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ORIGINAL RESEARCH

Real-World Study Assessing the Efficacy and Safety of a Novel KLEx Procedure with a Next-Generation Femtosecond Laser for Refractive Error Correction

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Purpose: ELITA Femtosecond Laser System (Johnson & Johnson) is a next-generation ophthalmic laser platform designed for Smooth Incision Lenticular Keratomileusis (SILK). A retrospective study evaluated refractive outcomes, visual acuity, higher-order aberrations (HOAs), tear film parameters, and dry eye symptoms 30 days postoperatively.

Patients and Methods: A retrospective, non-comparative, case series analyzing real-world data from patients with myopia treated using the SILK procedure with the ELITA femtosecond laser. The study included 144 eyes from 73 consecutive patients (47 female, 26 male) with myopia (−4.51 ± 1.36 D; range −1.50 D to −8.250 D). Refraction and uncorrected distance visual acuity (UDVA) were assessed preoperatively and at 1, 7, and 30 days postoperatively. A subset of 18 patients (36 eyes) underwent additional evaluation of tear film (Keratograph, LipiView, Schirmer II, NIBUT), dry eye symptoms (OSDI), and HOAs/contrast sensitivity (iTrace).

Results: At 30-days, 96.5% of eyes (139/144) achieved 20/20 UDVA while the remaining 3.5% achieved 20/25. The mean spherical equivalent was −0.22 ± 0.68 D. No significant changes were observed in tear film metrics, HOAs, or contrast sensitivity. A statistically significant difference in vertical coma was noted (0.05 ± 0.04 µm vs 0.1 ± 0.09 µm, P = 0.008), though not clinically relevant. No serious adverse events occurred.

Conclusion: The SILK procedure with the ELITA femtosecond laser platform is safe and effective for myopia correction (with and without astigmatism), with no detrimental effect on tear film stability, dry eye symptoms, or visual quality at 30 days post-surgery.

Keywords: corneal refractive surgery, femtosecond laser, smooth incision lenticular keratomileusis, SILK, lenticular extraction

Introduction

Femtosecond lasers have revolutionized refractive surgery by offering unparalleled precision, consistency, safety, and customization. They are routinely used in cataract surgery procedures[1] and have become the standard for creating corneal flaps in laser-assisted in situ keratomileusis (LASIK).[2] They are also integral to kerato-refractive lenticule extraction (KLEx) procedure as in small incision lenticule extraction (SMILE) procedure, contributing to improved patient outcomes and satisfaction.[3] Compared to procedures using excimer laser, femtosecond lasers result in reduced keratocyte activation and immune response which could improve healing time and lead to reduced adverse responses.[4,5] Although the SMILE procedure has been shown to be safe and effective with less complications related to postoperative dry eye symptoms and corneal sensitivity, issues remain regarding slower recovery of vision compared to LASIK[6] and the steeper learning curve with the procedure.[7]

ELITA™ is a new generation of ophthalmic femtosecond laser surgical system (Johnson & Johnson) which has recently received CE Mark approval for Smooth Incision Lenticular Keratomileusis (SILK™).[8] Compared to IntraLase femtosecond laser (iFS), ELITA delivers a low energy treatment (~40 nJ/pulse vs ~750 nJ/pulse, ELITA vs iFS, respectively) by applying a smaller focus spot size (~1 µm vs 7 µm), shorter pulse duration (~150 fs vs 600–800 fs)

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and higher pulse frequency (10 MHz vs 150kHz). As the pulse application is contiguous, there is tissue-bridge-free resection which simplifies lenticule removal by the surgeon[9] with less ocular tissue changes and reduced immune response.[4] As the ELITA procedure simplifies tissue removal due to lower energy, the procedure is able to produce rapid visual recovery and healing postoperatively.[10] To the best of our knowledge, no study related to early visual outcomes, including tear film metrics and dry eye symptoms, after SILK using the ELITA platform for myopia correction is available.

The current study used real-world data to provide clinical evidence to assess the efficacy and safety of the ELITA Femtosecond Laser System using the SILK procedure for the correction of myopic refractive error, with and without astigmatism in the initial 30-day period. The research aims were addressed using a retrospective study design from patients who had undergone refractive laser surgery. Efficacy was assessed in terms of visual outcomes, higher order aberrations, tear film metrics, and patient reported dry eye symptoms. Safety was assessed in terms of any adverse effects and procedure-related complication.

Materials and Methods

Study Design

This retrospective, non-comparative case series assessed real-world clinical data from 73 consecutive myopic patients who underwent the SILK procedure with the ELITA femtosecond laser at a tertiary eye center in New Delhi, India, between April 2023 and February 2024. Appropriate patient consent was obtained for data sharing with the University of New South Wales, and the study was approved by the University of New South Wales Human Research Ethics Advisory Panel (iRECS6768) and was conducted in compliance with the principles of the Declaration of Helsinki. A waiver of approval from the ethics committee of Shroff Eye Center was sought in view of retrospective nature of the study. De-identified patient records included demographics (eg. identifier, eye, gender, age), procedural details, and up to 30-days post-operative follow-up.

