Clinical Outcomes in the First Two Years of Femtosecond Laser–Assisted Cataract Surgery

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• PURPOSE: To analyze outcomes of femtosecond laser cataract surgery cases in the first 2 years in an ophthalmic institution.
• DESIGN: Nonrandomized treatment comparison with matched, historical controls.
• METHODS: Outcomes and intraoperative events of all laser cataract surgeries (5.0- to 5.5-mm-diameter laser capsulotomies and nuclear fragmentation) at the Singapore National Eye Centre (May 2012–December 2013) were prospectively audited. The 6-weeks-postoperative unaided visual acuities (UAVA), mean absolute error (MAE), mean square error (MSE), and manifest refraction spherical equivalent (MRSE) results of surgeons with > 50 laser cases were compared with controls, a random sample of manual cases with similar age, axial length, and preoperative cylinders. Statistical analysis was performed with SPSS ($P < .05$).
• RESULTS: A total of 1105 eyes (803 patients) underwent laser cataract surgery by 18 surgeons. The majority were female (56.9%) and Chinese (90.9%) with mean age 66.1 ± 11.0 years. Intraoperative complications were subconjunctival hemorrhage (290, 26.2%), anterior capsule tear (9 eyes, 0.81%), posterior capsule rupture (3 eyes, 0.27%), suction loss (5 eyes, 0.45%), iris hemorrhage (1 eye, 0.09%), and endothelial incision (1 eye, 0.09%). There was no dropped nucleus. Visual outcomes of 794 laser surgeries were compared to 420 controls. The %UAVA 20/25 or better was higher in laser cases (68.6% vs 56.3%; $P < .0001$) but MAE (0.30 ± 0.25 diopter [D] vs 0.33 ± 0.25; $P = .062$) and MSE (0.16 ± 0.27 D vs 0.17 ± 0.28 D; $P = .065$) were not significant. MRSE comparison was significant (target plano, preoperative cylinder <1.5 D −0.08 ± 0.36 D vs −0.13 ± 0.40 D; $P = .034$).
• CONCLUSIONS: Femtosecond laser cataract surgery has a low complication rate. Cases compared to controls had statistically better %UAVA ≤20/25 and MRSE, although MAE was not significant. (Am J Ophthalmol 2015;159:714–719. © 2015 by Elsevier Inc. All rights reserved.)

FEMTOSECOND LASER–ASSISTED CATARACT SURGERY is gradually gaining popularity, and is currently most prized for facilitating the creation of a precise anterior capsulotomy and assisting nuclear fragmentation and softening. The laser also has an important role for customized corneal incisions and astigmatic keratotomies. Recent publications highlight the reproducibility and precision of the anterior capsulotomy size and centration,[1–5] thereby affording less lens tilt and improved biometry predictability.[6–9] Additional advantages reported include the reduction in phacoemulsification energy[4,10–12] and superior wound healing and sealing[13] achieved by the femtosecond laser. Despite better precision, there is a paucity of data demonstrating a consistent improvement in visual acuity following laser cataract surgery. Published literature thus far have also documented a learning curve with only incremental improvements in biometry and optical aberrations.[9,14]

The Singapore National Eye Centre (SNEC) is a tertiary referral public institution with over 15 000 cataract surgeries performed annually. Senior cataract surgeons started using the laser cataract technique in May 2012 with a gradual roll-out across faculty. We have been auditing the outcomes and complications of all cases and herein report our results.

PATIENTS AND METHODS

THIS IS A NONRANDOMIZED TREATMENT COMPARISON with matched, historical controls study that examined the intraoperative events and outcomes of laser cataract cases using the VICTUS femtosecond laser platform (Bausch + Lomb, Munich, Germany) from May 1, 2012 to December 31, 2013. This study was conducted in accordance with the principles of the Declaration of Helsinki. The Singapore Health Services Centralized Institutional Review Board waived the need for approval of this study of audit data.

The visual outcomes of cases by the highest-volume laser cataract surgeons were benchmarked against a random cohort of their conventional cases. The controls were identified from the SNEC clinical audit database with similar

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demographic profiles, axial lengths, and preoperative cylinders.

• **BIOMETRY:** Keratometric readings were captured with an autorefractor keratometer (Topcon KR-8800; Topcon, Tokyo, Japan). Biometry was performed using the IOL Master Version 5.4 (Carl Zeiss Meditec, Jena, Germany) or immersion biometry (Ocuscan RxP; Alcon, Fort Worth, Texas, USA). Optimized A-constants (ULIB) and SRK/T formula was applied for lens power calculation.

