Comparative clinical study of Whitestar Signature phacoemulsification system with standard and Ellips FX handpieces

Daniele Tognetto · Rossella D'Aloisio · Paolo Cecchini · Marta Di Nicola · Giuseppe Di Martino

Abstract

Purpose To compare the intraoperative parameters and postoperative outcomes using two different phaco handpieces with different energy delivery systems of the same phacoemulsification machine.

Methods One hundred and sixty eyes of 160 cataract patients were randomly assigned to 2.40 mm phacoemulsification using the AMO WhiteStar Signature® phaco system with the standard phaco handpiece (Group 1) or the Ellips FX phaco handpiece (Group 2). According to the lens opacities classification system III, each group was divided into four subgroups of 20 patients each. U/S total time (UST), total phaco time (TPT), mean effective phaco time, cumulative dissipated energy (CDE) and balanced salt solution (BSS) consumption were studied. Visual acuity, corneal endothelium cell count and corneal pachymetry were evaluated before surgery and 1, 7 and 30 days after surgery.

Results No statistically significant difference in terms of visual acuity was observed between the two groups. The postoperative endothelial cell loss and corneal pachymetry were similar between the two groups. In higher density cataracts, Ellips FX showed the lower CDE and the lowest UST. TPT and BSS consumption were significantly lower in the Ellips FX handpiece group.

Conclusions The two phaco handpieces appeared to be safe. AMO Ellips FX handpiece showed better performances and may be safer in lens removal, especially in hard cataract patients.

Keywords Cataract surgery · Phacoemulsification · Phaco handpieces · Visual acuity · Corneal endothelium

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Introduction

In the last years, many efforts have been made in order to improve the efficiency of phacoemulsification surgery [1–4]. It has been observed that the pulsed and burst modalities may reduce the phaco time and the amount of energy delivered [5–7]. Side effects like

corneal burns, endothelial cell loss and postoperative inflammation appear to be reduced [8–10].

More recently, Alcon and Abbott Medical Optics (AMO) have introduced new lens removal modalities. In 2005, Alcon launched the torsional OZil™ system, which achieves the lens fragmentation through a torsional movement producing a shearing effect rather than a conventional jackhammer effect [11, 12]. AMO Ellips technology is based on a transversal energy delivery system that generates an elliptical pattern of the phaco tip. In this modality, the lens material is cut both by a jackhammer effect and a side-to-side movement [13–16].

The first version of this technology was called Ellips, launched in 2008. In 2009, AMO introduced the new Ellips FX system, coupled with a new handpiece. The Ellips FX should offer better performances in terms of phaco efficiency in comparison with the standard handpiece with longitudinal movement.

In this study, we compared intraoperative parameters and postoperative outcomes using WhiteStar Signature phacoemulsification system with two different phaco handpieces having different energy delivery systems: standard longitudinal and Ellips FX with elliptical tip movement.

Table 1 Presurgery parameters expressed as median and interquartile range (IQR)

Variable		NO	NC
LOCS A	Standard	2.00 (1.90–2.20)	2.15 (2.00–2.30)
($n = 40$)	Ellips Fx	2.00 (2.00–2.00)	2.05 (2.00–2.30)
	p value[a]	0.414	0.837
LOCS B	Standard	3.20 (3.00–3.30)	3.20 (2.93–3.30)
($n = 40$)	Ellips Fx	3.10 (3.00–3.28)	3.10 (3.00–3.20)
	p value[a]	0.689	0.740
LOCS C	Standard	4.00 (3.83–4.20)	4.20 (4.00–4.28)
($n = 40$)	Ellips Fx	4.00 (4.00–4.30)	4.05 (4.00–4.30)
	p value[a]	0.195	0.815
LOCS D	Standard	5.25 (5.00–5.57)	5.30 (5.05–5.40)
($n = 40$)	Ellips Fx	5.30 (5.03–5.38)	5.30 (5.00–5.50)
	p value[a]	0.712	0.956
Overall	Standard	3.45 (2.33–4.78)	3.55 (2.48–4.70)
($n = 160$)	Ellips Fx	3.60 (2.50–4.80)	3.60 (2.63–4.88)
	p value[b]	0.870	0.929

LOCS III lens opacities classification system III, *NO* nuclear opalescence, *NC* nuclear color, *n* number of patients

[a] Differences of presurgery parameters in the same group of lens opacity density assessed by Mann–Whitney *U*-test