Inclusion and Exclusion Criteria

The SILK procedure was performed by a single surgeon (RS) on patients deemed suitable based on pre-operative screening. Inclusion criteria were: age >18 years, myopic spherical equivalent ≤ 8.50 DS, astigmatism ≤ 3.00 DC, ≤ 0.75 DS difference between cycloplegic and manifest refraction, residual corneal stroma ≥ 300 microns, uncorrected distance visual acuity (UDVA) ≤ 20/40, corrected distance visual acuity (CDVA) ≥ 20/20 and, ≥ 2 lines better than UDVA, no contact lens wear for ≥ 1 week (soft) or ≥ 4 weeks (rigid). Exclusion criteria included: systemic or ocular conditions, or concurrent use of medications, that may impair wound healing, diabetes mellitus, implanted electronic device, prior ocular surgery, active ophthalmic disease (eg, dry eye, glaucoma, keratoconus, corneal dystrophy, or degeneration), pregnancy or lactation, or known drug sensitivities.

Examination Procedure

All 73 patients underwent comprehensive preoperative and postoperative examination. Preoperative (PREOP) examinations included UDVA, manifest refraction, CDVA, Ocular Surface Disease Index (OSDI) questionnaire,[11] higher order aberrations (HOA), contrast sensitivity (iTrace, Tracey Technologies, USA), corneal tomography (Pentacam, Oculus Optikgerate GmbH, Germany), tear break-up time (Ocular Keratograph 5M; Oculus Optikgeräte GMbH, Germany), lipid layer thickness (LipiView; TearScience, USA), and Schirmer II test. Visual acuity was measured using an Early Treatment Diabetic Retinopathy Study (ETDRS) computerized vision chart at 4.0 meters (13 feet) under photopic conditions (85 cd/m2 [range 80–110 cd/m2]). For the entire cohort (n = 73), postoperative assessment at 1(POD1), 7 (POD7), and 30 days (POD30) included UDVA and autorefraction.[12] In addition, a subset of 18 consecutive patients only, underwent additional tear film (OSDI, tear break-up time, lipid layer thickness, and Schirmer II) and HOA (across a 5 mm pupil) assessments at POD30. Subjective dry eye symptoms were assessed on this subgroup using the OSDI questionnaire.

Surgical Procedure

The lenticule was created using the ELITA femtosecond laser (Johnson & Johnson Surgical Vision, Inc. Milpitas CA, USA) with a radial scanning pattern. Intended cap thickness was 110 µm, with lenticule and cap diameters of 6.0 and 7.6 mm, respectively. Entry incision of 4 mm was created superiorly. During ELITA lenticule cutting procedure, the posterior cut was performed first, followed by the ring, anterior, and entry incisions. The refractive lenticule of intrastromal corneal tissue was then dissected and separated through the entry incision and manually extracted. A Siebel spatula was used to smooth the anterior cap surface for 30 seconds with moderate pressure. Postoperative treatment included topical moxifloxacin hydrochloride 0.5% (Vigamox®, Alcon Laboratories, Inc, Fort Worth, TX, USA) 4 times a day for 2 weeks, topical prednisolone acetate 1% ophthalmic suspension (Pred Forte; Allergan, Inc., Irvine, CA) starting from 4 times a day and tapered over 1 month, and lubricating drops (Optive, Allergan, Inc., Irvine, CA) as needed.

Statistical Analysis

Data underwent data quality checks and cleaning to ensure validity and consistency. Collection occurred at PREOP, POD1, POD7 (± 3 days), and POD30 (± 5 days). Primary outcomes were UDVA and procedure-related complications/adverse events; secondary outcomes included contrast sensitivity, HOAs, and dry eye metrics (OSDI, non-contact tear break-up time, lipid layer thickness, Schirmer II). Explanatory variables included patient identifier, eye, gender, and age. The efficacy index at POD30 was calculated as the ratio of postoperative UDVA to preoperative CDVA, with success defined as > 0.80.[13] Summary statistics (mean, standard deviation, range) were computed and significance set at $P < 0.05$.

Results

All patients meeting the inclusion/exclusion criteria were included in the analysis. Seventy-three consecutive patients (146 eyes) were assessed at PREOP, POD1, POD 7, and POD30. Two eyes were excluded due to a dark spot (patient [Px] #57; left eye) and suction loss (Px #53; left eye), resulting in 144 eyes analyzed (Table 1). A subset of 18 consecutive patients (36 eyes) underwent additional assessments of tear film metrics, dry eye symptoms, and HOAs at PREOP and POD30. Baseline characteristics, including age, sex, visual acuity, and refractive error are summarized in Table 1.