• **LASER CATARACT CASE SELECTION AND SURGICAL TECHNIQUE:** At the start (first 4–10 cases), laser cataract cases consisted of technically straightforward cases (ie, large palpebral apertures and well-dilated pupil). Thereafter, the procedure was offered to all private patients who were deemed cooperative and consented, except for those with contraindications to laser treatment such as glaucoma with visual field defects, significant cornea scars, or ocular surface disease such as pterygium. Patients with dry eyes were pretreated prior to surgery.

Patients with challenging cataracts such as brunescent, white, posterior polar, or subluxated or low endothelial cell counts were encouraged to have laser cataract surgery, but their outcomes were not included for visual analysis.

Anterior capsulotomy was between 5.0 and 5.5 mm and was automatically downsized for small pupils (<6 mm), maintaining a safety margin of 0.5 mm. The following fragmentation algorithm (based on nuclear opalescence [NO], LOCS III classification[15]) was applied: (1) NO1-2: 4 segments; (2) NO3-4: 6 segments; (3) NO5-6: 8 segments. Radial cuts were up to 7 mm long, with a 700 μm posterior safety margin to the posterior capsule. Preset energy for anterior capsulotomy was 7000–7400 nJ, and nuclear fragmentation varied from 8000 to 9000 nJ. Docking was performed without a speculum. Early cases (n = 64, until June 14, 2012) received 2 drops of saline into the suction clip well, and this was increased to 6–8 drops to avoid corneal folds, which led to incomplete capsulotomies. Following femtosecond laser treatment, topical ketorolac tromethamine 0.4% and phenylephrine 10% were instilled and phacoemulsification completed in the adjacent operating room.

• **CONVENTIONAL PHACOEMULSIFICATION CASES (CONTROLS):** A continuous circular capsulotomy was created under dispersive viscoelastic using capsulorrhexis forceps, targeting 5 mm. After hydrodissection, the nucleus was removed using a "stop and chop" or "direct chop" technique.

All cases had clear corneal incision phacoemulsification (1.8–2.65 mm) with dispersive viscoelastic under topical anesthetic. Cohesive viscoelastic was removed from behind the intraocular lens implant after it had been injected into the capsular bag. Standard postoperative medications consisted of 1 month of topical corticosteroids and antibiotics.

• **DATA COLLECTION CRITERIA:** *Laser cataract surgeries*. Intraoperative and postoperative complications were collected for all surgeons. Data captured included the success of docking, completion of laser treatment, and complications such as loss of integrity of the anterior and posterior capsules. Incomplete capsulotomies were graded as tags (localized postage-stamp adhesions) or bridges (continuous tags). Postoperative subconjunctival hemorrhage was subjectively graded absent, mild, moderate, and severe. For visual outcome analysis, only cases of surgeons who continued to routinely perform laser cataract surgery beyond the expected learning curve and with higher volumes were reviewed. In this study, this was taken as >50 cases. These consisted of cases with normal ocular findings except for cataract, and dry eye patients were pretreated before listing for surgery. The following cataract/patient types were excluded: white, brunescent, traumatic, subluxated cataracts, and post–refractive surgery eyes. Patient demographics, type of intraocular lens implant (IOL) (classified as toric or nontoric implants), unaided (UAVA) and best-corrected visual acuity (BCVA), mean absolute error (MAE), mean square error (MSE), and manifest refraction spherical equivalent (MRSE) at 6 weeks were recorded.

Controls. A random sample of controls was identified from the clinical audit database of the preceding 2 years. A longer time frame for random sampling of controls was required to reduce risk of selection bias and achieve an adequate sample size for comparison, because of the change in clinical practice owing to a diminished number of manual cases by approximately half, when laser cataract surgery was offered. The control cases were by the same surgeons with >50 laser cataract surgeries and exclusion criteria were similar to the laser cataract group. Based on the assumption of a type I error (α) of 0.05, power ($1-\beta$) of 0.8, and to detect a 10% difference between the cases and controls (according to our first 100 laser cataract surgeries where %UAVA 20/25 or better for laser cataract surgery was 66.7% vs 52.0% for controls), the control group sample size was determined to be approximately 400.

