mean value of $45.01 \pm 7.60 \text{ mm}^2$ and 44.98

Table 1 Patient Demographic and Clinical Characteristics

Parameter	FLACS (n=82) CP (n=82)		p value
	Mean ± SD (mm ²)		
Nuclear sclerosis (LOCS III)	3.45 ± 0.71	3.41 ± 0.67	0.733
Time duration (s)	13.62 ± 1.03	13.66 ± 0.98	0.805
Axial length (mm)	21.87 ± 1.60	21.75 ± 1.64	0.776
Anterior chamber depth (mm)	3.17 ± 0.22	3.19 ± 0.26	0.831

Abbreviations: CP, conventional phacoemulsification; FLACS, femtosecond laser-assisted cataract surgery; LOCS III, Lens Opacities Classification System III; n, number of eyes; SD, standard deviation.

Table 2 Comorbidity

Comorbidity	Number of Eyes	%
Pseudoexfoliation glaucoma	22	13.4
Shallow anterior chamber	10	6
Mild non-proliferative diabetic retinopathy	8	4.8
Fuchs dystrophy	4	2.4
High myopia	2	1.2
Post-retinal central venous thrombosis ^a	1	0.6
TOTAL	47	28.7

Note: ^aCondition present in only one eye.

$\pm 7.61 \text{ mm}^2$, respectively (Figure 1). The mean change in pupil area between preoperative and post-laser treatment was $0.02 \pm 0.12 \text{ mm}^2$ (median: 0.01, minimum: -0.02 , maximum: 1).

Regarding the comparison between FLACS and CP, pupil area measurements were performed along surgical time-points for both techniques (Figure 2). The intraindividual analysis (within-subjects) revealed a marked difference, close to the limit of significance, between FLACS and CP techniques at the end of surgery, with a mean pupilar area of $38.41 \pm 7.01 \text{ mm}^2$ and $38.33 \pm 7.04 \text{ mm}^2$, respectively ($p=0.051$). More distinctly, a statistically significant difference between the techniques was shown at 10 minutes intraoperatively, with a slightly larger pupil in the FLACS group (mean difference of $0.09 \pm 0.38 \text{ mm}^2$) as opposed to CP ($p=0.032$, CI: 0.01 to 0.17).

The mean change in pupil area from the beginning until the end of surgery (total variation) was $6.59 \pm 2.08 \text{ mm}^2$ in the FLACS group and $6.67 \pm 2.13 \text{ mm}^2$ in the CP group; the mean difference between the two techniques was $0.07 \pm 0.38 \text{ mm}^2$, associated to less narrowing of pupil area with FLACS, although not statistically significant ($p=0.080$) (Table 3).

Pupil narrowing was correlated positively with the duration of surgery, being similar in both techniques ($R=-0.401$ and $R=-0.426$; $p<0.001$).