Table 1 Baseline (Preoperative, PREOP) Patient Demographics, Visual Acuity, Refractive Errors, Dry Eye Symptoms, and Eye Physiology Measures (Mean ± SD)

Baseline	
Patients/eyes	73 (144)
Age	26.6 ± 4.7 years (range: 19 to 41 years)
Sex - female:male (%)	47: 26 (64%: 36%)
LogMAR uncorrected distance visual acuity (UDVA)	0.78 ± 0.15 (range: 20/80 – 20/200)
LogMAR corrected distance visual acuity (CDVA)	0.0 ± 0.0 (range: NA)
Manifest refraction sphere	−4.51 ± 1.36 D (range: −1.50 to −8.25 D)
Manifest refraction cylinder	−0.62 ± 0.50 D
Manifest spherical equivalent	−4.84 ± 1.61 D
OSDI*	15.5 ± 9.7
Schirmer II*	23.8 ± 8.0 mm
Lipid layer thickness*	44.0 ± 16.3 µm
Non-contact break-up time*	12.6 ± 5.3 s

Note: *18 patients/36 eyes for indicated variables.

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Visual Outcomes

LogMAR UDVA was 0.05 ± 0.12 (POD1), 0.02 ± 0.08 (POD2), and 0.00 ± 0.02 (POD30). Preoperatively, UDVA ranged from 20/80 to less than 20/200. At POD1, 95% of eyes (137/144) achieved 20/32 UDVA or better, and 74% of eyes (107/144) achieved 20/20 UDVA (Figure 1a and b). By POD7, 88% of eyes (127/144) achieved 20/20 UDVA, with the remainder reaching 20/32 or better (Figure 1a and b). At POD30, 96.5% of eyes (139/144) achieved 20/20 UDVA and the remaining 3.5% achieved 20/25 (Figure 1a and b). The efficacy index exceeded the 0.80 threshold at all time points: 0.9 ± 0.2 (POD1), 1.0 ± 0.1 (POD7), and 1.0 ± 0.0 (POD30).

Refractive Outcomes

Preoperatively, the mean manifest spherical refractive error was −4.51 ± 1.62 D (range: −1.50 to −8.25D) improving to −0.07 ± 0.49 D (range: +1.12 to −1.62 D) at POD30. The preoperative mean manifest cylinder error was −0.67 ± 0.50 D (range 0.00 to –2.50 D) and was, as measured by autorefraction, −0.31 ± 0.39 D (range: +0.87 to −1.75 D) at POD 30. The baseline spherical equivalent was −4.84 ± 1.61 D, shifting to 0.09 ± 0.68 D (POD1), −0.14 ± 0.77 D (POD7), and −0.22 ± 0.68 D (POD30). Changes in spherical error are shown in Figure 2.

Predictability

At POD30, 68.8% (99/144) and 92.5% (133/144) of eyes were within ±0.50 D and ±1.00 D, respectively, of the attempted spherical equivalent plano target, as assessed by autorefraction (Figure 3). Regarding astigmatism, 97.9% of eyes (141/144) were within ±0.50 D and 100% (144/144) within ±1.00 D of the attempted astigmatism plano target (Figure 4). Distribution across diopter ranges for spherical equivalent and astigmatism is shown in Figures 3a and 4, respectively, with a scatter plot of attempted versus achieved spherical equivalent shown in Figure 3b.

Higher-Order Aberrations

HOAs and contrast sensitivity were assessed at PREOP and POD30 using a 5.0 mm analysis diameter (Supplementary Figure 1a–e). No significant changes were observed in spherical aberrations (0.07 ± 0.06 µm vs 0.08 ± 0.15 µm, P = 0.706), vertical trefoil (0.05 ± 0.06 µm vs 0.06 ± 0.05 µm, P = 0.716), or root mean square of HOAs (0.12 ± 0.08 µm

