

Improved Refractive Outcomes in Femtosecond Laser Assisted Cataract Surgery (FLACS)

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Key Take-Aways

- Significantly more eyes achieved a target spherical equivalent refraction of $\pm 0.50D$, with Femtosecond Laser Assisted Cataract Surgery (FLACS) vs manual cataract surgery (MCS)¹⁶
- Significantly more patients achieved uncorrected distance visual acuity (UCDVA) of 20/20 or better with FLACS (53.3%) vs MCS (28.1%)¹⁶
- Mean postoperative astigmatism was significantly lower with FLACS vs MCS¹⁶
- Refractive outcomes were superior with FLACS in this study using a single femto-second laser platform (LenSx®, Alcon Inc., Fort Worth, TX) compared to MCS¹⁶

Introduction

The demand for cataract surgery has been growing worldwide due to ageing populations and increased life expectancy.¹ The goal of cataract refractive surgery is to provide patients with spectacle independence and a postoperative visual outcome that can meet the demands of their increasingly active lifestyles.² For many of these patients, this means they have similar expectations as refractive surgery patients and demand distance vision without supplemental correction. Additionally, with the introduction of multifocal and toric intraocular lenses (IOLs), patients also expect clear functional vision at near and intermediate working distances.^{3,4}

Manual cataract surgery (MCS) using conventional phacoemulsification is amongst the safest elective surgical procedures performed worldwide.^{3,5-7} MCS has several steps including the creation of corneal incisions, capsulorhexis, manual splitting and phacoemulsification of the cataract, lens aspiration, and insertion of an intraocular lens into the capsular bag. Femtosecond lasers for cataract surgery can automate several of these steps. Aimed at improving safety and refractive outcomes, femtosecond lasers automate the creation of self-sealing corneal incisions, capsulotomy, and lens fragmentation.^{4,8,9}

Previous studies have shown that FLACS may result in a more accurate, centered, and circular capsulorhexis compare to MCS, which can affect intraocular lens (IOL) position and potentially affect refractive outcomes.^{5,10-12} Additionally, some studies have shown that FLACS helps to reduce phacoemulsification time and energy, decrease corneal endothelial injury, and aid in faster visual recovery.¹³⁻¹⁵ Alternatively, other studies have not been able to demonstrate a difference between FLACS and MCS. Recent meta-analysis studies were unable to demonstrate equivalence or superiority consistently across surgical endpoints citing potential limitations of small sample sizes, within-person analysis, unclear methodology, multiple femtosecond laser platform usage, and surgeon experience.^{3,5-7} Safety, as measured by the occurrence of ocular adverse events such as elevated intraocular pressure and macular edema, was generally similar between the two groups.⁷ This paper will discuss the results of a new retrospective study that compared the 1-month postoperative refractive outcomes of eyes that underwent elective FLACS versus MCS.¹⁶

Additional Evidence for Superior Refractive Outcomes in Femtosecond Laser Assisted Cataract Surgery

A recent retrospective study, presented at the 2018 American Society of Cataract and Refractive Surgery, compared the 1-month postoperative refractive outcomes of 225 eyes that underwent elective FLACS and 231 eyes that underwent MCS.¹⁶ Importantly, this study was conducted by two experienced surgeons using a single femtosecond cataract laser platform. All FLACS procedures were completed using the LenSx[®] Laser System (Alcon Inc., Fort Worth, TX), with consistent settings for clear corneal incisions, capsulotomy, and fragmentation. All subjects were implanted with a monofocal IOL (Alcon AcrySof[®] SA60WF or SN60WF) and were operated on using the same phacoemulsification system. Only first eyes of each treatment group were analyzed. Preoperatively, there were no statistically significant differences reported between the treatment groups in terms of gender, age, axial length, flat anterior keratometry (K), and steep anterior K. Eyes with any potentially confounding ocular comorbidities, including prior corneal refractive surgery; known retinal, macular, or corneal pathology; surgical complications; postoperative cystoid macular edema, rebound inflammation, and significant ocular surface disease were excluded.