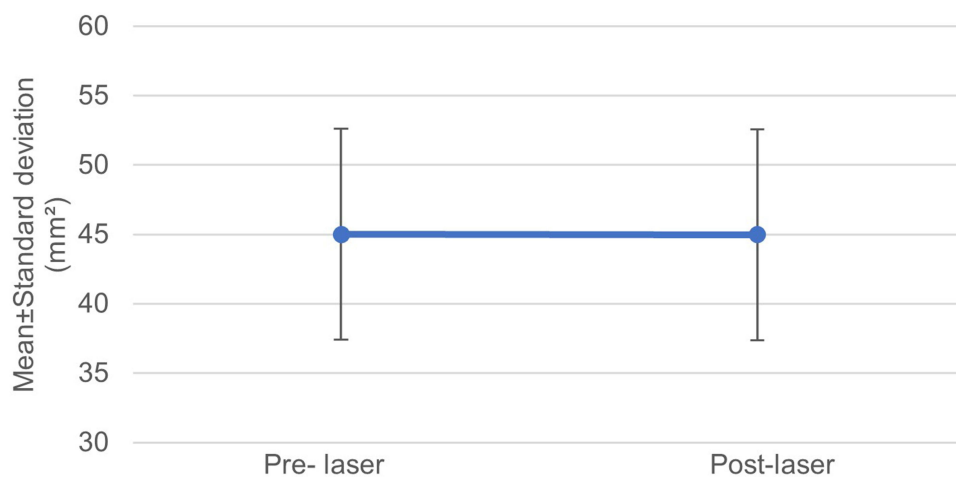


Figure 1 Means \pm standard deviations of preoperative and post-laser pupil areas in 82 eyes undergoing low-energy femtosecond laser assisted cataract surgery (FLACS).

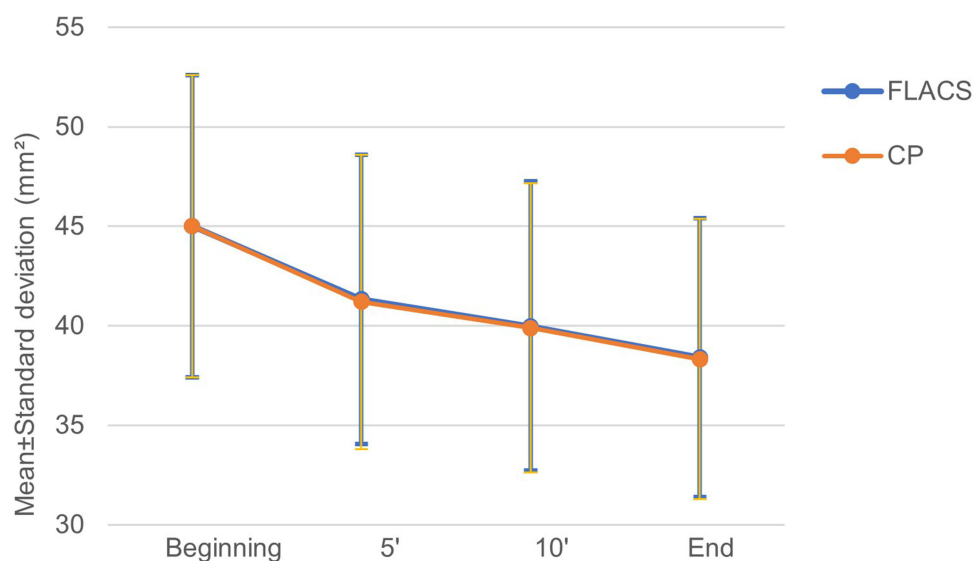


Figure 2 Mean \pm standard deviation of pupil area in 164 eyes undergoing low-energy FLACS (82 eyes) and CP (82 eyes), along different timepoints.

Abbreviations: FLACS, femtosecond laser assisted cataract surgery; CP, conventional phacoemulsification.

Table 3 Comparison of Mean Pupilar Area Along Surgical Timepoints Between FLACS and CP

Surgical Timepoints	FLACS	CP	p value
	Mean ± SD (mm ²)		
Beginning	45.01 ± 7.60	45.00 ± 7.60	0.748
5 minutes intra-op	41.33 ± 7.27	41.21 ± 7.40	0.076
10 minutes intra-op	39.98 ± 7.26	39.89 ± 7.27	0.032*
Final	38.41 ± 7.01	38.33 ± 7.04	0.051
Total variation	−6.59 ± 2.08	−6.67 ± 2.13	0.080

Note: *Statistically significant.

Abbreviation: SD, standard deviation.

Concerning the comparison of total pupil variation between techniques in eyes with ocular comorbidities versus eyes without ocular morbidities (as a between-subject factor), a non-statistically significant difference of 0.07 ± 0.04 mm², although close to the limit of significance, was shown ($p=0.071$; 95% CI: -0.01 to 0.16]. When comorbidity was present, the mean difference between techniques in total pupil variation was 0.19 ± 0.59 mm², with less narrowing in the FLACS group, but not statistically significant ($p=0.131$, 95% CI: -0.06 to 0.44), whereas in eyes without comorbidity, the mean difference between techniques was 0.03 ± 0.22 mm² ($p=0.391$, 95% to CI: -0.03 to 0.08) (Figure 3).

