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Visual and Refractive Outcomes in Manual versus Femtosecond Laser–Assisted Cataract Surgery

A Single-Center Retrospective Cohort Analysis of 1838 Eyes

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Purpose: Femtosecond laser–assisted cataract surgery (FLACS) has emerged as an alternative to manual cataract surgery (MCS) for corneal incision and capsulorhexis creation, as well as nuclear fragmentation. This study compares postoperative refractive and visual outcomes in eyes receiving MCS or FLACS.

Design: Single-center, comparative, retrospective cohort analysis.

Participants: Consecutive eyes receiving FLACS and MCS from July 1, 2012, to July 31, 2015, at a single tertiary care center.

Methods: Demographic data, ocular history, preoperative measurements and biometry, and postoperative surgical results were retrospectively obtained and statistically analyzed using a generalized linear mixed model adjusting for differences in baseline characteristics and within-patient correlation. A 2-tailed P value <0.05 was considered statistically significant throughout the study.

Main Outcome Measures: Percentage of eyes achieving absolute error (AE) $\leq$0.5 diopters (D). Secondary outcomes included percentage of eyes with AE $\leq$0.25 D and $\leq$1.0 D, and percentage of distance-targeted eyes achieving uncorrected distance visual acuity (UDVA) of 20/20 or better, 20/25 or better, and 20/30 or better.

Results: A total of 883 eyes received MCS and 955 received FLACS among 1089 patients. Some 82.6% of FLACS eyes and 78.8% of MCS eyes had $\leq$0.5 D of AE at 3 weeks, representing an adjusted odds ratio (OR) of 1.28 (95% confidence interval [CI], 0.98–1.66) of FLACS relative to MCS being within target. Some 97.1% of FLACS and 97.2% of MCS eyes had $\leq$1.0 D of AE (OR, 0.96; 95% CI, 0.57–1.60) and 49.3% of FLACS and 46.3% of MCS eyes, $\leq$0.25 D of AE (OR, 1.13; 95% CI, 0.91–1.39). Factors predictive of a favorable refractive outcome included axial length between 22 and 24.8 mm, receiving a toric intraocular lens, less preoperative cylinder, and greater preoperative average keratometry. There was no significant difference in the percentage of patients targeted for distance who achieved UDVA of 20/20 or better ($P = 0.30$), 20/25 or better ($P = 0.06$), or 20/30 or better ($P = 0.66$) vision.

Conclusions: Postoperatively, there was no statistically significant difference found between eyes undergoing FLACS and eyes undergoing MCS with respect to refractive and visual outcomes. *Ophthalmology 2018;■:1–9 © 2018 by the American Academy of Ophthalmology*

Femtosecond laser–assisted cataract surgery (FLACS) is a novel technology available to cataract surgeons. First used in the eye for the creation of intrastromal LASIK flaps, the femtolaser's ultrahigh frequency energy bursts (10^{-15} seconds) create expanding microcavitation plasma bubbles that precisely split tissue planes with virtually no surrounding collateral damage. It has emerged as an alternative to manual cataract surgery (MCS) for corneal incisions, anterior capsulotomies, and nuclear fragmentation.[1]

In a recent meta-analysis, our group reviewed the currently published literature comparing FLACS with MCS with respect to surgical efficacy and safety.[2] No statistically significant difference was observed between FLACS and MCS in terms of postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), or mean absolute error (AE) outcomes from the pooled results of the 15 randomized controlled trials and 22 observational studies included. Several methodological limitations were found to be prevalent in many of the currently published studies comparing FLACS visual and refractive outcomes with those of MCS.[2] Small sample sizes,[3–7] incomplete surgical usage of the femtolaser,[5–9] a lack of comparability of cohorts at baseline, and failure to adjust for within-patient correlation when including both eyes for 1 patient[4–9] prevented a more definitive conclusion from being reached regarding the role of FLACS in cataract surgery. Hoffer et al[10] outlined recommendations to ensure methodologically consistent and fair comparisons when

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testing the accuracy of novel formulas, methods, and instruments in refractive surgery. These include comparing median instead of mean AEs, reporting categoric outcomes of patients within reasonable refractive targets, reporting manifest refractions only for patients with vision of 20/40 or better, accounting for within-patient correlation between eyes, and reporting the instruments used to obtain various study measurements.[10]

Observational studies conforming to these guidelines are needed to provide surgeons with reliable data to inform their patients of the benefits and limitations of FLACS relative to MCS during preoperative surgical planning. Thus, we conducted a large retrospective cohort analysis comparing the refractive and visual outcomes of eyes receiving FLACS with those of eyes receiving MCS while adhering to the aforementioned methodological and statistical guidelines.[10]

Methods

Study Design

This study included consecutive eyes that underwent FLACS or MCS at a single center (Mississauga, Ontario, Canada). Five experienced cataract surgeons consecutively performed the surgeries between July 1, 2012, and July 31, 2015. Patients with significant ocular comorbidity affecting visual acuity or refractive outcome other than cataract (i.e., significant maculopathy, corneal pathology, optic neuropathy) were excluded. Extremes of patient age (<25 or >90 years), axial length (AL) (<20 or >30 mm), preoperative spherical equivalent refraction (SER) (<−15 or >+10 diopters [D]), preoperative average keratometry (avg K) (<35 or >47 D), preoperative cylinder (>5 D), intraocular lens (IOL) power (<−5 or >+32 D), and predicted postoperative SER (<−5 D or >+5 D) were also excluded, as were eyes that did not have optical biometry performed.