[b] Overall differences of presurgery parameters between standard and Ellips Fx probe assessed by Mann–Whitney *U*-test

Materials and methods

This study enrolled 160 cataract patients (160 eyes). The mean age was 77.08 ± 5.0 years. Patients were randomly assigned to receive cataract surgery by means of AMO WhiteStar Signature® phacoemulsification system using standard handpiece with longitudinal tip movement (Group 1, 80 patients), or using Ellips FX phaco handpiece with elliptical tip movement (Group 2, 80 patients). Each group was divided into four subgroups of 20 patients each (A, B, C, D), according to the hardness of the cataract, using the LOCS III cataract classification system [17, 18] (Table 1). No statistically significant difference was observed between standard and Ellips Fx subgroups in terms of cataract density (Table 1).

Patients with other ocular pathologies such as glaucoma, diabetes, age-related macular degeneration

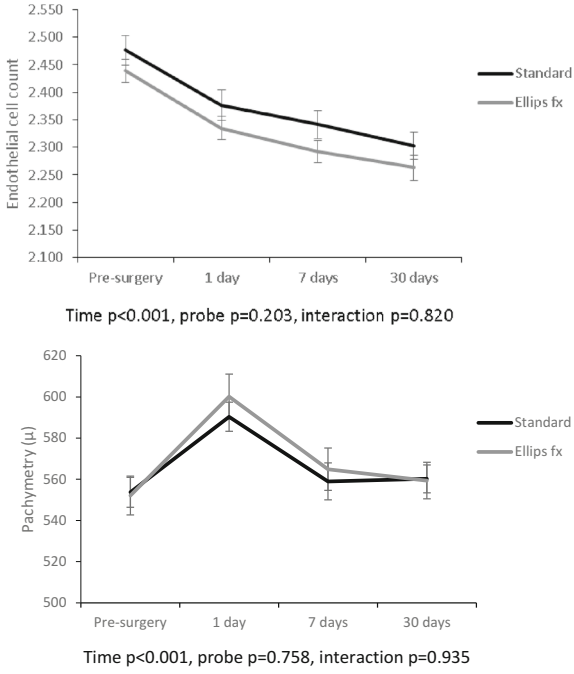

Fig. 1 Two-way ANOVA models for repeated measures assessed to evaluate endothelial cell count and pachymetry in different time points in LOCS A group. Data are expressed as mean and standard error

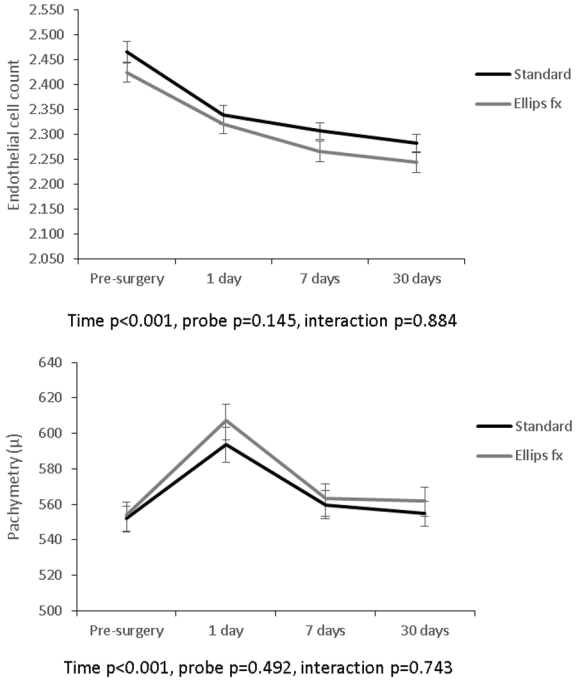

Fig. 2 Two-way ANOVA models for repeated measures assessed to evaluate endothelial cell count and pachymetry in different time points in LOCS B group. Data are expressed as mean and standard error