Regarding the comorbidity subgroups analysis, the pseudo exfoliation syndrome subgroup showed the higher degree of myosis during surgery amongst all subgroups, which was similar for both techniques ($p=0.614$) (Table 4). However, comparison between the two techniques revealed a mean difference of 0.78 ± 0.95 mm² ($p=0.176$), close to the limit of significance, in eyes with shallow anterior chamber, associated with a lesser pupil narrowing in the FLACS group.

Two subgroups were created, considering the median age (74 years old). In eyes of patients aged ≤ 74 years, the mean difference in pupil variation between techniques was 0.06 ± 0.44 mm² ($p=0.379$), whereas the mean difference in pupil variation was 0.09 ± 0.28 mm² in eyes of patients above 74 years old, close to the limit of significance ($p=0.058$). An independent *t*-test (between-subjects) comparing the two age subgroups (above and below 74 years of age), showed no statistically difference significance between FLACS and CP ($p=0.716$).

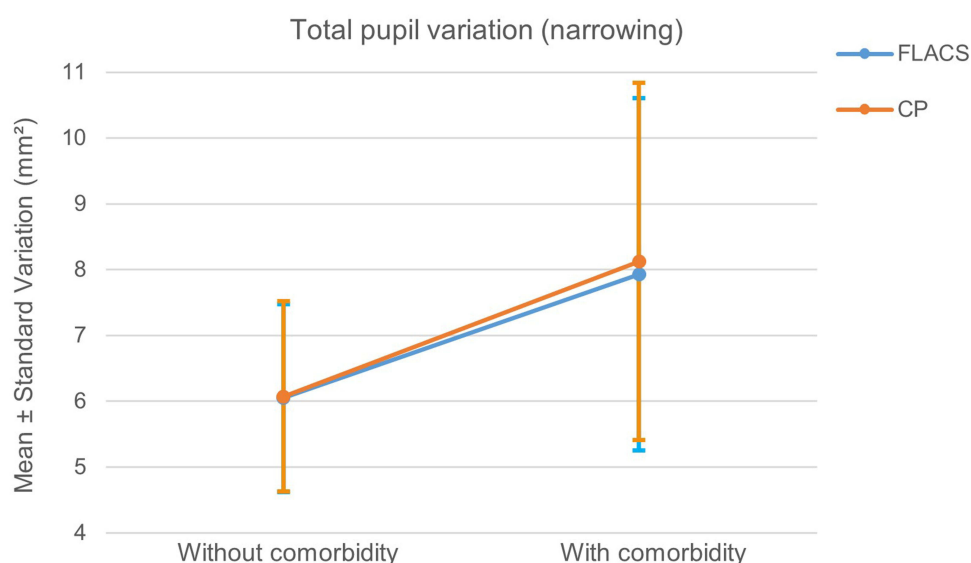


Figure 3 Mean \pm standard deviation values of pupil area narrowing (total pupil variation) for both techniques and presence or absence of ocular comorbidity.

Abbreviations: FLACS, femtosecond laser assisted cataract surgery; CP, conventional phacoemulsification.

Table 4 Comparison of Total Pupil Variation Between FLACS and CP According to Comorbidity

Ocular Comorbidity (n)	FLACS	CP	Mean Diff [95% CI]	p value
	Mean ± SD (mm ²)			
None (58)	6.05 ± 1.43	6.07 ± 1.44	0.03 [-0.03;0.08]	0.391
Pex (11)	8.69 ± 2.78	8.74 ± 2.85	0.06 [-0.19;0.31]	0.614
Shallow AC (5)	6.69 ± 0.78	7.47 ± 1.40	0.78 [-0.54;2.10]	0.176
Others (8)	7.67 ± 2.95	7.67 ± 2.94	0.003 [-0.08;0.09]	0.919

Abbreviations: CI, confidence interval; Diff, difference; n, number of eyes; SD, standard deviation.

