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ORIGINAL RESEARCH

Initial Visual and Refractive Outcomes of Keratorefractive Lenticule Extraction Using 2MHz Femtosecond Laser Platform

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Purpose: To report the initial refractive and visual outcomes of keratorefractive lenticule extraction (KLEx) procedures using the 2MHz femtosecond laser platform in myopia and myopic astigmatism.

Methods: All eyes meeting the following inclusion and exclusion criteria from April to June 2024 were selected for the study. The study included patients >18 years of age with vision 20/25 or better, myopia with SEQ of −0.5D to −12.5D, residual stromal thickness >300 microns and stable refraction for one year. Excluded were those with hypermetropia, mixed astigmatism, corneas <480 microns, corneal diseases, active illnesses, pregnancy, abnormal corneal shape, and patients not able to commit to a 3-month follow-up.

Results: A total of 198 eyes (102 patients) comprising 45 (44.1%) females and 57 (55.9%) males, with a mean age of 23.9 ± 4.8 years, were considered for statistical analysis. 90.4% of the eyes achieved 20/20 UDVA or better after surgery. Correlation between attempted SEQ and achieved SEQ was 0.9636 implying high predictability. Our study demonstrated high accuracy with 100% eyes achieving SEQ ± 1.00D of intended target and 91.9% of eyes within 0.5D of intended target SEQ. The present study confirms the refractive stability with minimal changes (−0.04D relative to the intended target) over 3 months of follow up.

Conclusion: The present study shows that the KLEx procedure is highly efficacious and safe, with visual and refractive outcomes showing good predictability and stability.

Keywords: refractive surgery, cornea, SMILE Pro, Visumax, femtosecond

Introduction

The incidence of myopia and, in turn, the need for laser vision correction procedures is rising worldwide. In recent years, minimally invasive corneal surgery has seen significant advancements with the emergence of lenticule based procedures commonly known as keratorefractive lenticule extraction (KLEx).[1] Pioneered by Sekundo et al in 2007, Small Incision Lenticule Extraction (SMILE) is a flapless technique. This method involves a 500 kHz VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, Jena, Germany), creating an intrastromal lenticule, which is then manually extracted through a small peripheral corneal incision.[2,3] KLEx eliminates potential complications associated with creating a flap while maintaining safety and efficacy regardless of environmental factors.[4,5] KLEx by SMILE technique is a minimally invasive flapless procedure compared to laser in-situ keratomileusis (LASIK). Hence, KLEx has very nominal dry eye prevalence and better postoperative corneal biomechanics.[6]

A newer version of the femtosecond laser (Visumax 800, Carl Zeiss Meditec AG, Jena, Germany), promised significant advancements over its predecessor. While they share the same laser head and optical pathway, the new platform has 2 key differences: a faster pulse frequency (2,000 kHz). This innovation significantly cuts the lenticule creation time from around 30 seconds to under 10 seconds, thereby reducing the risk of suction loss. Another difference is the introduction of the CentraLign system, which allows laser delivery over the corneal vertex by manually entering the polar coordinates of the corneal vertex into the software and visual overlays on the treatment monitor help to guide

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the surgeon in aligning with the visual axis. Research on lenticule based procedures on the new platform is still emerging, with the first reports on surgical outcomes surfacing in 2023.[7,8]

The aim of the current paper is to report the initial efficacy, safety, predictability and sustainability of KLEx procedures using the 2 MHz femtosecond laser platform in India with a 3-month follow-up.

Methods

A prospective single-arm interventional study was conducted on patients who underwent KLEx procedure for myopia and myopic astigmatism between April and June 2024 at a tertiary multi-speciality hospital in Western India. All patients provided informed written and verbal consent regarding the procedure's potential benefits, risks, and available alternatives, as well as for the data to be utilised for general analysis and publication. The study adhered to ethical principles outlined in the Declaration of Helsinki, and the KD Hospital Academics Ethics Committee approved it. The 2 MHz femtosecond laser platform was used according to its standard clinical indications without subjecting patients to additional invasive procedures.