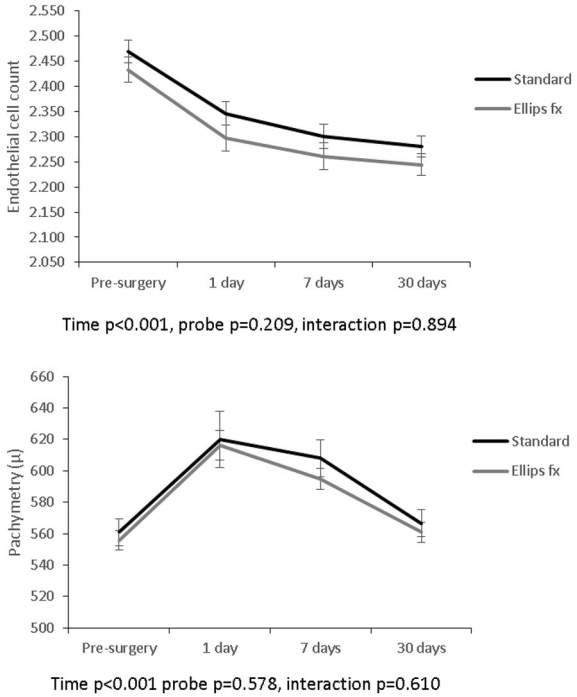

Fig. 3 Two-way ANOVA models for repeated measures assessed to evaluate endothelial cell count and pachymetry in different time points in LOCS C group. Data are expressed as mean and standard error

or previous ocular surgeries were excluded from the study.

The study adhered to the tenets of the Declaration of Helsinki and was approved by our Institutional Review Board, the Department of Medicine, Surgery and Health Sciences, University of Trieste, Trieste, Italy.

All patients received standard cataract procedure: after a 2.40 mm near clear corneal tunnel, DiscoVisc (1.6% hyaluronic acid–4.0% chondroitin sulfate; Alcon Laboratories, Inc., Fort Worth, TX, USA) injection into the anterior chamber, circular curvilinear capsulorrhexis, the lens material was removed performing a phaco chop technique. The phaco settings were: 360 mmHg panel vacuum, 38 cc/min linear flow rate, 100% linear U/S power, 20–67% linear "variable" micropulsed duty cycle. The phaco tip used was an AMO 20 Gauge phaco microtip. After lens removal, AMO PCB00 acrylic intraocular lens (IOL) was implanted.

All the surgical procedures were performed by the same surgeon (DT). Visual acuity expressed as LogMAR values, endothelial cell count (ConfoScan 4—Nidek Technologies, Inc., Padova, Italy) and central corneal pachymetry (bon SIRIUS—3D Rotating Scheimpflug Camera & Topography System—bon Optic Vertriebsges. mbH, Stellmacherstr. 14. 23556 Lübeck, Germany) were measured before surgery and 1, 7 and 30 days after surgery. For statistical purposes, we considered the percentage of cell loss and corneal thickness variation in comparison with the baseline values.

In order to assess phaco efficiency the following intraoperative variables were considered: U/S total time (UST), the total phaco time (TPT), the mean effective phaco time (EPT) expressed in seconds, the cumulative dissipated energy (CDE) expressed as percentage and the balanced salt solution (BSS) consumption, expressed in cubic centimeter (cc).

Statistical analysis

The quantitative variables were summarized as mean and standard deviation (SD) or median and interquartile range (IQR) according to their distribution. Qualitative variables were summarized as frequency

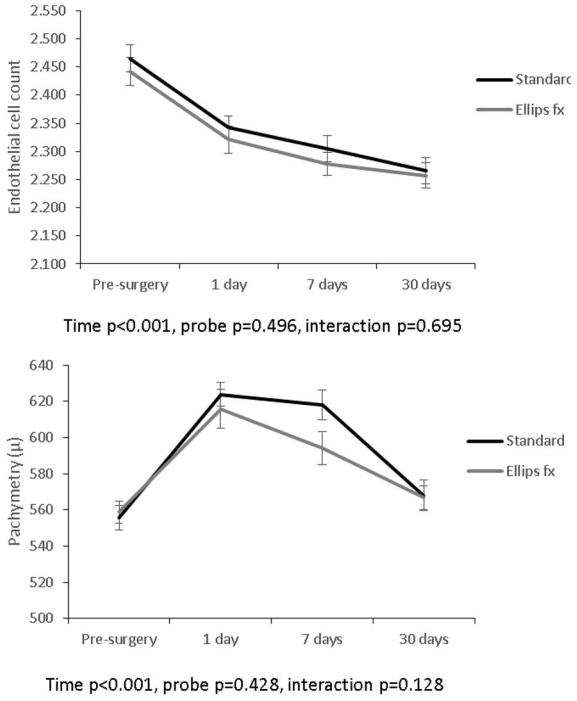

Fig. 4 Two-way ANOVA models for repeated measures assessed to evaluate endothelial cell count and pachymetry in different time points in LOCS D group. Data are expressed as mean and standard error

and percentage. A Shapiro–Wilk's test was performed to evaluate the departures from normality distribution for each variable. Mann–Whitney *U*-test was assessed to evaluate differences of all presurgery and intra-surgery parameters between two probe groups. Different two-way ANOVA for repeated measures were assessed to evaluate the effect of time, probe and their interaction on endothelial cell count and on pachymetry in all LOCS group. $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS® software 11.0 (SPSS Inc, Chicago, IL, USA).