Discussion

To this point, no other intraindividual study comparing low-energy femtosecond laser with conventional phacoemulsification was performed regarding pupil area variation.

The vast majority of publications approach mainly high-energy femtosecond laser devices, with strong evidence of laser-induced myosis by this type of laser.^{20,21} On the other hand, some recent evidence is being apparent that low-energy femtosecond laser does not induce such narrowing of the pupil.²²

Our study's results agree with the published literature regarding the same type of femtosecond pulse.^{18,19,22} No significant pupil changes were observed in the present study with low-energy FLACS, in contrast with the reported common association of laser-induced myosis with high-energy and low-frequency femtosecond pulse machines available in the market.^{23,24} Again, the rationale for this difference may be that smaller laser spots, as produced by a high numerical aperture in the laser optics of "low-energy" devices, would reduce associate damage to the neighbouring tissues. Consequently, this weaker impact would translate into a lower prostaglandins level, and thus producing lesser intraoperative myosis.

Aside from tissue interaction, another aspect may contribute to the loss of preoperative mydriasis, such as the patient transfer time. This transfer process is mandatory for most platforms using high-energy pulse,^{25,26} since the related FS machines are not portable; in contrast, portability is a feature of the low-energy pulse platform available in the market. Similarly, in our study, no complications regarding capsule-related events were observed; namely, no incomplete capsulotomies, anterior capsular tags, and anterior or posterior capsular tears were registered. This evidence is opposed to most reviews' conclusions about FLACS, but it should stressed that these reports neither contemplate "low-energy" devices or, if included, differentiate between the two types of femtosecond pulse.^{10,11,27}

This study found some differences in pupil area variation between FLACS and CP along surgical time (timepoints), although not statistically significant. Reports of a significant higher pupil area with FLACS immediately after suction,¹⁹ were not apparent in our study. In those studies, anti-inflammatory eye drops were placed preoperatively on the eye population. It should be stressed that opposed to such reports, no anti-inflammatory drug was administered in any of our study eyes. Therefore, no potential bias in laser interaction on ocular tissues due to the myosis inhibition's role of such drugs was registered in the present study.

The findings regarding a greater amount of pupil narrowing in eyes with comorbidities during conventional cataract surgery are consistent with the published literature. Nevertheless, the present study further reveals that there is a strong but non-statistically significant difference in eyes with a shallow anterior chamber (<2.5 mm), between FLACS and CP.

A possible explanation for this difference may rely on the fact that the time of anterior chamber exposure with CP is longer than with FLACS (as several surgical steps are performed with a “closed” eye globe, through laser). This, in turn, would facilitate reflective myosis upon “open-eye” manipulation with CP.

In this study, surgical procedure time (from beginning to the end), was similar in both techniques, with no statistically significant difference between FLACS and CP ($p>0.05$); the portability of the employed femtosecond machine may contribute to this aspect, as the patient remains in the same surgical environment (same bed and a single operating room) during the whole femtosecond-phacoemulsification sequence. Our study results are in agreement with few other published reports,²⁸ regarding the negligible impact on surgical time associated to portable femtosecond devices.

Conclusion

In conclusion, this intraindividual study provides extended evidence of lack of laser-induced myosis with low-energy FLACS. Furthermore, regarding pupil status, low-energy femtosecond laser-assisted energy seems to compare favorably with conventional phacoemulsification in the presence of certain ocular comorbidities. Although not statistically significant, this difference arises an interesting discussion and, also in line with contemporary literature, it recommends revision of some established, global opinions on FLACS. Further studies on low-energy femtosecond laser-assisted cataract surgery, involving higher samples and rigorous variable control, are in demand for this matter.

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Disclosure

The authors have no financial conflicts of interest to disclose.

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