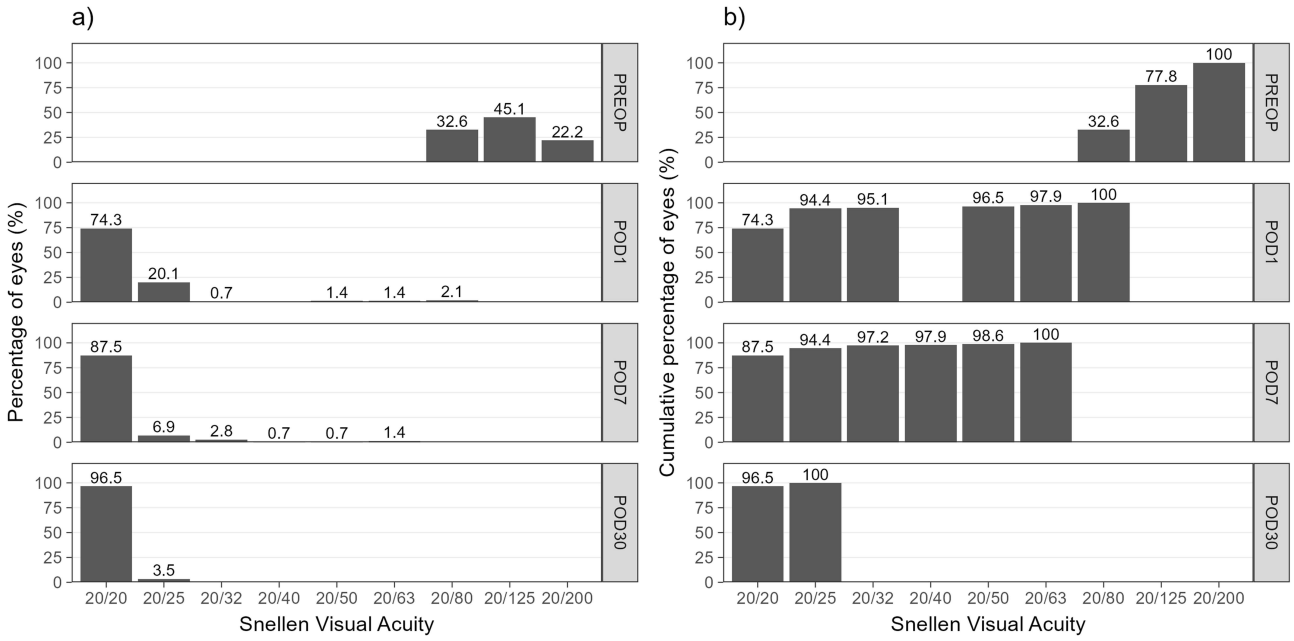

Figure 1 (**a**) Percentage, and (**b**) cumulative percentage, of eyes with uncorrected distance visual acuity (UDVA) at the 1-, 7-, and 30-days post-operative visits compared to the UDVA at the preoperative visit (N = 144 eyes; Plano target).
Abbreviations: POD, postoperative day; PREOP, preoperative.

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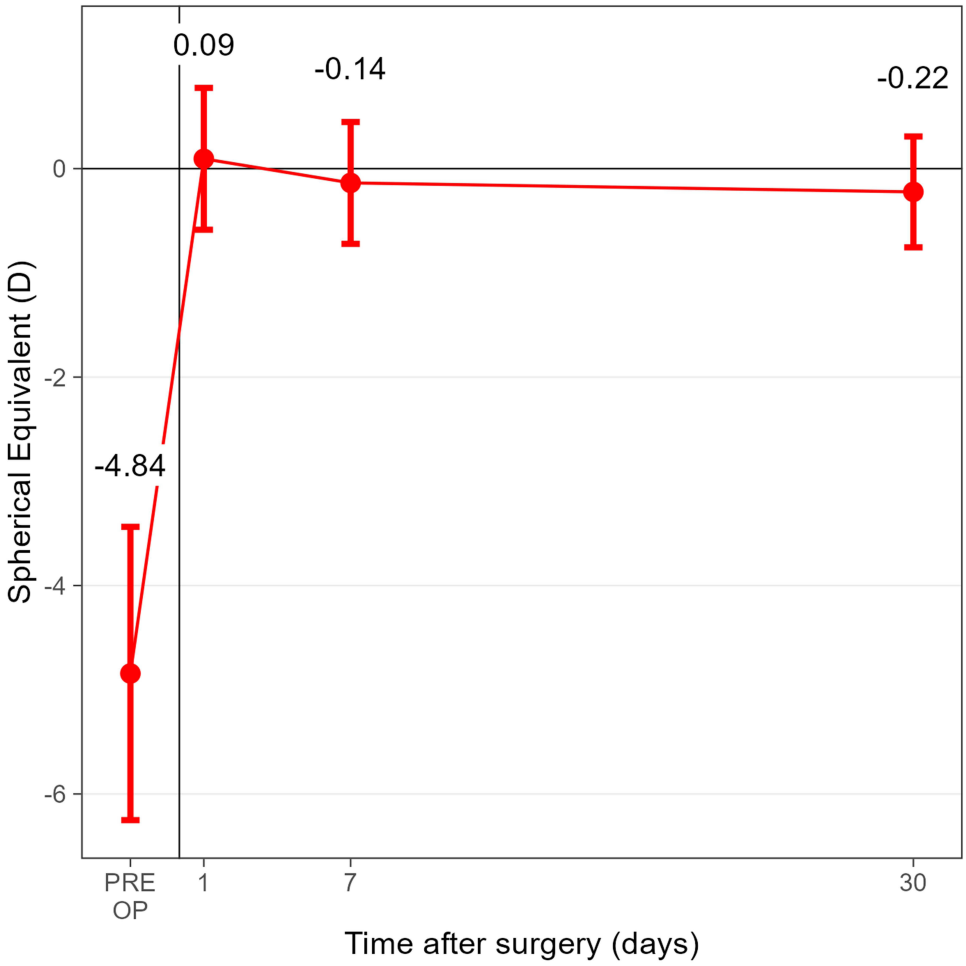

Figure 2 Change of spherical equivalent over time (preoperative, 1-, 7-, 30 days post-operative) after SILK procedure (N = 144 eyes; Plano target). Points and error bars are mean and SD; mean values are displayed.