Significantly Better Visual Outcomes Reported Using FLACS versus MCS

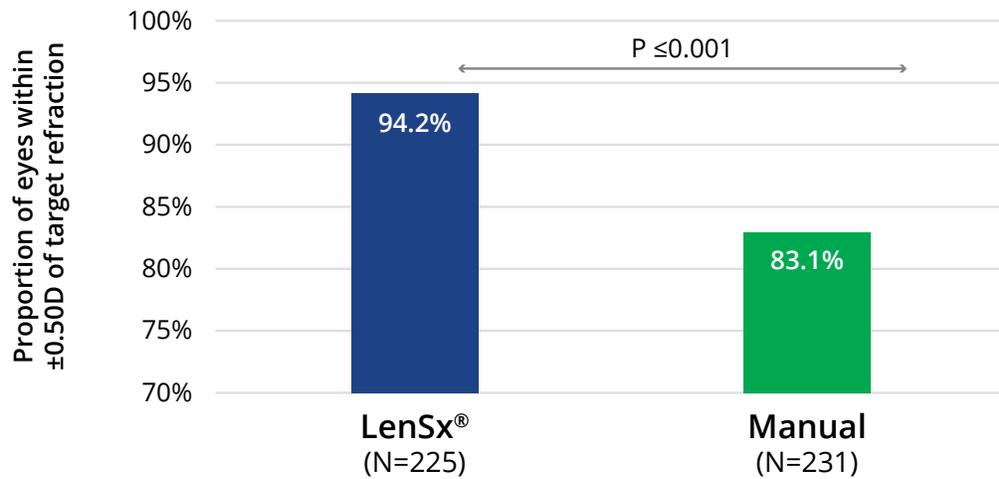


Figure 1: Significantly more subjects achieved target spherical equivalent refraction of ±0.50D, with 94.2% patients for FLACS vs 83.1% for MCS (p<0.001).

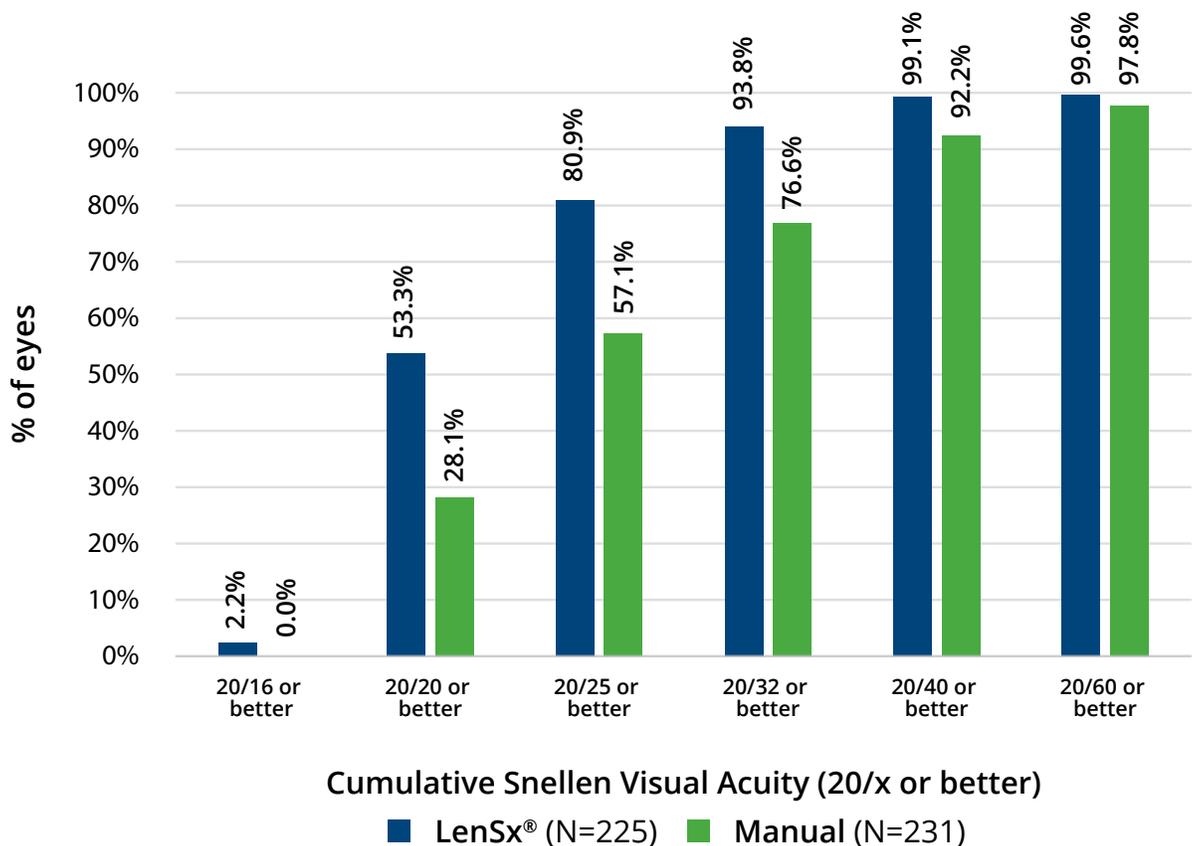


Figure 2: The proportion of subjects with uncorrected distance visual acuity (UCDVA) of 20/20 or better was significantly higher with FLACS (53.3%) vs MCS (28.1%), a difference of 25.2% in favor of FLACS (p<0.001). For 20/40 or better the proportion of subjects was significantly higher for FLACS (99.1%) vs 92.2% with MCS (92.2%) (p<0.001).

