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ORIGINAL PAPER

Presbyopic lens exchange (PRELEX) cataract surgery outcomes with implantation of a rotationally asymmetric refractive multifocal intraocular lens: femtosecond laser-assisted versus manual phacoemulsification

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Abstract
Purpose To compare the visual and refractive outcomes obtained with the implantation of a rotationally asymmetric refractive multifocal IOL after femtosecond laser-assisted cataract surgery (FLACS) and conventional lens extraction (CLE).
Methods A total of 78 eyes of 58 patients that had undergone conventional phacoemulsification (36 eyes, CLE group) or FLACS (37 eyes, FLACS group) with the implantation of the toric multifocal IOL LU-313 MF30T (Oculentis, Germany) were enrolled in this retrospective study. Mean age was 57.0 years at the time of surgery, ranging from 44 to 69 years. Visual and refractive outcomes were evaluated during a 12-month follow-up. Likewise, contrast sensitivity was assessed at the end of the follow-up.
Results Significant improvements were observed in both groups in uncorrected distance (UDVA) and near visual acuity (UNVA) at 1 month postoperatively ($p < 0.001$). Differences between groups in these parameters as well as in sphere and cylinder did not reach statistical significance during the whole follow-up ($p \geq 0.079$), except for UNVA only at 12 months postoperatively ($p = 0.018$). Concerning corrected near visual acuity, only significant differences between groups were found preoperatively ($p = 0.020$). Furthermore, only a minimal but significant difference between groups was found at 12 months postoperatively in contrast sensitivity for the spatial frequency of 18 cycles/° ($p = 0.029$).
Conclusions The rotationally asymmetric toric multifocal IOL LU-313 MF 30T provides good visual rehabilitation for near and distance vision after presbyopic lens extraction in eyes with preexisting astigmatism, independently whether the cataract surgery is performed with the FLACS or conventional technique.

Keywords Presbyopia · Refractive lens extraction · Clear lens extraction · Phacoemulsification · Femtosecond laser-assisted cataract surgery · Multifocal intraocular lens · Rotationally asymmetric multifocal intraocular lens

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Introduction

Presbyopic refractive lens exchange (PRELEX) surgery is usually performed in active patients that lose their accommodation ability and need spectacle independence [1]. The typical patient would be over 50 years old, with commonly a mild hyperopic refractive error. The surgical procedure is basically the same as for cataract surgery, but it is done for refractive reasons and not for the presence of an opacification of the crystalline lens [2]. Likewise, as these patients require good distance, intermediate and near vision without wearing spectacles or contact lenses, multifocal intraocular lenses (MIOLs) are implanted in PRELEX surgery [2]. One type of MIOL is the Mplus (Oculentis GmbH, Berlin, Germany) which has a rotationally asymmetrical refractive design [3]. Several studies have confirmed the ability of this specific type of MIOL of restoring the visual function after cataract surgery [4–13], with high levels of quality of life and patient satisfaction associated [5, 10].

In PRELEX surgery, as in conventional cataract surgery, the natural lens nucleus and cortex are removed, being the gold standard or conventional method for removing the lens nucleus the phacoemulsification, which was introduced by Charles Kelman in 1967 [14]. However, in the last years, the evolution of femtosecond lasers has led to the development of platforms allowing the performance of laser-guided corneal incision, capsulotomy and lens fragmentation [15]. Femtosecond laser-assisted cataract surgery (FLACS) offers the possibility of creating a precise and predictable capsulotomy leading potentially to a more stable position of the IOL within the capsular bag compared to phacoemulsification, which is especially critical when implanting MIOLs and toric IOLs [16]. Although there are studies showing the results of MIOL implantation using FLACS [17], there are no comparative studies evaluating the potential benefit in terms of visual performance of implanting a MIOL using FLACS compared to conventional phacoemulsification. It should be considered that the impact of tilt and decentration on optical quality has been shown in optical bench experiences to be more severe with rotationally asymmetric refractive IOL in comparison with other MIOLs [3]. The aim of the current study was to compare the visual and refractive outcomes obtained with the implantation of the toric version of the Mplus multifocal IOL after FLACS and conventional phacoemulsification in eyes with preexisting astigmatism.

