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Review Article

Comparing Refractive Outcomes of Standard Phacoemulsification with Femtosecond Laser-Assisted Cataract during the Initial Learning Curve and with More Experience

Ildamaris Montes de Oca, Sumitra S Khandelwal, Eric J Kim, Tim Soeken, Ryan Barrett, Li Wang, Mitchell P Weikert, Douglas D Koch and Zaina Al-Mohtaseb*

Department of Ophthalmology, Cullen Eye Institute, Baylor College of Medicine, 6565 Fannin, NC205, Houston, TX, United States

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***Corresponding author**

Zaina Al-Mohtaseb, Department of Ophthalmology, Cullen Eye Institute, Baylor College of Medicine, 6565 Fannin, NC205, Houston, TX, United States;
Tel: 713-798-5143;
Email: zaina@bcm.edu

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Abbreviations SP: Phacoemulsification; FLACS: Femtosecond laser-assisted cataract surgery; RP: Mean absolute refraction prediction errors

Abstract

Purpose: To analyze and compare the refractive outcomes of standard phacoemulsification with femtosecond laser-assisted cataract surgery performed during the initial learning curve and a year later by experienced surgeons.

Methods: This single-center retrospective study was divided into 3 groups: Group 1, 63 patients who underwent standard phacoemulsification (control group) prior to femtosecond laser acquisition by two anterior segment surgeons; Group 2, the first 104 patients who underwent femtosecond laser-assisted cataract surgery by the same surgeons from Feb 19, 2014 to April 30, 2014 (learning curve group) and Group 3,108 patients who underwent femtosecond laser-assisted cataract surgery by the same surgeons a year later from Feb, 2015 until June 30, 2015 (experienced group).

Results: Mean absolute refraction prediction errors were 0.37 ± 0.25 Diopters (D) in the control group, 0.30 ± 0.24 D in the "learning group" and 0.30 ± 0.24 D in the experienced group with no significant differences among groups. The percentages of eyes within 0.5 D of the targeted refraction were 69.8%, 90.5% and 82.5% in the control group, learning group, and experienced group, respectively ($p < 0.05$ comparing the control and the learning groups).

Conclusion: There was no statistically significant difference in the mean postoperative refraction prediction errors between femtosecond laser-assisted cataract surgery and standard phacoemulsification in either the learning curve or experienced group. However, a higher percentage of patients were within 0.5 D of the targeted refraction in the learning curve femtosecond laser-assisted cataract surgery group compared with the standard phacoemulsification group.

Introduction

Cataract extraction is the most commonly performed ophthalmic surgical procedure in the world. It has grown dramatically in the past few decades with new surgical techniques and technologies, bringing improvements in visual outcomes and patient safety [1]. Femtosecond laser-assisted cataract surgery (FLACS) is a technological advance that emerged in 2008. Femtosecond lasers use near-infrared light (wavelength of 1053 nm) with ultra-short pulse durations on the order of 10^{-15} s (quadrillionth of a second), disrupting the tissue with micron precision and a smaller zone of collateral damage [2,3].

FLACS is a growing technology that allows automation of the early steps of cataract surgery with the creation of an anterior capsulotomy, lens fragmentation, astigmatic corneal relaxing incisions, and Clear Corneal Incisions (CCIs), including the main cataract incision and paracenteses [2]. The potential advantages of FLACS as compared to conventional phacoemulsification include a more precise capsulotomy, significant reduction in required ultrasonic energy, more exact wound architecture, and decreased collateral tissue damage. These benefits may result in enhanced safety and precision, leading to more predictable refractive outcomes and reduced incidence of intra-operative and post-operative complications [4,5].

The purpose of this study was to analyze and compare the outcomes of standard phacoemulsification with Femtosecond Laser-Assisted Cataract Surgery (FLACS) during the initial learning curve and a year later as experienced surgeons at a single academic center.

Patients and methods

This retrospective study included patients who underwent cataract and IOL surgery by

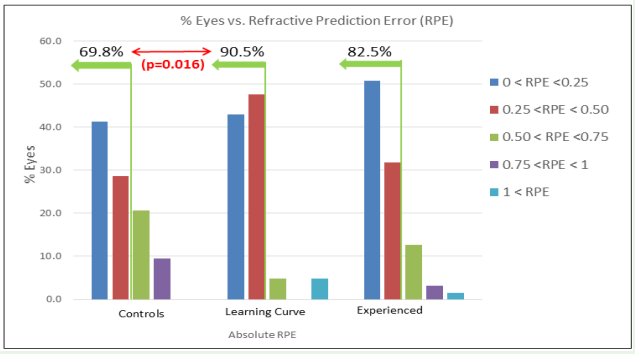

Figure 1: Percentage of eyes vs Refractive Prediction Error (RPE). Only the control group compared to the learning group showed a significant difference in eyes within 0.5 D.