This study was approved by the Research Ethics Board of Trillium Health Partners and was conducted in accordance with the tenets of the Declaration of Helsinki.

Interventions and Assessments

All patients underwent routine baseline preoperative anterior and posterior segment examinations and biometry measurements, and were prescribed topical nepafenac 1 drop daily and topical moxifloxacin 1 drop 3 times daily for 2 days before surgery. Biometry was measured using the IOLMaster 500 (Carl Zeiss AG, Oberkochen, Germany), and the predictive refractive outcome was obtained from the third-generation Holladay 1 formula. If the measured AL was >25 mm, the AL was first optimized using the adjustment equation described by Wang et al[11] for myopic eyes before inputting the value into the Holladay 1 calculation formula.

In the MCS group, if a toric IOL was to be implanted, the cornea was first premarked on the steep meridian using the Davis MD OneStep marker (Mastel Precision Surgical Instruments Inc., Rapid City, SD). Once in the operating room, a 0.8-mm sideport was created and a dispersive viscoelastic was then injected followed by a cohesive viscoelastic using the soft shell technique.[12] A 2.2-mm clear corneal incision was created with a metal keratome, and a 5.0-mm-diameter continuous curvilinear capsulorhexis fashioned using sharp-tip capsulorhexis forceps. Phacoemulsification was performed using a phaco-chop technique with the Infiniti Vision System Unit (Alcon Inc., Fort Worth, TX), with cortical removal achieved using the irrigation and aspiration hand piece. The capsular bag was inflated using cohesive viscoelastic to facilitate IOL implantation, after which the irrigation and aspiration hand piece was used to remove the remaining viscoelastic. The wounds were finally hydrated to ensure a watertight seal.

The FLACS cases were completed using the LenSx Laser System (Alcon Inc., Fort Worth, TX). A 5.0-mm-diameter anterior capsulotomy, 4.5-mm-diameter lens fragmentation, 2 corneal incisions (a 2.2-mm main incision and a 0.8-mm sideport incision), and steep meridian corneal markings (when a toric IOL was to be implanted) were each created using the femtolaser. After laser treatment, the corneal incisions were opened with a blunt spatula, dispersive and then cohesive viscoelastics were injected into the anterior chamber, the capsulotomy was removed, and phacoemulsification, cortical removal, IOL implantation, and viscoelastic aspiration were then performed in the same manner as for the MCS cases.

After surgery, both MCS and FLACS patients were prescribed topical nepafenac 1 drop daily for 1 month, moxifloxacin 1 drop 4 times daily on the day of surgery and then 1 drop 3 times daily for 1 week, and difluprednate 1 drop 2 times daily for 1 month. Patients were reviewed 1 day and 3 weeks postoperatively. A complete slit-lamp examination, applanation tonometry, visual acuity measurement, and manifest refraction were all performed at each follow-up visit.

Outcome Measures

Our primary outcome measure was the odds ratio (OR) of achieving an AE within 0.5 D of refractive target 3 weeks postoperatively. This outcome was only assessed for patients with a CDVA of 20/40 or better to ensure the manifest refraction was accurate.[10] The 3-week time point has shown refractive stabilization.[13–16]

Secondary outcome measures included the OR of achieving an AE within 0.25 D and 1.0 D of refractive target 3 weeks postoperatively. The percentage of distance-targeted eyes (refractive target >−0.5 D) with <1.5 D of predicted residual cylinder that achieved incremental 3-week postoperative UDVA targets was also assessed.

The percentages of FLACS eyes and MCS eyes that experienced intraoperative complications (posterior capsular tears, anterior capsular tears that ran posteriorly, intraoperative surgeon decision to change IOL or leave temporarily aphakic, primary corneal incision requiring suture) and postoperative complications (mild/marked corneal edema, cystoid macular edema) or that received additional postoperative refractive procedures were also evaluated.

Statistical Analysis

Categoric and continuous baseline characteristics were reported as proportions and means with standard deviations, respectively, with differences between the cohorts investigated using the Fisher exact test and *t* test, respectively. Snellen visual acuity measurements were converted to logarithm of the minimum angle of resolution (logMAR) equivalents for the purpose of data analysis. A generalized linear mixed model was used to account for within-patient correlation for patients who received surgery in both eyes. The primary outcome of the percentage of eyes that achieved an AE within 0.5 D was presented for both FLACS and MCS unadjusted, and then in an explanatory model that included potential confounders. The potential confounders were identified a priori and included age (<70 or ≥70 years), gender, first versus second eye, left versus right eye, anterior chamber depth (ACD) (≥3.5 mm = deep; ≤2.5 mm = shallow), AL (≥24.8 mm = axial myope; ≤22 mm = axial hyperope), preoperative cylinder, preoperative avg K, preoperative CDVA (≤0.2 logMAR = good