Original Article

Femtosecond laser-assisted cataract surgery versus 2.2 mm clear corneal phacoemulsification

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Purpose: Phacoemulsification is the surgical procedure of choice for cataract, providing excellent visual and safety outcomes. Femtosecond laser-assisted cataract surgery (FLACS) is an addition to the surgical armamentarium. The study aims to compare the outcomes of FLACS using LenSx™ (Alcon Inc., USA) to standard 2.2 mm clear corneal phacoemulsification. Prospective case–control, comparative, interventional study was conducted in a tertiary care center. **Methods:** In each group, 55 eyes of 55 patients underwent cataract surgery using either FLACS or conventional phacoemulsification (control group). The primary outcome variables, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), specular microscopy, pachymetry, mean absolute error (MAE), and anterior chamber depth (ACD) were compared between two groups at 4 weeks postoperatively. Intraoperative effective phaco time (EPT), postoperative circularity of the rhexis, capsular overlap over the edge of the intraocular lens (IOL), and decentration of the IOL were the secondary variables which were compared. **Results:** No significant difference was found between the groups for UCVA, pachymetry, MAE, and ACD at 4 weeks postoperatively. The FLACS group had better BCVA ($P = 0.0294$). Circularity of capsulorrhexis ($P = 0$), circular overlap over the edge of IOL ($P = 0$), and centration of IOL ($P = 0.002$) at 4 weeks postoperatively were better in the FLACS group. EPT was lower in FLACS for similar grade of cataract ($P = 0$). Endothelial cell loss in FLACS group was 4.2% more ($P = 0.032$). **Conclusions:** FLACS is superior to conventional phaco in the circularity of rhexis, capsular overlap, and centration of the IOL and uses less EPT. However, conventional phacoemulsification is equivalent to FLACS in most other parameters.

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Phacoemulsification is the surgical procedure of choice for cataract routinely providing excellent visual and safety outcomes. Nevertheless, it is not a perfect procedure and room for improvement exists.[1] Femtosecond laser is now commercially available to perform three steps in cataract surgery such as capsulotomy, lens fragmentation and corneal incisions.

In this study, we attempt to compare the outcomes of femtosecond laser-assisted cataract surgery (FLACS) using LenSx Femtosecond laser to standard 2.2 mm clear corneal phacoemulsification. The aim of this study is to compare the outcomes of FLACS to standard 2.2 mm clear corneal phacoemulsification.

Methods

Fifty-five patients who opted for FLACS constituted the study group. The control group was chosen consecutively from among the patients undergoing standard 2.2 mm clear corneal phacoemulsification, matched for the nuclear hardness of the study group after the fulfillment of inclusion and exclusion criteria. This was because the study was not supported by any industry contribution or funded from other sources. Both surgeries of study and control group were done by the same surgeon.

We compared the primary outcome variables which were uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) at 4 weeks, difference in specular microscopic endothelial counts pre- versus post-operative at 4 weeks, pachymetry pre- versus post-operative at 4 weeks, fluid used intraoperatively, mean absolute error (MAE), and comparison of incidence of complications and wound integrity as assessed by Seidel test after the surgery.

We also compared secondary outcome variables which were anterior chamber depth (ACD) preoperatively versus postoperatively, circularity of the capsulorhexis, capsular overlap over the edge of the intraocular lens (IOL) optic, decentration of the IOL, and effective phaco time (EPT). All patients signed informed consent and the tenets of the Declaration of Helsinki were adhered to.

Patients with visually significant cataract undergoing cataract surgery were included. Exclusion criteria were

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coexistent retinal pathology, glaucoma, nondilating pupils, and subluxated lens/zonular weakness, or preoperative endothelial counts <2000 cells/mm^2.

Preoperatively, we documented BCVA as assessed by Snellen chart, grade of cataract as per the LOCS III classification, fundus examination, biometry with the third generation formulas, specular microscopy to record endothelial cell count, pachymetry, and slit lamp photograph (retro illumination and slit). A single surgeon (PRM) performed both the surgeries for all study patients.