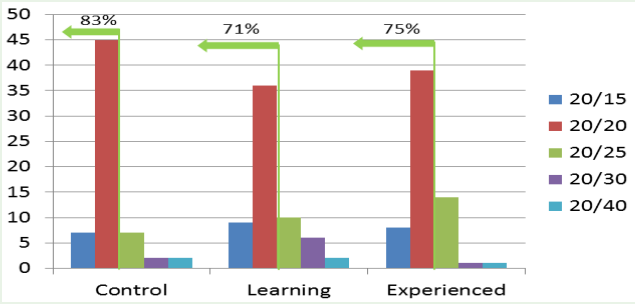

Figure 2: Percentage of eyes in each group with postoperative CDVA better than 20/25. No statistically significant difference among the three groups (p>0.05).

two anterior segment surgeons (DDK, MPW). The study was divided into 3 groups: Group 1: patients who underwent standard phacoemulsification (control group) prior to acquisition of the femtosecond laser, Group 2: the first patients who underwent FLACS using the Catalys femtosecond laser (Abbott Medical Optics, Santa Ana, CA, USA) from Feb 19, 2014 to April 30, 2014 (learning curve group), and Group 3: patients who underwent FLACS a year later from Feb, 2015 to June, 2015 (experienced group). All surgeries were performed at a single center (Alkek Eye Center, Baylor College of Medicine). The inclusion criteria were patients who underwent standard phacoemulsification or FLACS using the Catalys femtosecond laser for anterior capsulotomy creation, lens fragmentation, and relaxing incisions, and who achieved best-corrected visual acuity of at least 20/40 or better by one month postoperatively. Exclusion criteria were prior ocular surgery, implantation of a multifocal IOL, and complications requiring additional surgery or vitrectomy. The data collected were entered into a standard computerized database for subsequent analysis and included patient demographics (age, gender), preoperative target spherical equivalent (SE) value measured by the Lenstar (Haag-Streit, Koeniz, Switzerland) using the Holladay 1 formula, postoperative month one Corrected Distance Visual Acuity (CDVA), and manifest refraction.

Statistical and data analysis

For the sample size calculation, we wish to detect a difference of 2/3 of the standard deviation of differences between the two groups. With a significance level of 5% and a test power of 80%, 36 eyes are required in each group. We included 63 eyes in each group.

All data were collected on an Excel spreadsheet (Microsoft Office 2010). The refractive prediction error (RPE) of each group was calculated by subtracting each patient's one-month post-operative refraction from their predicted post-operative refraction (based on the LenStar optical biometry data and the Holladay 1 formula).

A one sample t-test was used to assess if the mean arithmetic RPEs produced by each group was significantly different from zero. The nonparametric Mann-Whitney test was used to compare the absolute RPEs between groups and the chi-square test was performed to compare percentage values between groups. SPSS 22.0 for Windows (SPSS Inc, Chicago, IL) was used for statistical analysis. P<0.05 was considered statistically significant.

Results

Patient demographics were similar between the three groups. The mean age was 73.7 years ± 7.0 (SD) in the control group, 70.8 years ± 8.5 (SD) in the learning group, and 70.9 years ± 8.3 (SD) in the experienced group. The number of patients enrolled in each group was 48, 54 and 49, respectively. Each group in our study had 63 eyes: control group (36 right, 27 left), learning group (36 right, 27 left), and experienced group (29 right, 34 left).

Table 1 shows the mean absolute and numerical RPE of each group. Mean absolute Refraction Prediction Errors (RPEs) were 0.37 ± 0.25 D in the control group, 0.30 ± 0.24 D in the learning curve group, and 0.30 ± 0.24 D in the experienced group with no significant differences among groups. Mean numerical RPEs were not significantly different from zero (all p>0.05) (Table 1).

The percentages of eyes within 0.5D of the targeted refraction were 69.8%, 90.5%, and 82.5% of eyes in the control, learning, and experienced groups, respectively (Figure 1). The difference between the control group and the learning group was statistically significant (p<0.05). The percentages of eyes with postoperative CDVA better than 20/25 were 83%, 71%, and 75% in the control group, learning group, and experienced group, respectively, (all differences p >0.05) (Figure 2).

