Review of “Femtosecond laser-assisted cataract surgery versus standard phacoemulsification cataract surgery: Case-control study from the European Registry of Quality Outcomes for Cataract and Refractive Surgery”

by Michael Lin, MD, Elizabeth Rossin, MD, Natalie Homer, MD, Huy Nguyen, MD, and Seanna Grob, MD, MAS, Harvard Medical School ophthalmology residents

Background

Over the past 5 years, excitement has grown in the field of ophthalmology over the use of femtosecond laser-assisted cataract surgery (FLACS). Since the 1970s, clinicians and researchers have been in search of a laser to use in corneal and cataract surgery that causes minimal thermal damage to adjacent tissues. The femtosecond laser delivers ultra-short pulses of laser energy and thus minimizes collateral tissue damage. Its original use was primarily for corneal flap creation in LASIK. Since the first report of femtosecond laser use in cataract surgery in 2009, the technique has been rapidly adopted and implemented by cataract surgeons in the U.S., Europe, and Australia. The steps employed by the femtosecond laser include the creation of clear corneal incisions, corneal astigmatic treatment, creation of the capsulotomy, and softening of the nucleus to allow more efficient aspiration.

Recent studies found that in comparison to conventional phacoemulsification cataract surgery (CPCS), FLACS results in a significantly greater reproducibility of the capsulotomy (more regularly shaped, accurate, and precise, with better centration and intraocular lens/capsule overlap) and clear corneal wounds, as well as a significant decrease in the amount of energy required during phacoemulsification. However, no study to date has rigorously evaluated the traditional and more clinically relevant outcome measures including visual acuity, refractive outcomes and rate of complications. Manning et al. are the first to conduct a large, well-powered, matched comparison of CPCS versus FLACS in terms of the aforesaid clinically relevant outcomes.

Study summary

This paper reports the results of a multicenter case control study using the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) that was conducted in 18 European countries and Australia. Consecutive FLACS cases performed from December 2013 to May 2015 were compared to CPCS cases performed from January to December 2014. Surgeons had to have completed at least 50 FLACS cases to participate in order to account for the learning curve associated with the new technology, and FLACS eyes were matched to CPCS eyes from the existing EUREQUO CPCS database.

In total, there were 2,814 FLACS cases matched to 4,987 CPCS cases. The study intended to have a 1:2 case-control ratio, but only achieved 1:1.8 (only 2,814 of 3,379 [83%] of FLACS cases were able to be matched) because there were not enough CPCS controls in the database with matching characteristics.

The criteria included exact matching for preoperative logMAR corrected distance visual acuity (CDVA), age within 2 years, and same number (but not type) of ocular comorbidities (glaucoma, AMD, diabetic retinopathy, amblyopia, other) and same number (but not type) of surgical difficulty variables (previous corneal resection surgery, white cataract, pseudexfoliation, previous vitrectomy, corneal opacity, small pupil, other). There were differences in types of ocular comorbidities and surgical difficulty variables between groups because they were not matched exactly for each possible type of ocular comorbidity and surgical difficulty variable. The FLACS group included more eyes with amblyopia, previous corneal resection surgery, and pseudexfoliation, while the CPCS group included more eyes with diabetic retinopathy, white cataracts, small pupils, and other surgical difficulty variables (deep set eyes, narrow palpebral fissure, ptosis, pterygium, kyphosis, and inability to position) that prevented safe surgical docking of the femtosecond laser device. FLACS was used for corneal incisions in 34.7% of cases in the FLACS group, capsulotomy in 99.4%, nucleus fragmentation in 94.7%, and corneal astigmatism treatment in 4.5% of cases.

The overall intraoperative complication rate for FLACS was 2.9%, compared to 1.5% for CPCS. However, 2% of FLACS complications were minor FLACS-specific complications that are not relevant to CPCS, such as imperforate laser corneal incisions, capsular tags, and incomplete laser capsulotomies. Notably, rate of posterior capsule complications was not significantly different (FLACS 0.4% vs. CPCS 0.7%), and there was no significant difference in rate of vitreous loss or dropped lens material. The study did not collect data on anterior capsule tears, circularity or centration of the capsulorhexis, or phaco energy used as there were no comparators in the EUREQUO database for matching.

The study followed patients for 7 to 60 days, although it did not specify the exact time point at which postoperative outcomes were recorded. Postoperative logMAR CDVA was worse in FLACS by one letter (FLACS: 0.05, CPCS: 0.03). FLACS also had a statistically significantly lower percentage of patients with postoperative gain of one line of vision compared to CPCS (56.7% vs. 66.1%, p<0.001) and greater percentage of patients with postop decrease in CDVA (1.0% vs. 0.4%, p=0.001). In addition, FLACS showed a statistically significantly lower percentage of patients achieving vision equal to or better than 0.0 and 0.1 logMAR CDVA (70.8% vs. 76.1% for logMAR 0.0; 87.8% vs. 90.4% for logMAR 0.1; p<0.001 for both). Absolute biometry prediction error (BPE) was greater in FLACS versus CPCS (0.43 D vs. 0.40 D), a finding that was statistically but not clinically significant, and excluding FLACS cases with previous corneal refractive surgery gave a similar BPE of 0.41 D. Separate subgroup analysis of only FLACS patients with monofocal IOL implantation was performed due to the high rate of multifocal IOL use in the FLACS group (35.8% vs. <0.5% in CPCS), and this showed similar CDVA results.