Femtosecond laser-assisted cataract surgery

Under topical anesthesia, in the laser operation theatre (OT), FLACS standard procedure was used with Soft fit™ patient interface, and femtosecond laser was used to make the rhexis, nucleofractis, main and two-side port incisions. The patient was shifted to the OT, and under topical anesthesia, the subsequent steps of the surgery was done after the incisions were opened. The phacoemulsification machine used was Infinity™ (Alcon Inc., USA). The viscoelastic used was Viscoat™. Preset parameters were used for each grade of cataract. Wherever mydriasis was insufficient, intracameral adrenaline was used.

Standard 2.2 mm phacoemulsification: Under topical anaesthesia, clear corneal incisions, and two-side port incisions were made by keratome and side opening knives. The phaco technique used was direct Phaco chop technique. Viscoat™ was the viscoelastic used, and the machine used was Infinity™ (Alcon Inc., USA). The same preset parameters were used for each grade of cataract. Intraoperatively, we documented EPT, volume of fluid consumed, and any complications during the surgery.

Postoperatively, seidel test was done at the end of procedure, at end of 1 h of surgery, and at 1st postoperative day. At 1st postoperative day; visual acuity and anterior segment examination of the operated eye in both procedures were assessed. At postoperative 4th week, in both procedures, following were assessed: UCVA, BCVA, anterior segment examination, residual refractive error (analyzed using the MAE, i.e., the difference between predicted and achieved postoperative spherical equivalent refraction), documentation of anterior chamber depth, specular microscopy for endothelial cell count, and pachymetry. Dilated pupil slit lamp retro-illuminated photograph of the eye to assess circularity of capsulorrhexis and capsular overlap, and decentration of IOL was also taken. Photographs were imported into Adobe Photoshop CC 2014 version (Adobe Systems Inc., San Jose, California, USA) to measure the circularity, capsular overlap over the edge of the IOL, and decentration of the IOL. The above parameters were measured by Adobe Photoshop software [Fig. 1].

Circularity is a parameter used to determine the regularity of the shape of the capsulotomy according to the following formula: Circularity = $4\pi \times (\text{area}/\text{perimeter}^2)$. The values of 1.0 indicate a perfect circle/superior circularity [Fig. 2]. Capsular overlap was evaluated to record whether the capsulotomy shows uniform overlap over the edge of the IOL optic. Capsular overlap is the ratio of the shortest and longest distance between the edge of the capsulorhexis and the edge of the IOL optic (distance minimum/distance maximum). A value close to 1 indicates a superior capsular

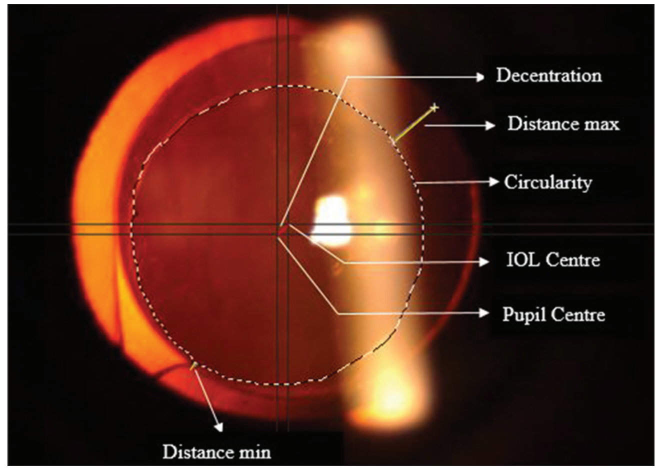

Figure 1: Calculation of secondary outcome variables using Adobe Photoshop software