Discussion

Previous publications concerning femtosecond laser assisted cataract surgery discuss several aspects of the emerging technology, such as intraoperative complication rate, efficacy of capsulotomy, Effective Phacoemulsification Time (EPT), reduction to zero ultrasound (US) energy, and endothelial cell loss over time [4,6-8] As with the introduction of any new technology, a learning curve is associated with the use of this laser technology, which seems to

Table 1: Refractive prediction error for each group.

	Control group		Learning group		Experienced group	
	Absolute (D)	Numerical (D)	Absolute (D)	Numerical (D)	Absolute (D)	Numerical (D)
Mean	0.37	-0.03	0.30	0.04	0.30	0.01
SD	0.25	0.45	0.24	0.38	0.24	0.38
Min	0.00	-0.84	0.0	-1.05	0.01	-0.81
Max	0.93	0.93	1.06	1.06	1.06	1.06

D= Diopters.

improve with experience. To our knowledge, there are no published data comparing a control group with both early and late FLACS refractive outcomes, as is done in this study.

Several peer-reviewed articles report refractive outcomes of femtosecond laser cataract surgery compared to standard phacoemulsification (Table 2).

Chee et al. [9] compared visual outcomes of 794 surgeries using the VICTUS femtosecond laser (Baush & Lomb, Rochester, NY, USA) to 420 conventional phacoemulsification surgeries (controls). The mean absolute errors (MAE) of 0.30 ± 0.25 diopters and 0.33 ± 0.25 diopters, respectively, (p=0.062) and the mean squared error (MSE) of 0.16 ± 0.27 diopters and 0.17 ± 0.28 diopters, respectively, (p=0.065) were not statistically significant. Only the Manifest Refraction Spherical Equivalence (MRSE) was found to be statistically significantly lower among the laser surgeries cases (-0.08 ± 0.36) compared to the control cases (-0.13 ± 0.41) (p=0.034). However, this difference might be considered clinically negligible.

In a prospective study comparing 77 eyes who underwent laser refractive cataract surgery with the LenSx (Alcon, Fort Worth, TX, USA) to 57 eyes who underwent conventional cataract surgery, Filkorn et al. [10] found that 41.6% of eyes were within ± 0.25 D of the target refraction in the laser group compared to 28.1% in the conventional group; however, 68.8% and 64.9% were within ± 0.50 D respectively. The MAE at least 6 weeks after surgery was significantly lower in the laser group (0.38 ± 0.28 D) than in the conventional group (0.50 ± 0.38 D) (p=0.04), although no statistically significant difference was found between the two groups in the MRSE. Roberts et al. [11] conducted a prospective study with the initial 113 consecutives eyes who underwent laser cataract surgery and 105 who had undergone manual phacoemulsification. In this study, 83.2% of patients in the laser group and 81.9% in the manual group fell within ± 0.50 D of the intended correction. The MAE was 0.29 ± 0.25 D and 0.31 ± 0.24 D for each group respectively, which was not statistically significant.

We are aware of three published studies evaluating refractive outcomes when using the Catalys femtosecond laser. In a prospective consecutive case control study, Abell et al. [7] compared 150 eyes who underwent FLACS with the Catalys laser system to 51 eyes who underwent conventional phacoemulsification and found no significant difference in MAE at the 3-week postoperative visit (0.51 ± 0.50 D and 0.45 ± 0.71 D, respectively). They also found that 57.4% and 53.6% of femtosecond laser and conventional phacoemulsification cases, respectively, were within 0.5 D error.

Conrad-Hengerer et al. [12] in a prospective study compared 100 eyes treated with the Catalys femtosecond laser and 100 fellow eyes who had conventional phacoemulsification. At the 6-month follow up visit, 90% and 70% of eyes in each group were within ± 0.50 D of the predicted refractive outcome, respectively. They also reported earlier postoperative visual recovery with FLACs when compared to the conventional group, as well as earlier refractive stability in the femtosecond laser group.

Recently, Ewe et al. [13] in a prospective, multicenter study evaluated the visual outcomes after femtosecond laser-assisted cataract surgery using the Catalys with phacoemulsification cataract surgery. They compared 988 eyes in the femtosecond laser group with 888 in the phacoemulsification cataract surgery group. At the 6 month follow up, they reported 72.2% and 82.6% of eyes within 0.5D of the predicted refractive outcome in the femto and standard groups, respectively, and a CDVA better than 20/25 of 53.3% and 53.1% in each group, respectively. Interestingly, mean absolute error was higher in the femtosecond group compared to the standard group (0.41D vs. 0.35D; p<0.0001).