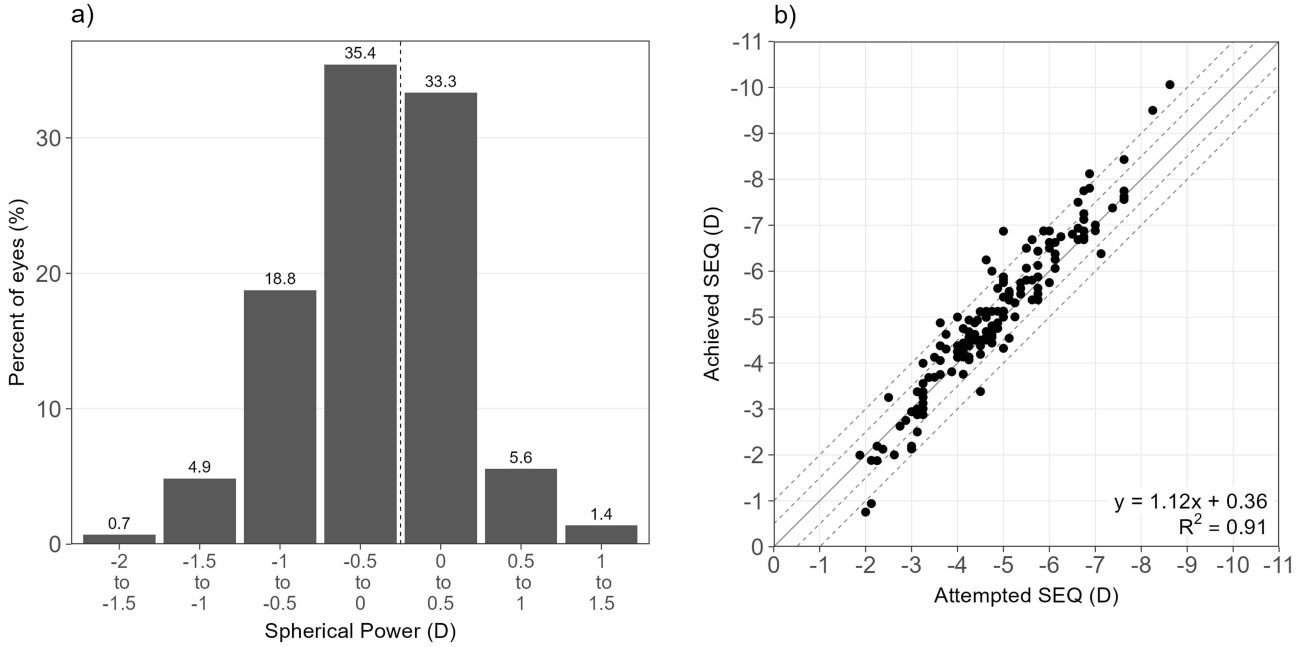

Figure 3 (**a**) Percentage of eyes within different spherical diopter ranges from the target correction (Plano) 30-days (POD30) following surgery; (**b**) Spherical equivalent attempted vs achieved 30 days following surgery (dashed lines represent ± 0.5 and ± 1.0 D). (POD30, N = 144 eyes; plano target).

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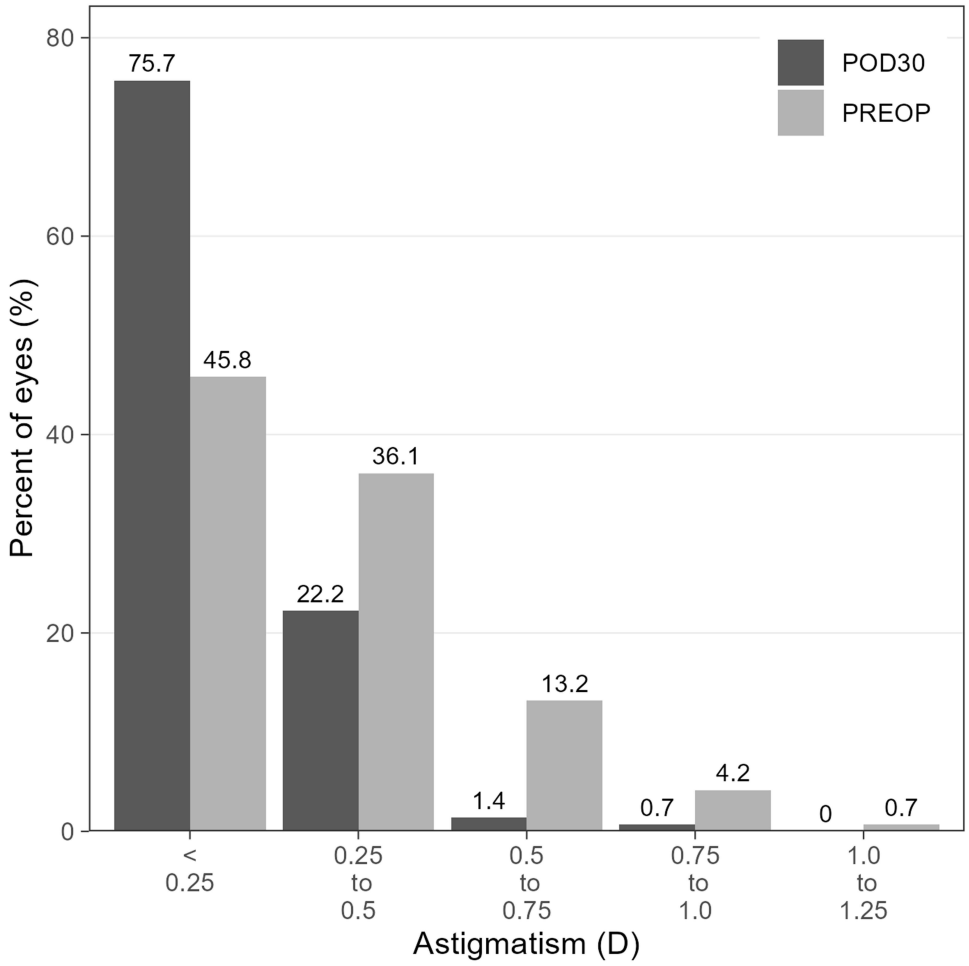