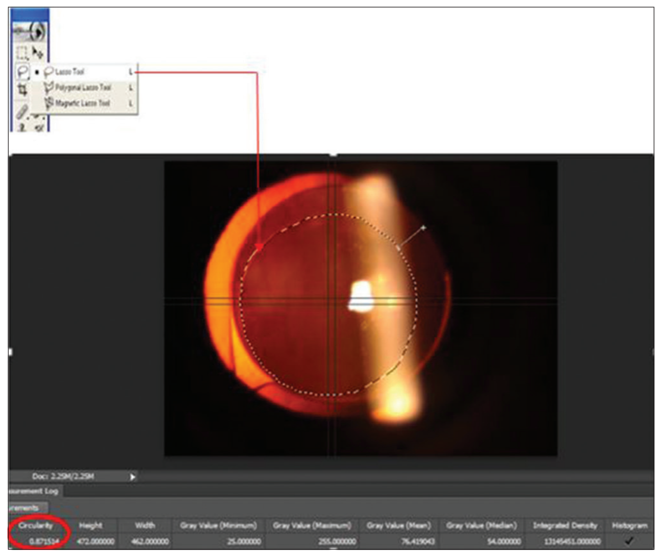

Figure 2: Calculation of circularity

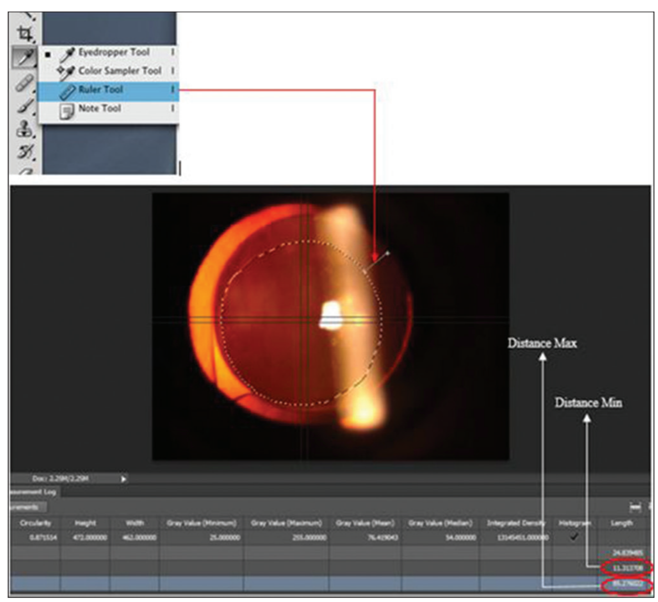

Figure 3: Calculation of capsular overlap

Figure 4: Calculation of decentration of intraocular lens

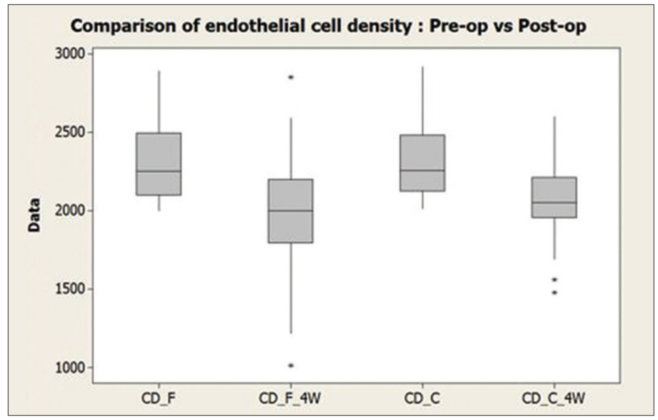

Figure 5: Comparison of specular microscopic endothelial counts. CD_F: Preoperative cell density in femtosecond group, CD_F_4W: Postoperative cell density in femtosecond group at 4 weeks, CD_C: Preoperative cell density in control group, CD_C_4W : Postoperative cell density in control group at 4 weeks

overlap [Fig. 3]. Decentration of IOL is the distance from center of the pupil to center of the optic of IOL. It is measured in the dilated pupil [Fig. 4].[2]

Statistical analysis

The study was analyzed using analytical and descriptive statistics. MINITAB Release 14 Statistical Software (Minitab Inc.) was used. For all statistical tests, the significance was taken as $P < 0.05$.