While our current study adds to the published experience with the Catalys laser, it is also unique in its comparison of three different groups: standard phacoemulsification (control group), initial FLACS cases (learning group), and FLACS cases a year later (experienced group). Currently no published study has reported refractive outcomes in these three distinct groups (control, learning, and experienced).

Our study showed no statistically significant difference in the RPE between all three groups (0.37 ± 0.25 D, 0.30 ± 0.24 D, and 0.30 ± 0.24 D in control, learning, and experienced groups, respectively). Our mean absolute RPE in all three groups was lower than with

Table 2: Outcomes of studies that compared femtosecond laser cataract surgery with conventional phacoemulsification.

Study	FS laser used	Type of Study	Postoperative time	Controls		FALCS	
				MAE (D)	MRSE (D)	MAE (D)	MRSE (D)
Chee et al.	Victus, Bausch + Lomb	Prospective	6 weeks	0.33 ± 0.25 (N=387)	-0.13 ± 0.40 * (N=331)	0.30 ± 0.25 (N=715)	-0.08 ± 0.36 * (N=578)
Filkorn et al.	LenSx, Alcon	Prospective	6-12 weeks	0.50 ± 0.38 † (N=57)	-0.58 ± 1.28 (N=57)	0.38 ± 0.28 † (N=77)	-0.50 ± 1.06 (N=77)
Roberts et al.	LenSx, Alcon	Prospective	3 months	0.31 ± 0.24 (N=113)		0.29 ± 0.25 (N=105)	
Lawless et al.	LenSx, Alcon	Prospective	3 months	0.23 ± 0.16 (N=29)	-0.06 ± 0.30	0.26 ± 0.25 (N=61)	-0.01± 0.35
Abell et al.	Catalys, Optimedica	Prospective	3 weeks	0.45 ± 0.71 (N=150)		0.51 ± 0.50 (N=51)	
Conrad-Hengerer et al.	Catalys, Optimedica	Prospective	6 months		-0.11 ± 0.55 (N=100)		-0.05 ± 0.28 (N=100)
Ewe et al.	Catalys, Optimedica	Prospective	6 months	0.35±0.38 (N=888)	-0.1 ± 0.50 (N=888)	0.41±0.37 (N=988)	-0.07 ± 0.54 (N=988)
Current Study	**Catalys, Optimedica**	**Retrospective**	**3 weeks**	**0.37 ± 0.25 (N=63)**	**-0.53 ± 0.89 (N=63)**	**0.30 ± 0.24 (N=63)**	**-0.53 ± 0.71 (N=63)**

MAE=Mean absolute error, MRSE= Manifest refraction spherical equivalent, n= number of eyes

* Target plano, preoperative cinlinder<1.5D, p=0.034

† Statistically significant p=0.04.

other studies. Compared to other studies, [7,10] our results showed a higher percentage of patients with 0.5 D or less error. 69.8%, 90.5%, and 82.5% of eyes in the control, learning, and experienced groups, respectively were within 0.5D of the targeted refraction, but only the difference between the FLACS learning curve group and the SP group was statistically significant (p=0.016). We are uncertain why there was no significant difference between the control and the experienced groups. This could be due to the fact that we were very careful with the first patients that we picked to perform FLACS on. As we became more comfortable with the technology, we performed the procedure on patients with denser and more difficult cataracts. The percentages of patients with BCVA better than 20/25 were equal among all three groups.

Our study showed similar refractive predictability when looking at RPE for femtosecond-assisted cataract surgery compared to standard phacoemulsification in both the learning curve and one year later, although we had a higher percentage of eyes within 0.5D in the FLACS groups. Conrad-Hengerer's study showed a statistically significant difference in the RPE. The difference between our study and theirs could be due to the fact that we compared the refractive outcomes of our groups at the 3-week postoperative visit, while they compared them at 6 months postoperatively. Theoretically, the benefits of FLACS and its precise capsulotomy might not occur until long after the three-week visit, when contraction of the bag can affect refractive outcomes, which could be why they found a difference.

Limitations of this study are: 1) It is retrospective; 2) the cases in the 3 groups were sequential and not randomized or even concurrent, so the superior outcomes in the early group could be due to selection bias or improved IOL calculation methodology, and 3) the short follow up, as noted above.

More prospective studies with the Catalys Femtosecond laser are needed. We conclude that both FLACS and manual phacoemulsification result in excellent refractive outcomes.

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