Figure 4 Percentage of eyes within different diopter ranges of astigmatism prior to surgery (PREOP) and at 30-days following surgery (POD30, N = 144 eyes; Plano target).

vs 0.15 ± 0.1 µm, P = 0.208). Vertical coma increased (0.05 ± 0.04 µm vs 0.1 ± 0.09 µm, P = 0.010). Contrast sensitivity was assessed using the modulation transfer function (MTF; iTRACE) and showed no significant change (0.61 ± 0.18 vs 0.52 ± 0.26, P = 0.215, PREOP vs POD30 respectively).

Ocular Surface and Tear Film Metrics

In a subset of 18 consecutive patients (36 eyes), dry eye symptoms and tear film metrics were assessed at PREOP and POD30 (Figure 5a–e). OSDI scores decreased from 15.5 ± 9.7 to 11.0 ± 6.7 (P = 0.114). Schirmer II values increased from 23.8 ± 8.0 mm to 26.9 ± 5.4 mm (P = 0.039), lipid layer thickness rose from 44.0 ± 16.3 µm to 51.1 ± 20.6 µm (P = 0.036). Non-contact break-up time showed no significant change (12.6 ± 5.3 s vs 12.0 ± 5.4 s, P = 0.646). Thinnest corneal thickness decreased significantly (551.5 ± 30.7 µm vs 461.8 ± 29.9 µm, P < 0.001).

Surgical Complications and Adverse Events

No serious adverse events occurred during the study period. Suction loss was noted in one eye (0.6%; 1/144; Px #53) due to sudden head movement and a dark spot was observed in one eye of another patient (0.6%; 1/144; Px #57), likely caused by meibomian secretions on the interface. Both procedures were aborted, and the affected eyes later underwent surface ablation, achieving 20/20 UDVA.