Results

Pre- and intra-surgery variables were summarized as median and IQR due to significant results at Shapiro–Wilk's test ($p < 0.05$).

No statistically significant difference in preoperative parameters among the four density cataract subgroups was found (Table 1). Pachymetry and endothelial cell count variables are summarized in Figs. 1, 2, 3 and 4 as mean and SD due to nonsignificant results at Shapiro–Wilk's test ($p > 0.05$). The mean visual acuity of the two groups, divided into four subgroups according to the cataract density (LOCS A, B, C and D), is shown in Table 2.

No statistically significant difference was observed between the two handpiece groups ($p > 0.05$).

The UST, CDE, TPT and BSS consumption are reported in Table 3. Due to the difference in technology of the two handpieces, the EPT results were not comparable. There was a statistically significant difference in the UST between the two handpiece groups when comparing LOCS subgroups B, C and D. In subgroup A (mild cataracts), the lowest UST was achieved by means of the normal longitudinal phaco even though the difference was not significant. For higher density cataracts (subgroups B, C, D), the lowest UST was observed using the Ellips FX handpiece. In terms of CDE, the standard longitudinal phaco performed better than the Ellips FX handpiece for cataract density subgroup A. No differences were observed in subgroup B while the Ellips Fx handpiece proved to perform better in LOCS subgroups C and D. The difference was statistically significant. The TPT was significantly different between the two handpiece groups in subgroups B and D with a lower value for Ellips FX. The BSS consumption was statistically different between the two handpiece groups in subgroups A, B and D, with lower values for Ellips

Table 2 Differences in visual acuity (logMar) between standard and Ellips Fx probe groups

	Standard				Ellips Fx			
	Preoperative	1 day	7 days	30 days	Preoperative	1 day	7 days	30 days
LOCS A	0.51 ± 0.24	0.18 ± 0.12	0.09 ± 0.07	0.03 ± 0.03	0.48 ± 0.18	0.13 ± 0.05	0.04 ± 0.03	0.02 ± 0.03
LOCS B	0.42 ± 0.08	0.18 ± 0.15	0.08 ± 0.04	0.03 ± 0.03	0.62 ± 0.24	0.11 ± 0.09	0.08 ± 0.08	0.02 ± 0.03
LOCS C	0.57 ± 0.20	0.19 ± 0.21	0.08 ± 0.04	0.03 ± 0.02	0.60 ± 0.22	0.16 ± 0.10	0.08 ± 0.04	0.03 ± 0.03
LOCS D	0.78 ± 0.26	0.30 ± 0.17	0.10 ± 0.05	0.03 ± 0.02	0.76 ± 0.22	0.26 ± 0.15	0.06 ± 0.07	0.03 ± 0.04

LOCS III lens opacities classification system III

Table 3 Intra-operative parameters expressed as median and interquartile range (IQR)