Methods

Patients

This was a retrospective study enrolling patients who underwent either conventional phacoemulsification (conventional lens extraction group, CLE group) or FLACS (FLACS group) followed by implantation of the multifocal IOL Mplus between January 2015 and January 2016. The inclusion criterion was presbyopic/pre-presbyopic patients demanding spectacle independence with corneal astigmatism over 1.00 D. Exclusion criteria were previous ocular surgery, antecedents of glaucoma, ocular inflammation or retinal detachment, active ocular disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy and neuro-ophthalmic disease. All patients were properly informed about their inclusion in the study and signed an informed consent form. The study complied with the principles of the Declaration of Helsinki and was approved by the ethics committee of the Jessenius Faculty of Medicine of Comenius University (JFMED CU). Only both eyes of the same patient were included in 20 patients from the whole sample (78), but in such cases each eye was assigned to a different group (CLE or FLACS), and therefore, a different surgical protocol was used.

Examination protocol

A complete ophthalmologic examination was performed preoperatively including refraction, keratometry, monocular uncorrected (UDVA) and corrected distance visual acuity (CDVA), monocular uncorrected (UNVA) and corrected near visual acuity (CNVA) measured at 33 cm, Goldmann applanation tonometry, slit lamp examination, corneal topography (OPD scan III, Nidek), biometry (IOL Master version 4.3, Carl Zeiss Meditec) and funduscopy. Visual acuities were measured using the ETDRS (Early Treatment Diabetic Retinopathy Study) charts. After optical biometry, IOL power calculations were performed using the Hoffer Q formula in all cases.

The following postoperative visits were scheduled: 1 day, 1 week, 1 month and 12 months after surgery. The same tests as preoperatively were done at 1 and 12 months after surgery, with the additional inclusion at 12 months postoperatively of the evaluation of photopic contrast sensitivity (LCD optotype CX-1000, Topcon, Japan).

Surgical procedure

Conventional phacoemulsification was performed in all cases with the 45° balanced tip with the Intrepid® Ultra Sleeve connected to the Constellation Vision System (Alcon Laboratories, Inc., Fort Worth, TX). Femtosecond laser nucleus cutting and capsulorrhexis were performed using the Victus Technolas Perfect Vision system (Bausch & Lomb, Munich, Germany). The procedures were performed in two surgical centers (Eye clinic in University Hospital and UVEA Mediklinik, both in Martin) by two experienced surgeons. Local anesthesia was instilled in all operated eyes prior to surgery. The 0-degree and 180-degree positions were marked on the slit lamp with a sterile Buratto marker after the patient's head was vertically aligned to control and prevent cyclorotations during surgery. After this, the patient was prepared and draped for surgery. Incisions were made at 90° in all cases. After nucleus extraction, irrigation–aspiration, anterior capsule cleaning from the inner side and posterior capsule polishing were performed. IOL was then inserted in the capsular bag through a 2.75-mm corneal incision using the Viscoject 2.2 injector (Oculentis, Germany), with the reading add placed inferiorly and the axis of astigmatism aligned to the external manual marks previously performed. If PRELEX was performed in both eyes, surgery in the second eye was usually performed 1 week after the first eye. Postoperatively, patients were instructed to instill 1 drop of levofloxacin 0.5% (Oftaquix) five times daily for 1 week and 1 drop of loteprednol 0.1% (Lotemax) five times daily for 1 month, and tapering.

Intraocular lens

All patients were implanted with the toric multifocal IOL LU-313 MF30T (Oculentis, Germany). It is a rotationally asymmetric multifocal IOL with a refractive design, combining an aspheric distance vision zone with a sector-shaped near vision zone with a +3.00 D add (Oculentis, Germany). This foldable IOL has an overall length of 12.0 mm, an optic diameter of 6.0 mm and a plate haptic design. The IOL is of a hydrophilic acrylic material with a hydrophobic surface.

Statistical analysis

Statistical analysis was performed using the software SYSTAT (Systat Software, San Jose, CA). Nonparametric statistics was used as any data distribution used in the study followed a normal distribution (Kolmogorov–Smirnov test). The Friedman two-way analysis of variance and multiple comparison tests (Wilcoxon rank test with Bonferroni correction) were used for all parameter comparisons between visits within a same group. The analysis between the two groups involved in the study was performed by using the nonparametric Mann–Whitney U test with Bonferroni correction. In all cases, the same level of statistical significance was considered significant, $p < 0.05$.