Results

Both the groups had similar demographics. We compared primary outcome variables and had following results: for UCVA and BCVA, at 4 weeks, as the data were not normally distributed in both the groups, Mann–Whitney test was used. It was found that there was no significant difference between the UCVA at 4 weeks in both the groups ($P = 0.2548$). About 95% confidence interval for the difference in UCVA after 4-weeks was found to be varying between 0 and 0.1250 [Table 1] however BCVA in the femtosecond group was better than BCVA in the control group at 4 weeks ($P = 0.0294$) with 95% confidence interval (−0.00001, 0.00002) [Table 2].

Comparing specular microscopic endothelial counts showed that postoperative endothelial counts decreased in both the groups. Sample *t*-test was used to compare the postoperative decrease in the endothelial cell count in both the procedures [Fig. 5]. Cell density decreased more in the femtosecond group (4.2% more) than in the control group ($P = 0.032$) [Table 3].

To compare pachymetry at 4 weeks, paired *t*-test was conducted in each group. It was found that there is no significant increase in the postoperative pachymetry values in each group as $P = 0.784$ in femtosecond group and $P = 0.845$ in the control group [Table 4 and Fig. 6].

The amount of irrigating fluid (BSS™) consumed intraoperatively for cataract surgery in both the groups was compared using two sample *t*-test. There was no significant difference in the fluid consumption in both the procedures ($P = 0.277$).

MAE was defined as the average of the absolute value of the difference between actual and predicted spherical equivalences of postoperative refractive error. Wilcoxon signed-rank test was used to compare the predicted refractive error from the achieved refractive error in each group [Table 5]. Actual refractive error was deviating away from the predicted value in both the groups (in femtosecond group at $P = 0$, in control group at $P = 0.004$). The distribution of MAE was similar for both the groups. Since the data were not normal, Mann–Whitney test was conducted on MAE between the groups to compare the residual refractive error. It was found that there is no significant difference in MAE between both the groups ($P = 0.3051$ with 95% confidence interval [−0.1700, 0.0400]) [Fig. 7].

Table 1: Comparison of uncorrected visual acuity at 4 weeks

	Median (Snellen equivalent)	Mean±SD
UCVA 4 weeks (femtosecond)	0.176 (6/9)	0.2127±0.1972
UCVA 4 weeks (control)	0.176 (6/9)	0.2337±0.1465

UCVA: Uncorrected visual acuity, SD: Standard deviation

Table 2: Comparison of best-corrected visual acuity at 4 weeks

	Median (Snellen equivalent)	Mean±SD
BCVA 4 weeks (femtosecond)	0 (6/6)	0.0648±0.1018
BCVA 4 weeks (control)	0.176 (6/9)	0.1069±0.1133

BCVA: Best-corrected visual acuity, SD: Standard deviation

For the comparison of the incidence of complications, Chi-square test was done. The incidence of complications was independent of the method of surgery ($P = 0.647$).

There was no need to perform statistical analysis for wound integrity as there was no wound leak found in any of the patients in our study.

We also compared secondary outcome variables and had following results:

Table 3: Comparison of specular microscopic endothelial counts preoperative versus postoperative

	Mean±SD		Mean change in cell density	Percentage decrease in mean cell count
	Preoperative	4 weeks		
Cell density femtosecond	2307.9±246.3	1975.6±323.7	332	14.4
Cell density control	2310.3±223.7	2073.7±236.6	237	10.2

SD: Standard deviation

Table 4: Comparison of pachymetry preoperative versus postoperative

	Mean±SD		Preoperative		Postoperative	
	Preoperative	4 weeks	Minimum	Maximum	Minimum	Maximum
Femtosecond	571.71±41.23	575.45±49.24	462	677	441	685
Control	567±31.29	571.04±32.48	500	648	490	660