Significantly Better Visual Outcomes Reported Using FLACS versus MCS (continued)

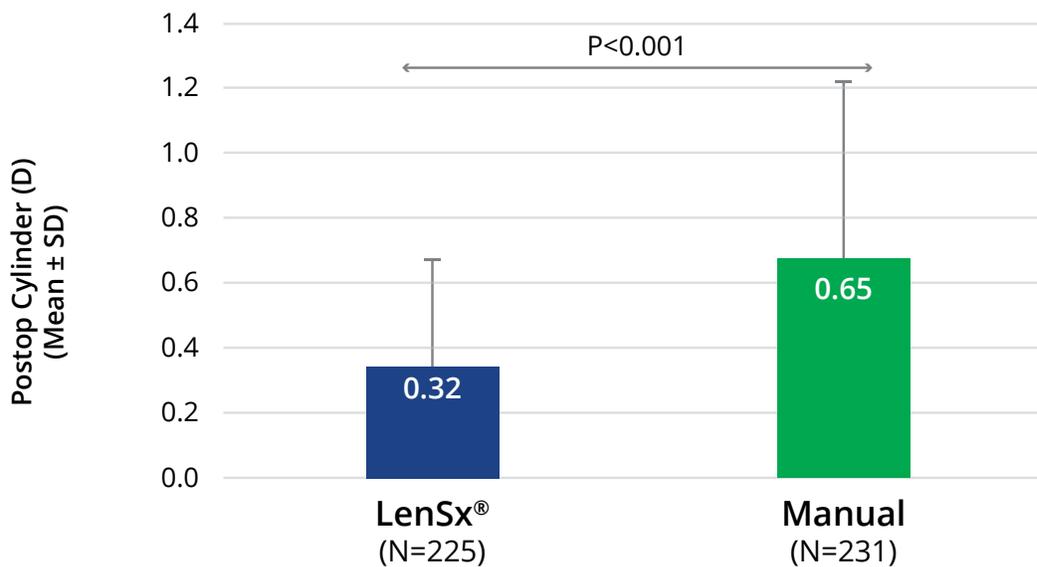


Figure 3: Mean postoperative refractive astigmatism was significantly lower with FLACS vs MCS, 0.32D vs 0.65D, respectively ($p < 0.001$).

Study Implications

Although the study design was retrospective, this study employed restrictive inclusion/exclusion criteria to minimize the impact from co-morbid ocular pathology and controlled for both laser platform and intraocular lens. Additionally, the two cohorts were comparable at baseline in terms of demographics and biometry data. The study authors hypothesized that the superior UCVA was partially a result of better astigmatism management with FLACS, and that the superior CDVA was partially a result of better capsulorhexis centration, capsulorhexis consistency, and uniform wound construction with FLACS. Several other clinical studies have similarly demonstrated superior capsulorhexis circularity and centration, resulting in better capsule/IOL overlap and IOL centration with FLACS.^{11,17,18} Impacting the predictability of postoperative refractive astigmatism, laser-created clear corneal incisions have been noted to have increased accuracy and precision compared to manual keratome-based incisions.¹⁹⁻²² As this study only used a single femtosecond laser platform and all subjects were implanted with a monofocal IOL with a consistent optical design, further investigations are warranted to generalize these refractive outcomes to all FLACS platforms or other intraocular lens designs.

This study demonstrated that eyes undergoing FLACS with the LenSx® femtosecond laser platform more consistently achieved both a target refraction within ± 0.50 D and a smaller absolute mean refractive error compared to MCS. Visual acuity and postoperative cylinder results were also better in the FLACS group compared the MCS group. This may be secondary to better capsulorhexis centration and uniform wound construction. By improving outcomes, FLACS can help meet the visual performance demands of modern refractive cataract surgery patients.

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LENsX® LASER IMPORTANT PRODUCT INFORMATION

CAUTION: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATIONS: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

RESTRICTIONS: Patients must be able to lie flat and motionless in a supine position. Patient must be able to understand and give an informed consent. Patients must be able to tolerate local or topical anesthesia. Patients with elevated IOP should use topical steroids only under close medical supervision

CONTRAINDICATIONS: Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength. Descemetocoele with impending corneal rupture. Presence of blood or other material in the anterior chamber. Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy. Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only). Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape. Corneal thickness requirements that are beyond the range of the system. Corneal opacity that would interfere with the laser beam. Hypotony or the presence of a corneal implant. Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease).

History of lens or zonular instability. Any contraindication to cataract or keratoplasty. This device is not intended for use in pediatric surgery.

WARNINGS: The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

PRECAUTIONS: Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser. Discard used Patient Interfaces as medical waste.

AES/COMPLICATIONS: Capsulotomy, phacofragmentation, or cut or incision decentration. Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure. Capsular tear. Corneal abrasion or defect. Pain. Infection. Bleeding. Damage to intraocular structures. Anterior chamber fluid leakage, anterior chamber collapse. Elevated pressure to the eye.

ATTENTION: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.



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