Results

A total of 78 eyes of 58 patients that had undergone conventional phacoemulsification (36 eyes, CLE group) or FLACS (37 eyes, FLACS group) were enrolled in the study. Mean age was 57.0 years at the time of surgery, ranging from 44 to 69 years, with no statistically significant differences between groups in this parameter ($p = 0.452$). Of the 58 patients, 35 were female (60.3%). Table 1 summarizes the preoperative and postoperative visual and refractive data in CLE and FLACS groups. As shown, no statistically significant differences were found preoperatively and postoperatively in UDVA, CDVA, refraction (sphere and cylinder) and keratometric data between CLE and FLACS groups ($p \geq 0.079$). Concerning CNVA, only statistically significant differences between groups were found preoperatively ($p = 0.020$). Likewise, only statistically significant differences in UNVA between groups were found at 12 months postoperatively ($p = 0.018$).

Concerning longitudinal changes, a significant improvement in UDVA was observed in both groups at 1 month after surgery ($p < 0.001$), with also a significant change during the remaining follow-up

Table 1 Comparative table showing the preoperative and postoperative clinical data of eyes included in the two groups of eyes of the current study

Mean (SD) Median (range)	Preoperative data			1-month postoperative data			12-month postoperative data		
	CLE group	FLACS group	*P* value	CLE group	FLACS group	*P* value	CLE group	FLACS group	*P* value
LogMAR UDVA	0.52 (0.42) 0.40 (0.10 to 1.70)	0.53 (0.34) 0.52 (0.00 to 1.30)	0.606	0.11 (0.19) 0.05 (− 0.08 to 0.80)	0.05 (0.12) 0.05 (− 0.15 to 0.30)	0.619	0.03 (0.10) 0.00 (− 0.18 to 0.30)	0.01 (0.08) 0.00 (− 0.08 to 0.22)	0.664
LogMAR CDVA	− 0.02 (0.06) 0.00 (− 0.08 to 0.22)	− 0.02 (0.05) 0.00 (− 0.18 to 0.05)	0.867	0.00 (0.06) 0.00 (− 0.08 to 0.15)	− 0.02 (0.10) − 0.04 (− 0.15 to 0.30)	0.079	− 0.04 (0.06) − 0.06 (− 0.18 to 0.10)	− 0.02 (0.07) − 0.04 (− 0.18 to 0.22)	0.254
LogMAR UNVA (33 cm)	0.91 (0.19) 1.00 (0.30 to 1.30)	0.97 (0.27) 1.00 (0.30 to 1.30)	0.291	0.05 (0.06) 0.00 (0.00 to 0.30)	0.08 (0.11) 0.00 (0.00 to 0.40)	0.632	0.04 (0.06) 0.00 (0.00 to 0.20)	0.11 (0.12) 0.10 (0.00 to 0.40)	0.018
LogMAR CNVA (33 cm)	0.01 (0.02) 0.00 (0.00 to 0.10)	0.00 (0.00) 0.00 (0.00 to 0.00)	0.020	0.01 (0.03) 0.00 (0.00 to 0.10)	0.00 (0.02) 0.00 (0.00 to 0.10)	0.162	0.01 (0.02) 0.00 (0.00 to 0.10)	0.00 (0.01) 0.00 (0.00 to 0.05)	0.933
Sphere (D)	2.38 (2.89) 1.88 (− 9.00 to 8.50)	2.45 (1.56) 1.75 (0.75 to 6.00)	0.698	− 0.23 (0.40) 0.00 (− 1.75 to 0.00)	− 0.09 (0.32) 0.00 (− 0.75 to 1.00)	0.194	− 0.11 (0.38) 0.00 (− 1.00 to 0.50)	− 0.04 (0.25) 0.00 (− 1.00 to 0.50)	0.535
Cylinder (D)	− 0.26 (0.39) 0.00 (− 1.50 to 0.00)	− 0.28 (0.38) 0.00 (− 1.00 to 0.00)	0.657	− 0.33 (0.45) 0.00 (− 1.50 to 0.00)	− 0.31 (0.46) 0.00 (− 1.75 to 0.00)	0.910	− 0.23 (0.37) 0.00 (− 1.00 to 0.00)	− 0.15 (0.32) 0.00 (− 1.00 to 0.00)	0.280
Spherical equivalent (D)	2.24 (2.87) 1.81 (− 9.38 to 8.00)	2.31 (1.52) 1.75 (0.50 to 6.00)	0.803	− 0.39 (0.53) − 0.13 (− 1.75 to 0.00)	− 0.25 (0.40) 0.00 (− 1.12 to 0.75)	0.440	− 0.23 (0.43) 0.00 (− 1.50 to 0.00)	− 0.11 (0.24) 0.00 (− 1.00 to 0.12)	0.606
J_0 (D)	− 0.01 (0.16) 0.00 (− 0.48 to 0.29)	0.02 (0.20) 0.00 (− 0.47 to 0.50)	0.995	− 0.09 (0.18) 0.00 (− 0.59 to 0.17)	0.01 (0.23) 0.00 (− 0.82 to 0.62)	0.026	− 0.03 (0.19) 0.00 (− 0.50 to 0.50)	0.00 (0.15) 0.00 (− 0.38 to 0.47)	0.184
J_{45} (D)	− 0.01 (0.17) 0.00 (− 0.38 to 0.57)	0.03 (0.12) 0.00 (− 0.17 to 0.47)	0.163	− 0.03 (0.20) 0.00 (− 0.47 to 0.74)	− 0.04 (0.16) 0.00 (− 0.49 to 0.25)	0.395	− 0.01 (0.10) 0.00 (− 0.32 to 0.24)	0.01 (0.10) 0.00 (− 0.37 to 0.32)	0.447
K1 (D)	42.90 (1.33) 42.52 (40.75 to 45.87)	42.54 (1.09) 42.50 (40.25 to 44.75)	0.436	42.92 (1.42) 42.63 (40.25 to 45.87)	42.73 (1.13) 42.50 (40.50 to 44.75)	0.778	42.92 (1.46) 42.63 (40.62 to 46.25)	42.61 (1.12) 42.50 (40.50 to 44.75)	0.603