SD: Standard deviation

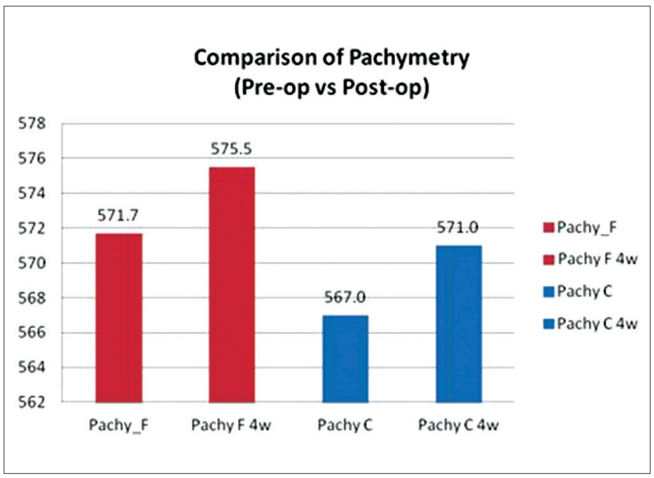

Figure 6: Comparison of pachymetry. Pachy_F: Preoperative pachymetry in femtosecond group, Pachy F 4w: Postoperative pachymetry in femtosecond group at 4 weeks, Pachy C : Preoperative pachymetry in control group, Pachy C 4w: Postoperative pachymetry in control group at 4 weeks

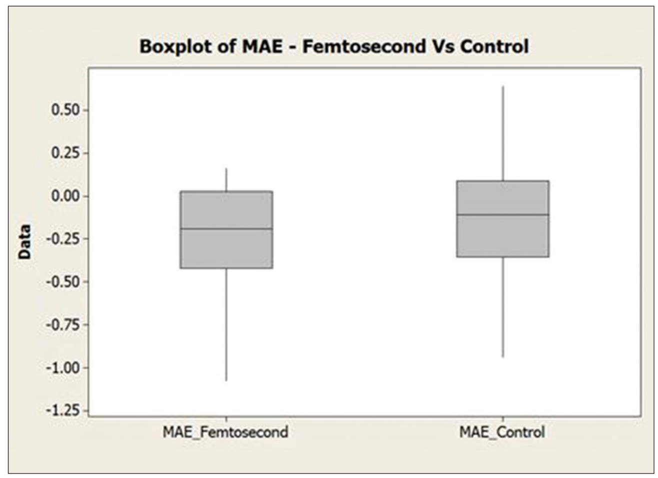

Figure 7: Comparison of mean absolute error

The preoperative and postoperative ACD was recorded in both the procedures and their differences was noted. Two sample *t*-test was done between the groups to compare ACD before and after the surgery [Table 6]. The change in the ACD was not statistically significant ($P = 0.829$) between the groups.

The comparison of circularity of capsulorhexis showed that the mean circularity in the femtosecond group was superior as compared to the control group because circularity in femtosecond group was closer to 1. Analysis of variance (ANOVA) was done between the groups to compare the circularity. It was found that there was a significant difference in the circularity of capsulorhexis between both the procedures ($P = 0$). It was superior in femtosecond group [Table 7].

The comparison of capsular overlap over the edge of IOL showed that the mean overlap in the femtosecond group was superior as compared to the control group because it was closer to 1 [Table 8]. The value of 1 indicates an absolute regularly overlapping anterior capsule on the optic of the implanted IOL. ANOVA was done between the groups to compare the capsular overlap over the edge of IOL. It was found that there is a significant difference in the capsular overlap over the edge of IOL between two procedures ($P = 0$).

For comparing decentration of IOL, in both the procedures, ANOVA was done. Decentration in the femtosecond group was less as compared to the control group ($P = 0.002$) [Table 9].

For analyzing the EPT in both the procedures, in all grades of nuclear cataract, the sample size was divided into 3 cataract groups [Fig. 8]. This was done based on the LOCS III classification of nuclear sclerosis (nuclear opalescence NO1–NO6, nuclear color NC1–NC6).