Patients included met the following criteria: preoperative corrected distance visual acuity of 20/25 or better, age >18 years, spherical equivalent of −0.5D to −12.5D with cylinder not more than −5D, residual stromal thickness of >300 microns, stable refraction over a period of 1 year and completion of KLEx procedure. Exclusion Criteria included hypermetropia, mixed astigmatism, central corneal thickness of <480 microns, corneal ecstatic disorders, any corneal haze or scars causing irregular astigmatism, any active ocular/systemic illness (including autoimmune conditions), pregnant or lactating mothers, abnormal corneal topography findings, eyes needing >40% of Tissue Ablation for full correction and patients not able to complete 3 months of follow up.

A complete preoperative checkup was performed for all patients, which included – history, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), binocular corrected distance visual acuity (Binocular CDVA), manifest refractions, dry eyes assessment including Schirmer and tear film break up time, intraocular pressure by non-contact tonometry, undilated and dilated retinoscopy, slit-lamp assessment and indirect ophthalmoscopy. Corneal tomographic measurements were done using a scheimpflug-based device[9] (Pentacam HR Oculus, Optikgeräte GmbH) and topography using a Placido disc-based device[10] (Atlas 500, Carl Zeiss Meditec AG). Epithelial mapping was done using the spectral domain –Optical Coherence Tomography[11] (Cirrus 500, Carl Zeiss Meditec AG).

All KLEx procedures were performed by a single experienced surgeon in a single centre using the small incision lenticule extraction technique on the 2-MHz femtosecond laser system (Visumax 800, Carl Zeiss Meditec AG). The target postoperative sphere was hyperopia for all patients younger than 40 years, and the target postoperative residual stromal thickness was >300um. Surgical parameters for the Visumax platform included cap thickness of 110–145 μm, diameter of 7.0 to 7.8 mm, optical zone of 6.0–6.8 mm with a 0.1 mm transition zone, 90° side-cut angles for all side-cut incisions, a 3.0 mm single incision width located at 135 degrees, the energy level optimised as per energy optimisation protocol (final energy settings: 125nj for 145um cap thickness and 120nj for 110um cap thickness), spot and track distance of 4.0 um each for both cap and lenticule cut, spot and track distance of 1.5 um each for cap and lenticule side cut and incision, minimum lenticule thickness of 10–20 um with increased thickness for low myopia,[12,13] S sized cone for all procedures, laser time of 8–10 seconds, and pulse duration of 220–580 fs, White-to-white of >10.8 and keratometry of > 40D.

Topical anaesthesia (Proparacain Hydrochloride 0.5% eyedrops) was applied. Head positioning was done to maintain the patient's comfort and making sure docking was easy. Afterwards, the surgeon taped the non-operating eye, applied a speculum in the operating eye, and the cornea was evenly wet using eye spears, and dried the excess fluid from the conjuctival cul-de-sac. A size "S" suction contact glass interface was used for all eyes to dock the cornea. Patients maintained fixation on a flashing green light to prevent misalignment. The CentraLign assistant function, utilising data from corneal topography (Atlas 500) and tomography (Pentacam HR), aided in aligning the treatment centre with the corneal vertex. Suction was initiated after checking that the interface was clear of debris. The OcuLign cyclotorsion screen was shown on the treatment monitor with a reticule guideline overlay representing the contact glass's horizontal axis. In eyes with myopic astigmatism >2D, the surgeon rotated the reticule guidelines to align with the pre-positioned corneal markers on the horizontal axis. The femtosecond laser then created an intrastromal lenticule in less than 10 seconds. Suction was automatically released, and the laser delivery arm returned to its home position. The surgical microscope arm was brought down for the lenticule extraction step. The steps of lenticule extraction were as per the standard protocol described

by Reinstein.[14] The incision was opened, and anterior and posterior pockets were created. Chansue advanced ReLex dissector and lifter was used to separate the lenticule, which was then removed through a peripheral corneal incision using micro forceps. The extracted lenticule was examined for its completeness using fluorescein dye under cobalt blue illumination. Both eyes were treated sequentially in the same session when indicated. Postoperative slit lamp examination was performed on all patients. All surgeries were recorded for potential complication documentation.