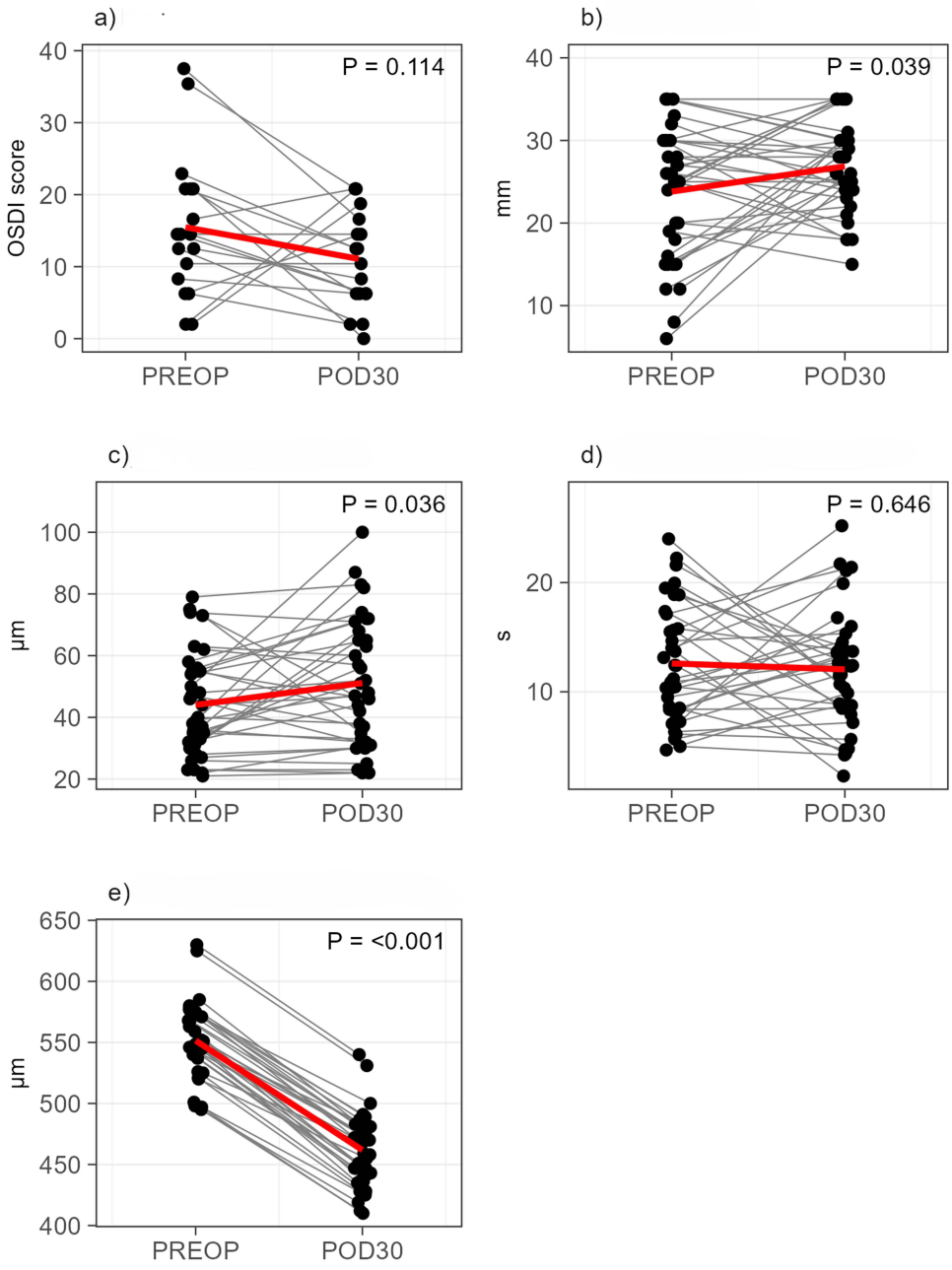

Figure 5 Pre- and 30 days post-operative (PREOP and POD30) (**a**) Ocular Surface Disease Index scores (OSDI) and tear film metrics, (**b**) Schirmer II, (**c**) lipid layer thickness, (**d**) non-contact break-up time, (**e**) thinnest corneal thickness. Patient eyes are connected with grey line; mean is the connected red line.

Discussion

The key advantage of refractive surgery is eliminating or reducing dependence on spectacles without compromising ocular health. Given the cohort of patients undergoing refractive surgery is typically young and active, rapid visual recovery is a priority. Although lenticule extractions with SMILE procedures have been shown to be safe and effective, slower recovery of vision compared to LASIK[6] and the steeper learning curve with the procedure[7] have been reported. The slower recovery with traditional kerato-lenticule extraction platforms may be due to greater surgical dissection leading to corneal stromal damage, inflammation, and visual impairment immediately after surgery.[10] Another possible reason could be an incongruity between anterior and posterior stromal beds after extraction of the lenticule leading to wrinkles in the Bowmans membrane and visual

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degradation.[14] Variations in femtosecond laser energy and spot spacing may also influence how smooth the lenticule surfaces are and anatomic irregularities at the stromal interface may result in greater optical degradation compared to LASIK.[10]

This study demonstrated rapid visual recovery following the SILK procedure. LogMAR UDVA improved from 0.05 ± 0.12 (POD1) to 0.02 ± 0.08 (POD7) and 0.00 ± 0.02 (POD30). At POD30, 95% of eyes achieved a UDVA of 20/32, and 74% of eyes reached 20/20; by POD7,88% achieved 20/20 UDVA and 100% reached 20/32. These outcomes align with prior studies which have demonstrated faster recovery using lower energies platforms like VisuMax 500.[15,16] The ELITA systems lower energy for lenticle creation may contribute to this rapid recovery observed in this study. Spherical equivalent shifted from 0.09 ± 0.68D (POD1) to −0.14 ± 0.77D (POD7) and −0.22 ± 0.68 D (POD30), with the initial hyperopic shift likely due to transient subclinical edema in adjacent stromal tissue in the immediate postoperative period which improves further by Day 7 and 30. At POD30, 96.5% of eyes achieved 20/20 UDVA and the remaining 3.5% achieved 20/25 UDVA. No eyes lost CDVA by POD30. Seventy percent of eyes were within ±0.50 D of spherical equivalent emmetropia target and 98.2% within ±0.50 D for astigmatism plano target. The efficacy index exceeded 0.80 at all timepoints indicating the procedure was successful,[13] and no serious adverse events were reported.