- Cataract group 1 includes NO1 NC1 to NO2.9 NC2.9
- Cataract group 2 includes NO3 NC3 to NO4.9 NC4.9
- Cataract group 3 includes NO5 NC5 and NO6 NC6.

EPT was recorded in both the procedures. The general linear model was used for analysis and it was found that there was significant difference in the phaco time used in both the procedures. It was found that femtosecond group utilizes less phaco time for similar grade of nuclear sclerotic cataract as compared to control group ($P = 0$) [Fig. 9]. Summary of statistical analysis is given in Table 10.

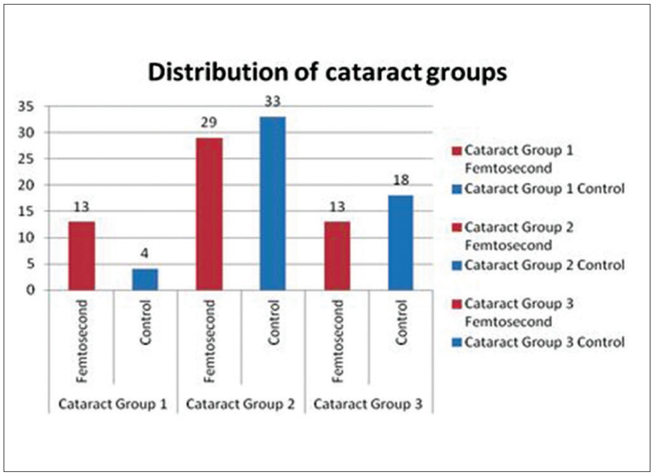

Figure 8: Division of sample size into three cataract groups as per nuclear opalescence and color of LOCS III classification

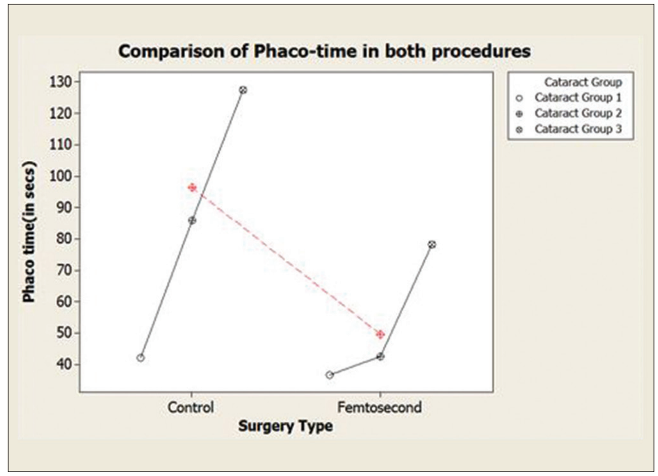

Figure 9: Multivariate chart showing comparison of effective phaco time

Discussion

Our study showed that FLACS and standard phaco were similar when UCVA was compared but BCVA at 4 weeks was found to be better in the femtosecond group. The amount of difference and statistical significance, however, is not very high ($P = 0.0294$), also no difference was seen between the groups in UCVA. The ESCRS study on long-term clinical outcome after femtosecond cataract surgery also showed only a slightly better mean postoperative BCVA in the femtosecond group[3] (96.37% vs. 93.55% achieving 6/12 or better, $P = 0.07$).

Specular microscopic central endothelial counts decreased postoperatively for both the groups but the percentage of cell loss in the femtosecond group was found to be higher (14.4% cell loss in the femtosecond group and 10.2% in the control group, $P = 0.032$) as compared to the control group. This slightly higher endothelial cell loss in the femtosecond group in our study could be due to the fact that the incisions in the laser group tend to be more corneal, which could have caused the drop in the central endothelial cell count due to turbulence of the fluid. The extent to which corneal incisions were into clear cornea from the limbus has not been analyzed in our study. Jun *et al*.[4] concluded in their study that the pupil size decreased significantly after femtosecond laser pretreatment of cataract surgery. Although we did not document the incidence of miosis after femtosecond laser pretreatment in our study, the intracameral use of adrenaline in patients with miotic pupil could have caused the loss of corneal endothelial cells in the femtosecond group. Although the endothelial cell count had decreased postoperatively, pachymetry was not significantly affected between both the groups. This shows that the reduction in the endothelial count in both the groups did not have a morphologically measurable effect and was not clinically significant. Other studies in literature have found no difference in endothelial counts between the two groups.[5]