Patients were prescribed Moxifloxacin eye drops 0.5% w/v 4 times per day for 1 week, Prednisolone eye drops 0.5% w/v on a tapering dose of 4/3/2/1 every 7 days, and preservative-free Sodium Hyaluronate eyedrops 0.1% w/v 6 times per day for 3 months. Protective goggles were also recommended. Postoperative checkup was performed on day 1, day 7, 1 and 3 months. Each follow-up included UDVA, CDVA and slit-lamp assessments. Corneal tomography and topography were performed at 3 months follow-up. At all follow-ups, eyes were examined for postoperative complications and patient complaints were documented.

Data were recorded using a pre-structured pro forma and entered into a Microsoft Excel (2016) database. The baseline characteristics of the patients were summarised as frequencies for categorical variables and as means with standard deviations for continuous variables.

Outcome analysis was conducted following the Standard Graphs for Reporting Refractive Surgery with the help of Visulyze software version 1.0 (Carl Zeiss), and vector analysis was performed using the Alpins method.[15,16] Unpaired sample T-tests and non-parametric Mann Whitney *U*-tests were used to compare outcomes between the two independent groups, while paired *T*-test were used to compare two paired groups. For determining the normal distribution of preop and postop variables, the Kolmogorov–Smirnov is used.

Results

Two hundred and seven eyes (107 patients) were recruited for the present study. Out of them, eight eyes of 4 patients were lost to follow-up and were excluded from the present study. One eye had suction loss during incision creation; hence, the procedure was abandoned. In total, 198 eyes (102 patients) comprising 45 (44.1%) females and 57 (55.9%) males, with a mean age of 24.13 ± 4.8 years (18–36), who underwent KLEx were considered for statistical analysis. Table 1 shows descriptive statistics for the treated eyes. The preoperative mean spherical equivalent (SE) was –3.43 D ± 1.12 D. Based on the nomogram, all eyes younger than 40 years were targeted for hyperopia, and follow-up evaluations were conducted 3 months postoperatively. Nine standard graphs were used for reporting visual and refractive outcomes (Figure 1).

The graphs A and B compare the post-op UDVA to the pre-op CDVA to evaluate the procedure's effectiveness in maintaining or improving vision quality. Most eyes (81.3%) had the same UDVA postoperatively as they did preoperatively with correction. Moreover, 9.1% of eyes had even better vision post-op than their corrected vision before surgery. A similar

Table 1 Demographic and Refractive Details

Demographics	Mean ± SD	Range
Attempted SEQ refraction correction (D)	−3.58 ± 1.8	−1.00, −11.25
Preoperative refractive astigmatism (D)	−0.98 ± 0.60	0, −3.50
Preoperative corneal thickness (um)	544 ± 28	487, 605
Scotopic pupil size (mm)	5.96 ± 0.84	3.68, 7.47
Preoperative average keratometry (D)	43.83 ± 1.19	39.1, 47.1
Lenticule thickness (um)	91 ± 23	55, 150
Cap thickness (um)	124 ± 10	110, 145
Optical zone (mm)	6.62 ± 0.26	6.00, 6.80

Abbreviations: D, Dioptres; um, micrometres; mm, millimetres.