Postoperative complications were higher in the FLACS group (3.8% versus 2.3%). This was driven by statistically significant increases in corneal edema, early posterior capsule opacification (PCO) reducing visual acuity, uveitis requiring treatment, and uncontrolled IOP. Data on cystoid macular edema was not captured by EUREQUO as a separate postoperative complication.

Comments

Interest in femtosecond lasers for cataract surgery has been steadily rising over the possibility of automated corneal incisions, corneal astigmatic treatment, anterior capsulotomy, and safe surgical docking of the femtosecond laser device.
and lens fragmentation. By creating a more consistent capsulotomy and reducing phacoemulsification energy requirements, FLACS theoretically could result in improved refractive outcomes as compared to conventional CPCS. However, the relative safety of FLACS as compared with CPCS remains unknown, and doubt exists over universally adopting the procedure. This report is the first well-powered, multicenter study that compares clinically relevant outcomes between FLACS and CPCS. In this registry-based, case-control study, both FLACS and CPCS showed excellent visual acuity outcomes with low rates of complications. However, the data failed to show that FLACS was safer or resulted in better visual outcomes as compared with CPCS.

Specifically, the study results did not show a clear difference between the two groups in intraoperative or postoperative complications. Despite overall intraoperative complication rates being statistically higher in the FLACS group compared with the CPCS group, they were similar when FLACS-specific complications were taken out of consideration. However, the FLACS-specific intraoperative complication rate was high at 2%, which included incision-related complications, anterior capsule complications, and capsulotomy complications. Overall visual outcomes were statistically worse in the FLACS group, although likely not clinically significant since the CPCS group saw on average just one letter better in the postoperative study period. Finally, overall postoperative complications were higher in the FLACS group in most of the parameters measured, including corneal edema, early PCO, uveitis, and intraocular pressure spikes. This difference in postoperative complications is likely to be clinically relevant regarding refractive outcomes and patient satisfaction. However, given the high percentage of multifocal IOLs in the FLACS group, a comparison was performed between postoperative complications in FLACS and CPCS using only monofocal IOLs. When evaluating monofocal lenses only, the overall percentage of postoperative complications between the two groups was not statistically significant. However, there still was a greater percentage of patients undergoing FLACS with postoperative corneal edema, early PCO, and uncontrolled IOP that was statistically significant. This data suggests that FLACS may be more pro-inflammatory, which may be mediated by elevated prostaglandin levels in FLACS cases. Interestingly, cystoid macular edema was not captured by EUREQUO as a separate postoperative complication, and therefore, the incidence of this commonly evaluated complication related to cataract surgery could not be compared between the two surgical techniques. If FLACS is more pro-inflammatory, there may be a higher percentage of these patients with postoperative macular edema.

There was a difference in the type of ocular comorbidities and ocular findings that could increase surgical difficulty between the two groups. There were a greater number of patients with diabetic retinopathy, white cataracts, small pupils, deep set eyes, kyphosis, or inability to position for surgery in the FLACS group. These differences may indicate some level of surgeon preference for eyes with less disease and ease of positioning to qualify for FLACS. Also, the laser has its limitations and may not be able to penetrate opaque material, may have more capsulotomy complications in the setting of a white cataract, may risk injuring the iris in the setting of a small pupil, or may not be able to dock to a patient due to positioning issues or facial anatomy. The FLACS group had a higher rate of patients with previous corneal refractive surgery, which may be related to FLACS surgeons having more corneal refractive surgery patients, who then subsequently need cataract surgery.

There are several limitations to this study. The follow-up period was limited to 2 months, although the primary distinguishing complications typically occur early. The study population was obtained retrospectively by registry review, and thus the decision for femtosecond laser use was made at the time of surgery based on patient preference and surgeon discretion. The authors attest that younger patients with better preoperative vision were more likely to undergo FLACS. After these patients were matched with similar database patients who underwent standard cataract surgery, the overall study population was likely younger and healthier than the EUREQUO patient database. Some key differentiating outcome measures such as shape and centration of the capsulorhexis, effective lens position, phacoemulsification energy used, and endothelial cell counts were not tracked. The extent of femtosecond laser use within the case was also not standardized, and thus laser was used to different extents in the various patients.

The advent of the femtosecond laser offers a potential improvement on the already successful cataract surgery. In an age with educated patients who desire the latest surgical technology, it is important that ophthalmologists offer innovative methods that are novel and proven to be of clinical benefit. This study found that postoperative visual outcomes, refractive outcomes, and intraoperative complications were similar between the different methods of cataract surgery with and without femtosecond laser use. The overall postoperative complication rate was higher in those with femtosecond laser assistance, largely due to minor laser-specific complications, with more small pupil, postoperative visual acuity due to corneal edema, early PCO, and uveitis. Based on these results, there is no evidence that FLACS is superior in comparison to CPCS. However, both options offer excellent visual outcomes and low complication rates.

**References**


**Contact Information**

Kloek: Carolyn_Kloek@meei.harvard.edu