In our study, there was no significant difference in the MAE between the femtosecond and the control group. Filkorn *et al*.[6] found that at 6 weeks after the surgery, MAE was significantly lower in the femtosecond group as compared to the control group ($P = 0.04$). This difference was accounted possibly due to more precise capsulorrhexis, resulting in more stable IOL position. Our study, however, despite demonstrating the

Table 5: Comparison of mean absolute error

	Mean±SD		MAE
	Predicted	Actual	
Femtosecond refractive error (Diopters)	0.0909±0.1383	0.2977±0.3085	0.2068±0.355
Control refractive error (Diopters)	0.0885±0.0503	0.2359±0.3157	0.14735±0.327

MAE: Mean absolute error, SD: Standard deviation

Table 6: Comparison of anterior chamber depth before and after surgery

ACD difference	Mean±SD	Minimum	Maximum
Femtosecond (mm)	−0.9795±0.4074	−1.97	−0.36
Control (mm)	−0.9122±0.4690	−2.02	−0.05

ACD: Anterior chamber depth, SD: Standard deviation

Table 7: Comparison of circularity of capsulorhexis

	Mean±SD
Circularity (femtosecond)	0.9082±0.0277
Circularity (control)	0.8482±0.0261

SD: Standard deviation

Table 8: Comparison of capsular overlap over the edge of intraocular lens

Overlap	Mean±SD
Femtosecond	0.371±0.102
Control	0.263±0.137

SD: Standard deviation

Table 9: Comparison of decentration of intraocular lens

Decentration	Mean±SD	Minimum	Maximum
Femtosecond (pixels)	17.361±6.069	6	31.401
Control (pixels)	20.581±4.608	0	27.803

SD: Standard deviation

Table 10: Summary of analysis

Parameter	*P*	Result
Primary outcome variables		
UCVA	0.2548	No significant difference between both groups
BCVA	0.0294	BCVA in femtosecond group better than control group
Specular microscopic endothelial cell count	0.032	Cell density decreased more in femtosecond group (14.4%) as compared to control group (10.2%)
Pachymetry femtosecond	0.784	No significant difference between both groups
Pachymetry control	0.845	
BSS compound used intraoperatively	0.277	No significant difference in fluid consumption in both the groups
MAE	0.3051	No significant difference between both groups
Incidence of complication	0.647	No significant difference between both groups
Wound integrity		No Would leak in both the groups
Secondary outcome variables		
Anterior chamber depth (ACD)	0.829	Change in ACD in both groups was not significant
Circularity of capsulorhexis	0	Circularity superior in femtosecond group
Capsular overlap at edge of IOL	0	Capsular overlap superior in femtosecond group
Decentration of IOL	0.002	De Centration was less in femtosecond group
Effective Phaco time	0	Less in femtosecond group for similar grade of cataract

superiority of the circularity of the rhexis and IOL centration, did not show difference in the MAE between the groups.

Intraoperatively, both the groups did not have any significant difference in the incidence of complications. Abell *et al*.[7] had similar results. The change in the ACD postoperatively is an indicator for lens positioning. In our study, it was found that both the procedures did not have any significant difference in the ACD change postoperatively. We could, therefore, infer that effective lens position postoperatively would be similar in the two groups. The findings in our study and other published reports do substantiate the fact that femtosecond cataract surgery results in a more consistent capsulorhexis and IOL centration with more ideal overlap of rhexis margin over the IOL.

The overall mean effective phacoemulsification time was significantly lower in femtosecond group (49.61 ± 38.87 s) as compared to the control group (96.43 ± 65.36 s) for similar grade of cataract. The ESCRS study[3] also showed that effective phacoemulsification time was reduced by 85% in the FLACS group.