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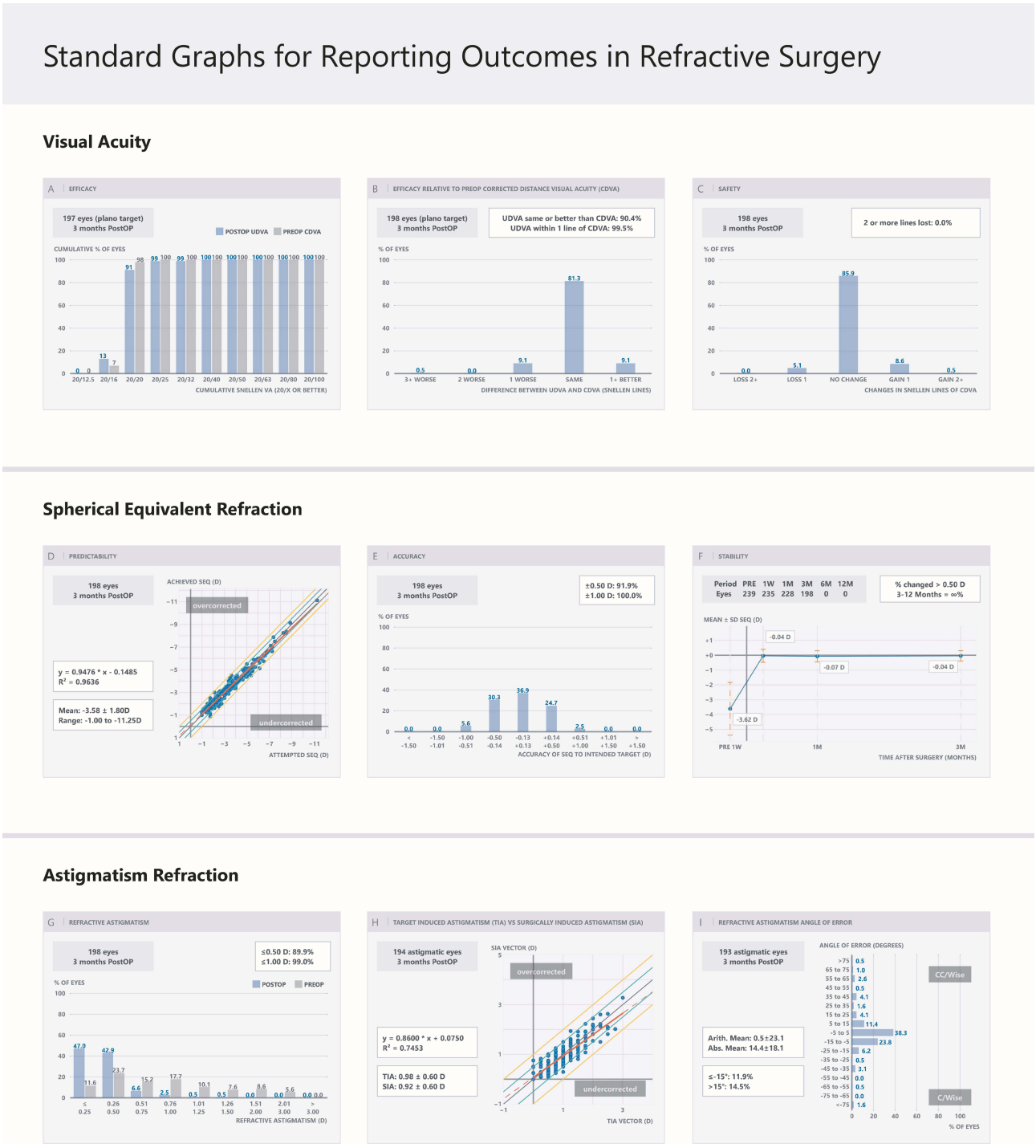

Figure 1 Nine standard graphs for reporting visual and refractive outcomes with 3months follow up after KLEx procedure. Graph (**A** and **B**) Efficacy (Relative to preoperative CDVA for 198 Eyes). Graph (**C**) Safety (% of eyes losing 2 or more lines). Graph (**D**) Predictability (3-Months postoperative Spherical Equivalent for 198 Eyes). Graph (**E**) Accuracy (3-Months postoperative accuracy of SEQ to intended target for 198 Eyes). Graph (**F**) Stability (Mean ± SD of SEQ Over Time). Graph (**G**) Refraction (Postoperative change in refractive astigmatism for 198 Eyes). Graph (**H**) Target-induced astigmatism (TIA) to surgically induced astigmatism (SIA) (194 astigmatic eyes at 3 months post-op). Graph (**I**) Refractive astigmatism angle of error (193 eyes at 3 months post-op). (Arith. Z arithmetic; Abs. Z absolute; CC/Wise Z counterclockwise; C/Wise Z clockwise).