Table 1 continued

Mean (SD) Median (range)	Preoperative data			1-month postoperative data			12-month postoperative data		
	CLE group	FLACS group	*P* value	CLE group	FLACS group	*P* value	CLE group	FLACS group	*P* value
K2 (D)	43.71 (1.47)	43.21 (0.95)	0.230	43.62 (1.44)	43.39 (1.03)	0.682	43.57 (1.56)	43.40 (1.21)	0.996
	43.46 (41.50 to 46.50)	43.00 (41.00 to 44.71)		43.38 (41.50 to 46.50)	43.50 (41.25 to 45.25)		43.19 (41.50 to 47.00)	43.25 (41.00 to 45.75)	
Scotopic pupil diameter (mm)	5.06 (0.98)	4.93 (0.70)	0.716	–	–	–	–	–	–
	4.93 (2.43 to 7.18)	4.87 (2.85 to 6.19)							
Photopic pupil diameter (mm)	3.36 (0.78)	3.46 (0.49)	0.244	–	–	–	–	–	–
	3.27 (1.84 to 5.54)	3.52 (2.49 to 4.74)							

The corresponding *P* values for the comparison between groups are shown for each parameter evaluated

SD standard deviation, *D* diopters, *CLE* conventional lens extraction, *FLACS* femtosecond laser-assisted cataract surgery, *UDVA* uncorrected distance visual acuity, *CDVA* corrected distance visual acuity, *UNVA* uncorrected near visual acuity, *CNVA* corrected near visual acuity, J_0 and J_{45} power vector components of refractive astigmatism, *K1* keratometric reading on the flattest corneal axis, *K2* keratometric reading on the steepest corneal axis