Variable		EPT	UST	CDE	TPT	BSS
LOCS A	Standard	0.7 (0.2–0.8)	14.0 (12.6–14.9)	15.0 (11.0–16.0)	86.5 (80.5–90.0)	155.0 (130.0–170.0)
($n = 40$)	Ellips Fx		16.4 (11.0–22.9)	18.0 (14.0–21.0)	80.0 (62.5–93.7)	115.0 (92.5–150.0)
	p value[a]		0.242	**0.009**	0.149	**0.003**
LOCS B	Standard	3.4 (0.7–4.8)	34.2 (27.9–37.4)	21.0 (16.5–24.0)	120.0 (111.2–125.0)	160.0 (150.0–170.0)
($n = 40$)	Ellips Fx		26.8 (19.9–34.3)	20.0 (18.5–21.0)	100.0 (90.0–110.0)	135.0 (112.5–160.0)
	p value[a]		**0.030**	0.461	**0.001**	**0.012**
LOCS C	Standard	4.3 (2.7–7.1)	42.6 (35.5–46.4)	26.0 (20.0–28.0)	128.5 (100.0–140.2)	170.0 (130.0–180.0)
($n = 40$)	Ellips Fx		31.7 (27.1–41.1)	21.0 (20.0–23.7)	120.0 (92.5–155.0)	170.0 (162.5–187.5)
	p value[a]		**0.024**	**0.038**	0.904	0.414
LOCS D	Standard	24.0 (18.6–28.0)	61.6 (52.1–83.7)	30.0 (24.2–36.7)	200.0 (180.0–250.0)	205.0 (182.5–230.0)
($n = 40$)	Ellips Fx		47.8 (34.5–59.8)	22.5 (20.2–24.0)	155.0 (132.5–177.5)	165.0 (130.0–197.5)
	p value[a]		**0.028**	**<0.001**	**<0.001**	**0.009**
Overall	Standard	3.80 (0.7–14.6)	35.10 (18.7–48.5)	22.0 (16.0–28.0)	122.5 (90.0–150.2)	170.0 (150.0–190.0)
($n = 160$)	Ellips Fx		28.80 (19.4–41.2)	21.0 (18.5–23.0)	110.0 (90.0–140.0)	150.0 (120.0–170.0)
	p value[b]		0.102	0.229	0.051	**0.002**

Bold values are statistically significant ($p < 0.05$)

LOCS III lens opacities classification system III, *UST* U/S total time, *TPT* total phaco time, *EPT* mean effective phaco time (expressed in seconds); *CDE* cumulative dissipated energy (expressed as percentage), *BSS* balanced salt solution consumption, expressed in cubic centimeter (cc)

[a] Differences of intra-surgery parameters in the same group of lens opacity density assessed by Mann–Whitney *U*-test

[b] Overall differences of intra-surgery parameters between standard and Ellips Fx probe assessed by Mann–Whitney *U*-test

FX. The postoperative endothelial cell loss and the corneal pachymetry were similar between the two groups in all the LOCS subgroups (Figs. 1, 2, 3, 4).

In all the patients enrolled no surgery-related complications were detected.

Discussion

Many efforts have been made in order to reduce phaco time and limit the side effects during cataract surgery [1–3, 11, 19]. The main manufacturers have addressed those issues in different ways in the recent years [16]. AMO has introduced in 2008 a new technology called Ellips, which aims to improve phaco efficiency while reducing the tissue damage [20]. The implementation of this technology led to the Ellips FX phaco handpiece and software in 2009. The elliptical movement of the phaco tip should improve lens fragmentation through a combined longitudinal and transversal movement. The goals of the new Ellips FX were to reduce the dissipated energy, to limit the BSS consumption, to improve the fluidics and the followability. All these advancements and optimizations would eventually lead to a reduced phaco time and a better performance.

Assil [21] compared Ellips FX with the OZil torsional handpiece, showing that the transverse ultrasound system allowed for a more efficient and faster surgical procedure with less BSS consumption, less phaco time and less power than the torsional phaco system.

In this study, the clinical data have demonstrated some differences comparing standard longitudinal to Ellips FX handpiece. The visual acuity postoperative improvement, the endothelial cell loss and corneal pachymetry were similar 1, 7 and 30 days after surgery. In our series of the patients enrolled in the study [14, 22]. Nevertheless, even if both handpieces appear to be safe, the Ellips FX using the elliptical movement of the tip offered better efficiency in hard cataract removal. These clinical data are well supported by the analysis of intraoperative parameters. The UST and CDE values indicated that the Ellips FX represents an improvement with respect to the standard longitudinal phaco, especially for hard cataracts.

For low-density cataracts, there is reasonably no difference between the two removal modalities. The BSS consumption follows the trend of the other intraoperative parameters and indicates again that the Ellips FX emerges as a useful new phaco modality in hard cataract patients.

In conclusion, the AMO Ellips FX handpiece may represent a safe and efficient lens removal modality. It performs similarly to the traditional handpiece in terms of postoperative visual acuity, endothelial cell loss and central corneal thickness. It outperformed the previous handpiece in terms of TPT, UST, CDE and BSS consumption especially in hard cataracts. Those results suggest that the use of Ellips FX handpiece, allowing to reduce the energy delivery and the phaco time, may be particularly advantageous when dealing with cataracts of greater hardness.

Compliance with ethical standards

Conflict of interest The 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 and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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

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