Comparison of laser cataract surgery cases and controls was performed to ensure that the 2 groups were similar in terms of age distribution, axial length, and amount of preoperative cylinder. In addition, the number of multifocal/multifocal toric and monofocal (including toric) implants were matched. Outliers with respect to axial length and preoperative cylinder for monofocal IOL patients were removed until both groups became similar. From this cohort, the UAVA were computed for cases with target spherical equivalent (SE) ±0.5 diopter (D). The MAE, MSE, and MRSE (for cases with target ±0.5 D) were compared between laser cataract surgeries and controls (Mann-Whitney *U* test). All statistical analysis was performed with SPSS (version 20; SPSS, Inc, Chicago, Illinois, USA). Statistical significance was defined as $P \leq .05$.

RESULTS

OF 1105 EYES (803 PATIENTS) THAT UNDERWENT LASER cataract surgery by 18 consultant surgeons, 90.9% (730 of 803) were Chinese and 56.9% (457 of 803) female; mean age was 66.1 ± 11 years (range 11–93 years). Most cases (92.0%, 1017 of 1105) underwent both femtocapsulotomy and nucleus fragmentation. NO grade was 1–2 (34.2%, 378 of 1105), 3–4 (57.4%, 634 of 1105), and 5–6 (7.0%, 77 of 1105). Thirteen (1.2%, 13 of 1105) were white cataracts and 3 had fibrotic anterior subcapsular cataracts with NO 0.

• **COMPLICATIONS:** Table 1 shows the main intraoperative and postoperative complications encountered in laser cataract surgery patients. The main intraoperative complications were subconjunctival hemorrhage after docking (26.2%, 290 of 1105), but most were graded as mild (24.2%, 267 of 1105). No cases of dropped nucleus occurred. Two of 3 posterior capsule ruptures (PCR, 0.3%, 3 of 1105) occurred during cortical aspiration. In 1 eye, PCR (without vitreous loss) occurred following posterior extension of an anterior capsule rip during phacoemulsification and in-the-bag IOL implantation was successful. Cases of anterior capsule rip or PCR (n = 12) had postoperative BCVA of 20/25 or better, except for 1 subluxated cataract case (BCVA 20/60 owing to cystoid macula edema). In 2 early cases (0.18%, 2 of 1105), the laser procedure was aborted at the halfway point owing to machine stoppage, and manual capsulorrhexis was completed without event.

Free-floating/complete anterior capsulotomies were achieved in 1008 of 1105 eyes (91.2%), with 97 incomplete owing to bridges (1.6%, 18 of 1105), tags (6.1%, 67 of 1105), and tags and bridges (1.1%, 12 of 1105). Early cases had a higher percentage of bridges (16.9%, 11 of 65) compared to later cases when 6 drops of saline were used for docking (19/1040; 1.83%). This difference was statistically significant (Fisher exact test, $P < .0001$), suggesting that more saline drops significantly improved laser capsulotomy completeness.

Of the complex cataracts (32 subluxated cataracts, 3 traumatic cataracts), 3 cases were converted to extracapsular extraction. Nucleus disassembly was complete in 95.2% of cases (1040/1092, excluding 10 cases without fragmentation and 3 cases converted to extracapsular extraction). Difficulty in aspiration of cortical material was encountered in 5.5% (61/1102) owing to cortical adhesion to the lasered lens capsule edge. These adhesions, seen as a whitened rim around the capsulotomy, were encountered less frequently when the capsulotomy energy was reduced.

TABLE 1. List of Intraoperative and Postoperative Complications Encountered in Femtosecond Laser Cataract Surgery Cases (N = 1105 Eyes)

Intraoperative Complications	Number of Eyes (%)
Subconjunctival hemorrhage	290 (26.2%)
Anterior capsule rip	9 (0.81%)
Suction loss	5 (0.45%)
Posterior capsule rupture	3 (0.27%)
Iris hemorrhage	1 (0.09%)
Endothelial incision	1 (0.09%)
Postoperative Complications	**Number of Eyes (%)**
Posterior capsule opacification	18 (1.7%)
Raised intraocular pressure	5 (0.5%)
Reversible corneal edema (1 case of Descemet membrane detachment)	4 (0.4%)
Cystoid macula edema	2 (0.2%)
Macula-on rhegmatogenous retinal detachment	1 (0.1%)

• **LASER CATARACT SURGERY VS CONTROLS:** Results of 2 surgeons (S.P.C., S.E.T.) were analyzed. There were initially 995 laser cataract cases with 520 controls identified from the random sampling of the preceding 2 years. We further excluded white and brunescent cataracts (cases = 74, controls = 15); subluxated cataracts (cases = 32, controls = 8); post–refractive surgery (cases = 27, controls = 5); traumatic cataracts (cases = 3, controls = 2); eyes with significant glaucoma, cornea, or retinal pathology (cases = 27, controls = 29); and loss to follow-up (cases = 3, controls = 10). Patients with dry eyes who had been pretreated and had no corneal epitheliopathy were included.