Two prior studies evaluated the efficacy and safety of the SILK procedure using the ELITA femtosecond platform. In a prospective, multicenter study of 85 myopic patients (170 eyes), over 91.5% of eyes achieved 20/20 UDVA at POD30, increasing to 96% at 3 and 6 months, with no loss of CDVA. For, postoperative spherical equivalent, over 90% of eyes were within ±0.50 D and 100% within ±1.00 D of the target plano refraction, with no serious adverse events.[9] Another prospective study (N = 24 eyes) reported 20/20 UDVA in 88%, 92%, and 100% of eyes at 1, 3, and 9 months, respectively, after the SILK procedure, with all eyes were within ±0.50 D for sphere and cylinder refraction at 9-months.[17] The current retrospective study showed comparable visual and safety outcomes to these initial prospective studies indicating good efficacy, predictability, and safety of the procedure. However, one difference was both previous studies showed that 90–100% of eyes were within ±0.50 D spherical equivalent/sphere power from plano,[9,17] whereas the current retrospective study recorded a rate of 70% of eyes. A trend was also observed where high degrees of myopia tended to be slightly overcorrected while lower degrees showed undercorrection. This discrepancy may be due to the use of autorefractor, which can over-minus compared to subjective refraction.[18]

This study also evaluated HOAs and contrast sensitivity at PREOP and POD30, showing minimal induction of spherical aberrations, vertical trefoil, and root mean square of HOAs. This is consistent with a previous study which also found the SILK procedure induced minimal HOAs, which was attributed to the greater precision of the femtosecond laser.[17] Another study further supports the accuracy of femtosecond lasers in refractive surgery, showing their use during LASIK results in fewer HOAs compared to microkeratomes.[19] However, vertical coma increased in this study, similar to findings in a ray-trace LASIK study, where it was hypothesized to arise from displacement between the ablation axis and the line of sight.[20] In SILK procedure, centration of the treatment currently relies on manually aligning the laser treatment pattern to the central mark placed by the surgeon just before the surgery begins. As manual marking may not be completely repeatable, a minor displacement in centration and the superior entry incision designed for lenticule removal may be responsible for the increase in vertical coma. The observed increase in vertical coma (0.05 ± 0.04 μm vs 0.1 ± 0.09 μm, P = 0.010) was lower than previously reported values (0.12 μm).[20–23] The ocular surface and HOA assessments at 30 days provide an early snapshot of physiological impact, but longer-term follow-up is essential to determine sustained changes. These preliminary findings suggest minimal disruption aligning with the expected benefits of low-energy femtosecond platforms but should be validated in future prospective studies.

Dry eye symptoms and tear film metrics were assessed at PREOP and POD30. While tear production and lipid layer thickness increased, no changes were observed in OSDI or non-contact break-up time, possibly due to the postoperative medication use. Compared to the approximately 20–24 mm flap incision in LASIK surgery,[24] laser-assisted lenticular extraction (LALEX) procedure uses a significantly smaller incision size (< 4 mm).[25] This less invasive approach better preserves corneal nerves and leads to fewer dry eye complications compared to both femtosecond-assisted and traditional LASIK.[26] Studies confirm that femtosecond LALEX procedures had less impact on dry eye symptoms compared to femtosecond laser-assisted LASIK.[25,27] Additionally, ELITAs rapid lenticule creation (approximately 16 seconds) minimizes the potential for loss of suction during the procedure and is more rapid than the VisuMax 500 (approximately 30 s) and comparable to the VisuMax 800.[10]

A potential limitation of the study was the use of autorefraction at follow-ups, which may overestimate myopia due to accommodation. However, as 96.5% of patients achieved 20/20 UDVA (and 3.5% achieving 20/25), the autorefraction results are unlikely to represent the true manifest refractive error. Real-world data, while inherently less controlled, offer valuable insights into how new technologies perform in routine clinical settings.[28] To minimize any potential bias, all patients that satisfied the inclusion/exclusion criteria during the 11-month period were included in the dataset. This study therefore reflects early visual outcomes from a diverse patient population treated by a single surgeon, providing practical evidence of the ELITA system's performance outside of trial environments.

Conclusion

The current study showed that the SILK procedure using the ELITA femtosecond laser was safe and effective treatment for lenticule extraction to correct myopic refractive error with and without astigmatism, with 96.5% of eyes achieving 20/20 UDVA and 100% of eyes achieving 20/25 UDVA or better at the 30-day postoperative visit. The surgical procedure induced minimal higher-order aberrations that were not clinically significant and did not affect contrast sensitivity. Additionally, the SILK procedure had no negative impact on patient-reported dry eye symptoms or tear film metrics, indicating minimal physiological impact. While the retrospective nature and 30-day follow-up limit the ability to assess long-term visual stability and complications, early postoperative data are critical for evaluating rapid visual recovery, which is a key consideration for younger, active patients. These findings complement existing prospective studies with longer follow-up[9,17] providing a broader understanding of the SILK procedure's performance across different timeframes.

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Author Contributions

Dr Jerome Ozkan received research funding from Johnson & Johnson Vision and contributed to data analysis and manuscript preparation. Dr Rushad Shroff performed procedures using the evaluated laser platform and contributed to manuscript writing. Dr Ritu Arora, Dr Apoorva Agrawal, and Dr Palak Gupta participated in critical revision of the manuscript. Ms Viven Chiang and Dr Brian Schwam contributed to study design and manuscript revision. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Ms Viven Chiang and Dr Brian Schwam are employees of Johnson and Johnson Vision. The authors report no other conflicts of interest in this work.

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