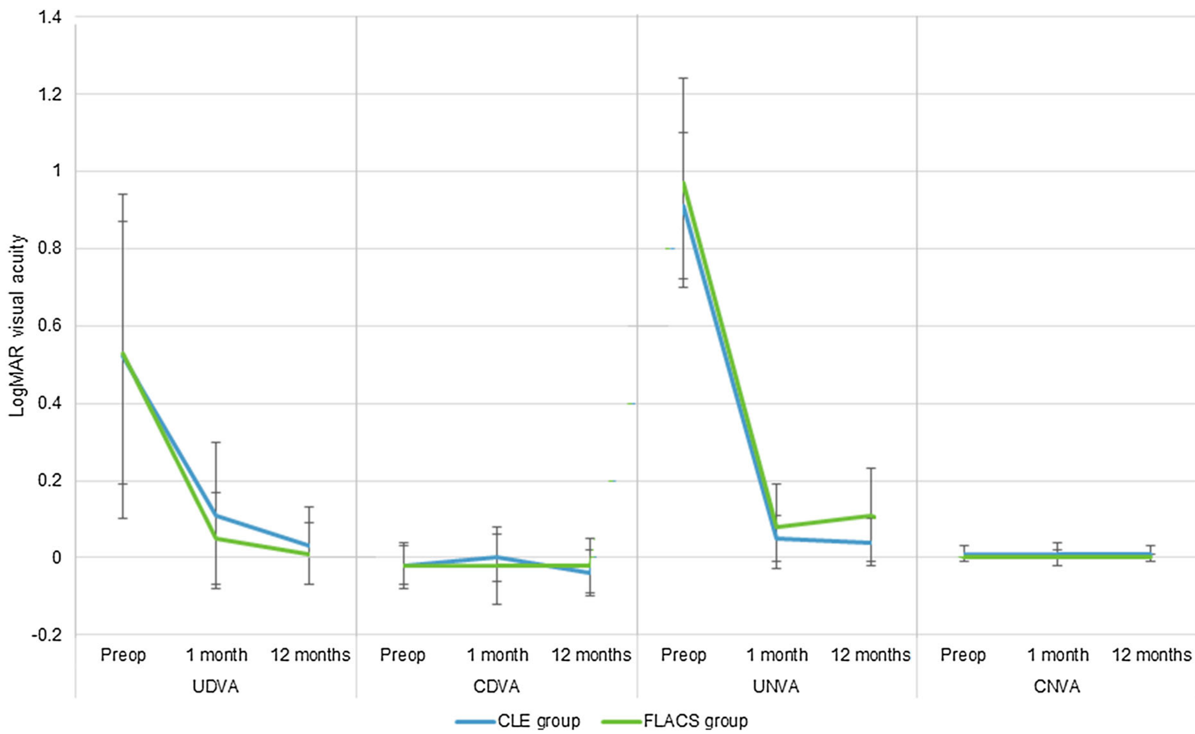

Fig. 1 Changes during the follow-up in uncorrected distance (UDVA) and near visual acuity (UNVA), as well as in corrected distance (CDVA) and near visual acuity (CNVA) in the two groups of the current study

(1–12 months: CLE group, $p = 0.010$; FLACS group, $p = 0.020$) (Fig. 1). Likewise, a statistically significant change was observed in both groups in UNVA at 1 month postoperatively ($p < 0.001$), with no significant changes afterward (1–12 months: CLE group, $p = 0.748$; FLACS group, $p = 0.191$) (Fig. 1). Concerning CDVA and CNVA, no significant changes were observed during the follow-up ($p \geq 0.201$), except for CDVA between 1- and 12-month postoperative visits in group 1 ($p = 0.004$) (Fig. 1). Concerning binocular measurements, no significant differences were found between groups in binocular UDVA at 1 (CLE 0.00 ± 0.07 vs. FLACS 0.01 ± 0.12, $p = 0.964$) and 12 months postoperatively (CLE -0.05 ± 0.08 vs. FLACS -0.04 ± 0.08, $p = 0.414$) as well as in binocular UNVA at 1 month after surgery (CLE 0.02 ± 0.06 vs. FLACS 0.05 ± 0.09, $p = 0.103$). In contrast, significant differences between groups were found in binocular 12-month postoperative UNVA (CLE 0.02 ± 0.05 vs. FLACS 0.08 ± 0.13, $p = 0.016$).

Figure 2 shows the contrast sensitivity outcomes in CLE and FLACS groups at 12 months after surgery for the four spatial frequencies evaluated. No statistically significant differences between groups were found in contrast sensitivity for 3 ($p = 0.999$), 6 ($p = 0.585$) and 12 cycles/° ($p = 0.847$). Only a significant difference between groups was found in contrast sensitivity corresponding to the spatial frequency of 18 cycles/° ($p = 0.029$).

Discussion

In the current study, the visual and refractive outcomes obtained after cataract surgery with implantation of a rotationally asymmetric refractive toric multifocal IOL were evaluated. Two groups were differentiated depending on whether the FLACS technique was used or not. As expected, in both groups, a significant improvement in uncorrected distance and near visual acuity was obtained postoperatively. These outcomes in distance and near vision were consistent with those obtained in previous studies implanting the same model of multifocal IOL with and without toricity [5, 12]. Likewise, the results obtained in our series in terms of UDVA and UNVA were consistent with those obtained with other models of multifocal IOLs, including diffractive lenses [18–22]. Visual acuity and refractive outcomes were excellent in both groups, with no statistically significant differences between them at 1 month or 1 year postoperatively, except for UNVA at 12 months. In this specific case, UNVA was significantly worse in FLACS group compared to CLE group at the end of the follow-up, although the difference was small in magnitude (approximately half a LogMAR line). Likewise, a small in magnitude but statistically significant difference in contrast sensitivity was also found at 12 months postoperatively for the highest spatial frequency, with the best outcome also in the CLE group. This confirms that although a minor difference was present between eyes