Visual outcomes were based on 794 laser cataract cases and 420 controls, after sequentially removing outliers (preoperative cylinder >1.5 D for nontoric monofocal IOL: cases = 14, controls = 16; axial length <22.0 mm and >30.5 mm: cases = 20, controls = 14). The following IOL types were recorded: toric (monofocal and multifocal): cases = 313, controls = 179; nontoric: (monofocal and multifocal: cases = 481, controls = 241). There was no significant difference (Pearson χ^2 test, $P = .28$).

Mean age of patients was 64.5 ± 9.86 years vs controls 65.5 ± 9.39 years (Mann-Whitney U test, $P = .047$). Distribution of axial length (22.0–30.5 mm) of cases (24.76 ± 1.74 [22.03–30.50]) mm and controls (24.56 ± 1.67 [22.07–30.16] mm) was not different between these 2 groups (Mann-Whitney U test, $P = .104$). The preoperative astigmatism for laser cataract surgery cases was −0.57 ± 0.27 (−1.50 to 0.00) D and for the controls was −0.60 ± 0.31 (−1.50 to −0.11) D. There was no significant difference between the 2 groups (Mann-Whitney U, $P = .416$).

• **VISUAL OUTCOME ANALYSIS AND COMPARISON BETWEEN LASER CATARACT SURGERY AND CONTROLS:** Mean logMAR UAVA for laser cataract cases (n = 637) was 0.11 ± 0.12, statistically better than that of controls (n = 358), which was 0.14 ± 0.12 (independent samples *t* test, *P* = .001). There was no difference in the mean logMAR BCVA (cases 0.03 ± 0.07 vs controls 0.04 ± 0.07; Pearson χ^2 test, *P* = .21).

UAVA analysis was performed for cases with target ±0.5 D (cases = 637, controls = 358). The %UAVA of 20/25 or better was significantly higher in laser cataract cases (cases = 68.9%, controls = 56.4%; Pearson χ^2 test, $P < .0001$). No significant difference occurred if UAVA was compared at the less stringent benchmark of 20/32 (Table 2).

Table 3 shows the outcomes of comparison of MAE, MSE, and MRSE between cases and controls. MAE and MSE were computed based on cases with postoperative refraction (cases = 715, controls = 387). MRSE was calculated in cases with a refractive target ±0.5 D (with preoperative cylinder <1.5 D). Only the MRSE was found to be lower among laser cataract cases (−0.08 ± 0.36 D) than controls (−0.13 ± 0.41 D) (Mann-Whitney *U*, *P* = .034). The MAE (cases 0.30 ± 0.25 D, controls 0.33 ± 0.25 D; *P* = .062) and MSE (cases 0.16 ± 0.27 D, controls 0.17 ± 0.27 D) values were not significantly different (Mann-Whitney *U*, *P* = .065).

TABLE 2. Comparison of Cumulative Unaided Visual Acuity in Eyes With Target Spherical Equivalent ±0.5 Diopter Between Femtosecond Laser Cataract Surgery Cases and Conventional Phacoemulsification (Controls) at 6 Weeks Postoperatively

UAVA	Cases (637 Eyes)	Controls (358 Eyes)	P^a
20/20 or better	242 (38.0%)	101 (28.2%)	.002
20/25 or better	439 (68.9%)	202 (56.4%)	.000
20/32 or better	551 (86.5%)	295 (82.4%)	.095
20/40 or better	618 (97.0%)	340 (95.0%)	.18
20/50 or better	630 (98.9%)	355 (99.2%)	>.999
20/63 or better	636 (99.8%)	357 (99.7%)	>.999
20/80 or better	637 (100.0%)	358 (100.0%)	
20/100 or better	637 (100.0%)	358 (100.0%)	

UAVA = unaided visual acuity.
[a]Fisher exact test.