The final results of the study from the European Registry of Quality Outcomes for Cataract and Refractive Surgery comparing the two surgical techniques, however, found that FLACS did not yield better visual or refractive outcomes than conventional phacoemulsification cataract.[8] Abell *et al*., in a study of more than 400 cases at a single center, found that the two cataract surgery techniques appear to be equally safe.[9]

Limitations

Our study does not include cost-effective analysis of the femtosecond laser pretreatment. As stated in the ESCRS study,[3] at current cost to patients and utilizing real comparative cohort data, femtosecond laser pretreatment does not represent a cost-effective addition to conventional phacoemulsification (≈$3500 AUD cost/quality-adjusted life year for conventional phacoemulsification).

The corneal incision of FLACS is planned on a two-dimensional image on the screen while the actual incision happens on a curved albeit applanated cornea through the patient interface. Sometimes, incisions end up being more corneal than planned. Due to blanching of the Limbal vessels, following application of suction by the patient interface, the incision may not be completed in a vascularized corneal periphery. The number of times a corneal incision failed to open or was placed in a position which was different than where it was intended could have been studied. Femtosecond laser takes more time compared to conventional surgery because it is a staged procedure. We have not assessed this aspect in our study.

Conclusions

The results of FLACS are by and large comparable to the results of standard 2.2 mm phacoemulsification. BCVA is slightly superior in FLACS in our study although the difference of significance is not very high. The secondary outcome variables are definitely superior in the FLACS group.

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Conflicts of interest

There are no conflicts of interest.

References

1. Sutton G, Bali SJ, Hodge C. Femtosecond cataract surgery: Transitioning to laser cataract. Curr Opin Ophthalmol 2013;24:3-8.
2. Nagy ZZ, Kránitz K, Takacs AI, Miháltz K, Kovács I, Knorz MC. Comparison of intraocular lens decentration parameters after femtosecond and manual capsulotomies. J Refract Surg 2011;27:564-9.

3. Vote B, Eve S, Abell R, Allen P, Kerr N, Howie A, *et al*. Long Term Clinical Outcomes after Femtosecond Laser Assisted Cataract Surgery: Results from a Multicentre Prospective Comparative Cohort Study. Poster Presented at: XXXII Congress of the ESCRS: London, UK; 13 Septemper, 2014.
4. Jun JH, Hwang KY, Chang SD, Joo CK. Pupil-size alterations induced by photodisruption during femtosecond laser-assisted cataract surgery. J Cataract Refract Surg 2015;41:278-85.
5. Chen X, Xiao W, Ye S, Chen W, Liu Y. Efficacy and safety of femtosecond laser-assisted cataract surgery versus conventional phacoemulsification for cataract: A meta-analysis of randomized controlled trials. Sci Rep 2015;5:13123.
6. Filkorn T, Kovács I, Takács A, Horváth E, Knorz MC, Nagy ZZ. Comparison of IOL power calculation and refractive outcome after laser refractive cataract surgery with a femtosecond laser versus conventional phacoemulsification. J Refract Surg 2012;28:540-4.
7. Abell RG, Kerr NM, Vote BJ. Femtosecond laser-assisted cataract surgery compared with conventional cataract surgery. Clin Exp Ophthalmol 2013;41:455-62.
8. Manning S, Barry P, Henry Y, Rosen P, Stenevi U, Young D, *et al*. Femtosecond laser-assisted cataract surgery versus standard phacoemulsification cataract surgery: Study from the European Registry of Quality Outcomes for Cataract and Refractive Surgery. J Cataract Refract Surg 2016;42:1779-90.
9. Abell RG, Darian-Smith E, Kan JB, Allen PL, Ewe SY, Vote BJ. Femtosecond laser-assisted cataract surgery versus standard phacoemulsification cataract surgery: Outcomes and safety in more than 4000 cases at a single center. J Cataract Refract Surg 2015;41:47-52.