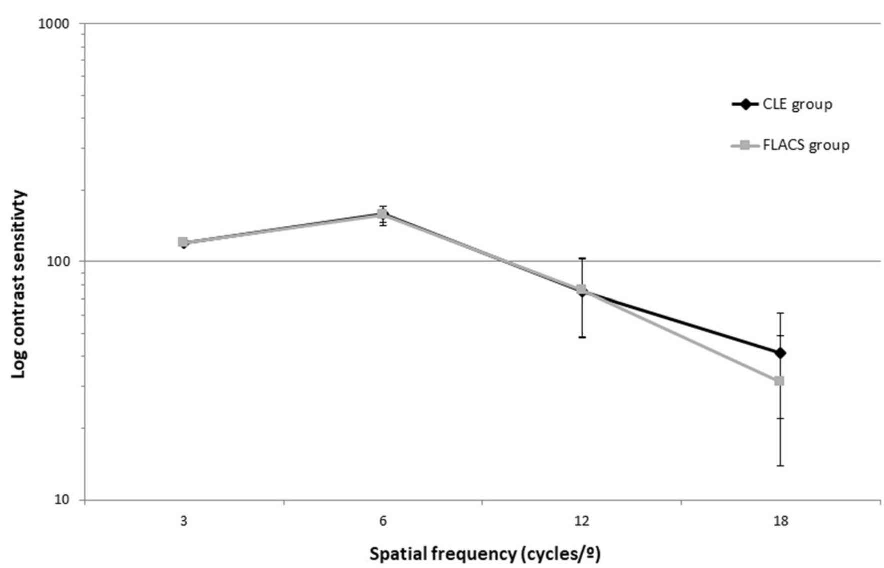

Fig. 2 Contrast sensitivity function at 12 months postoperatively in the two groups of the current study

operated on with femto-phaco over those undergoing conventional phacoemulsification, the general trend is an equivalence in visual acuity and refractive outcomes between procedures in spite of the implantation of an IOL with a toric multifocal optic.

Numerous studies have reported advantages of FLACS over conventional phacoemulsification cataract surgery [23]. One of the main advantages of FLACS is a shorter effective phacoemulsification time leading to better efficiency of femtosecond laser-assisted surgery [24], leading consequently to less endothelial cell loss and postoperative corneal edema [25]. Likewise, the higher level of control achieved with FLACS of capsulotomy diameter, shape and centration of the capsulorrhexis has been suggested to have a positive impact on IOL positional stability, with the consequent impact on visual quality and refractive outcomes [26]. However, a recent meta-analysis including 14,567 eyes did not find statistically significant differences between FLACS and manual cataract surgery with implantation of monofocal IOL in terms of patient-important visual and refractive outcomes and overall complications [27]. This has been also confirmed by other reviews and meta-analyses of the peer-reviewed literature [28, 29]. Our results are consistent with this previous analysis of the peer-reviewed literature. Furthermore, comparable results have been reported in eyes implanted with toric IOLs using FLACS and conventional phacoemulsification, suggesting that the impact of the control of capsulorrhexis with FLACS on IOL positional stability was not clinically relevant [30]. In our sample, the difference between FLACS and CLE has been evaluated in eyes implanted with an IOL with a more complex optics, a rotationally asymmetric refractive multifocal IOL combined with toricity. It should be considered that tilt and decentration with this type of multifocal IOL have been demonstrated to have a very significant negative impact on optical quality [3].

Finally, at the end of the follow-up, a small but statistically significant difference in UNVA and contrast sensitivity for 18 cycles/° was found, with the better outcomes in the CLE group. Several factors may have accounted for this finding, such as a trend to a more negative residual refractive error in FLACS, although the difference with CLE group did not reach statistical significance. Another potential factor may be the presence of some level of initial posterior capsular opacification in eyes from FLACS group, which has been shown to have the potential of limiting the near visual function in very early stages in eyes implanted with multifocal IOLs [31]. This would be evaluated in future studies analyzing the results of these two groups in the long term.

In conclusion, the LU-313 MF 30T rotationally asymmetric toric multifocal IOL provides good visual rehabilitation for near and distance vision after presbyopic lens extraction in eyes with preexisting corneal astigmatism, independently whether the cataract surgery is performed with the FLACS or conventional technique. This may suggest that the rotational stability of the IOL is excellent, with minor impact of a more controlled creation of the capsulorrhexis with FLACS.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Informed consent Informed consent was obtained from all individual participants included in the study.

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