DISCUSSION

OUR STUDY FOUND THAT FEMTOSECOND LASER CATARACT surgery using the VICTUS femtosecond laser platform (Bausch + Lomb) had a low complication rate. The most common complication was mild subconjunctival hemorrhage in 24.2% of eyes. The PCR rate in laser cataract surgery cases was low (0.3%) even within the Center's learning curve and compared favorably to our previous published audit results[16] for conventional phacoemulsification (faculty PCR rate = 1.4%). Only 1 eye sustained a laser procedure–related posterior capsule breach resulting from posterior extension of an anterior capsule rip. Our anterior capsule rip rate was 0.8%, higher than the 0.1% recorded by Day and associates[17] with the Catalys (Abbott Medical Optics Inc) and Roberts and associates'[18] rate of 0.31% with LensSx (Alcon Inc) but compares favorably with Abell and associates'[19] rate of 1.87% with the Catalys (Abbott Medical Optics Inc) and Chang and associates'[20] rate of 5.3% using the LensAR (LensAR Inc). In all these publications, the authors suggest that there is a learning curve. As in our series, which describes our results from the first case, early problems brought about changes in protocol, resulting in more complete capsulotomies. We encountered tight palpebral apertures, puffy eyelids, and sunken orbits among the Chinese patients, which accounted for over 90% of the cases. Metal lid speculums were quickly abandoned as they limited our ability to treat small eyes. For challenging small palpebral apertures with puffy lids and sunken orbits, cotton buds were helpful in stretching and rolling the lid margins apart to accommodate the patient suction clip. During docking, we ensured that there was an adequate fluid interface to prevent corneal-interface contact while the head position was supported to avoid movement. In addition, docking was gentle and the eye position was maintained level to avoid tilt, which was more likely to result in an incomplete capsulotomy. The vacuum pressure of the suction clip was kept to a minimum. Progressive attention to these docking details helped to improve patient comfort, completeness of capsulotomy, and reduction of subconjunctival hemorrhage.

The overall mean logMAR UAVA of eyes treated with femtosecond laser cataract surgery was better than that of controls. We achieved a higher percentage of patients with UAVA of 20/25 or better at 6 weeks compared to controls. MRSE for cases targeting emmetropia was smaller in the laser cataract group; however, there was no difference in MAE. Filkorn and associates[9] had reported a lower MAE in the laser cataract group (0.38 ± 0.28 D) compared to controls (0.50 ± 0.38 D, *P* = .04). The authors attributed this improved visual outcome to the superior refractive predictability[9] resulting from the centered, well-sized, and well-shaped capsulotomies. In 2012, Lawless and associates[21] had reported that both the refractive and visual outcomes using femtosecond laser were comparable with the manual cohort when implanting a diffractive multifocal IOL, and commented that as the MAE for their manual cases was already so small, it was difficult to better it. Although our visual outcome of laser cataract surgery cases appears

TABLE 3. Comparison of Refractive Predictability Between Femtosecond Laser Cataract Surgery Cases and Conventional Phacoemulsification (Controls) at 6 Weeks Postoperatively

	Cases	Controls	P[a]
Mean absolute error	0.30 ± 0.25 D	0.33 ± 0.25 D	.062
Mean square error	0.16 ± 0.27 D (N = 715)	0.17 ± 0.27 D (N = 387)	.065
Manifest refraction spherical equivalent	−0.08 ± 0.36 D (N = 578)	−0.13 ± 0.41 D (N = 331)	.034

D = diopter; N = number of eyes.
[a]Mann-Whitney *U* test.

to be superior to conventional phacoemulsification when statistical comparison is made at the UAVA 20/25 or better benchmark, no significance was reached if comparison is at the level of UAVA 20/32 or better. Therefore, this incremental benefit of enhanced visual outcome may not be subjectively appreciated by the average patient. However, it is arguable that this slight advantage may be important when implanting multifocal and toric implants.

Additional possible benefits contributing to the better visual outcomes following laser cataract surgery reported by others include reduced early postoperative corneal swelling and endothelial cell loss, and reduced higher-order aberrations (HOAs).[22–24] We were unable to compare the HOAs of the 2 groups as there was a wide range of types of IOLs with different inherent optical aberrations in each group that made the sample size too small for meaningful comparison.

These femtosecond laser cataract surgery audit data were prospectively collected at the time of surgery and visual acuity assessed at 6 weeks postoperatively. Limitations of this study include the control group, which was formed by cases randomly selected from retrospective clinical audit data that satisfied the same criteria as laser cases, as well as the relatively early postoperative results reported here. Furthermore, as many of the Centre's ophthalmologists had not done many cases, visual outcomes analysis was based on 2 senior surgeons' results. Despite these shortcomings, the authors believe our data support the marginal visual benefits of femtosecond laser cataract surgery.

In conclusion, the femtosecond laser cataract surgery using the VICTUS femtosecond laser platform was found to be successful and to have an acceptable complication rate in a public institution where a wide variety of challenging cataract cases of varying densities were treated.

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Biosketch

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