Abbreviations: CDVA, corrected distance visual acuity; D, diopters; Postop, postoperative; Preop, preoperative; SEQ, spherical equivalent refraction; SIA, surgically induced astigmatism; TIA, target induced astigmatism; UDVA, uncorrected distance visual acuity; VA, visual acuity.

percentage (9.1%) experienced a one-line decrease in UDVA. One patient experienced loss of 3 lines of UDVA compared to preoperative CDVA. This emphasises the high effectiveness of the KLEx procedure in maintaining or enhancing visual acuity.

A significant proportion of eyes (85.9%) had no change in CDVA as per Graph C, indicating that the surgery did not negatively impact their vision. Furthermore, 8.6% of eyes experienced a gain of one line of vision, while 0.5% gained two or more lines. 5.1% eyes experienced a loss of one line. This confirms the high safety profile of the KLEx procedure, with minimal risk of vision loss and a favourable potential for vision improvement.

Graph D assesses the relationship between the attempted spherical equivalent refraction (SEQ) and the achieved SEQ after surgery. The diagonal line represents perfect correction, where the attempted and achieved SEQ would be identical. The data points depict the actual results, which align with the target, with a mean SEQ of −3.58 D and a range from −1.00 D to −11.25 D. The R^2 value of 0.9636 indicates strong correlation between the attempted and achieved results, demonstrating high predictability. Most points cluster around the diagonal, showing that most corrections were highly accurate, with minimal over- or under-correction.

Bar graph E displays the percentage of eyes within specific accuracy ranges to the intended SEQ target. 91.9% eyes achieved results within ±0.50 D of the intended target. 5.6% had an under-correction of −0.51 D to −1.00 D and a small percentage of 2.5% had overcorrection by +0.51 D to +1.00 D. 100% of the patient's achieved accuracy of ±1.00 D to the intended target. This demonstrates that most patients achieved highly accurate outcomes, with very few experiencing significant deviations from the intended correction.

Graph F tracks the stability of the achieved SEQ over time, from pre-op to three months post-op. The mean SEQ was −3.62 D at pre-op, which stabilised to −0.07 D by post-op 1 month. By 3 months, the SEQ stabilised close to the intended target, with a mean SEQ of 0.04 D. There was negligible change in SEQ beyond the 1-month mark, with no shifts beyond ± 0.50 D. This highlights the stability of the refractive outcomes after surgery over three months of follow-up.

Graph G demonstrates that most eyes achieved low levels of refractive astigmatism following surgery, with 99% of patients having less than 1D of astigmatism. Overall, 89.9% of eyes had ≤0.50 D of astigmatism postoperatively, and 99.0% had ≤1.00 D. This shows that the procedure is highly efficacious in significantly reducing astigmatism and achieving stable refractive outcomes.

The mean TIA was 0.98 ± 0.60 D, while the mean SIA was slightly lower at 0.92 ± 0.60 D, showing some under-correction in Graph H. The predictability was good, with an $R^2 = 0.7453$, suggesting the results are variable but follow the intended correction. The chart demonstrates that the surgical outcomes closely align with the target but with a slight tendency toward under correcting astigmatism.

The absolute mean of angle of error in graph I was 14.4 ± 18.1 and arithmetic mean of 0.5 ± 23.1. The histogram shows that for majority of the cases (73.5%), the angle of error was within ±15° of intended refractive correction.

Regarding complications, difficult lenticule extraction was observed in 6.1% of eyes. Epithelial defects were reported in 5.6%, while Opaque Bubble Layer (OBL) was seen in 7.1% of eyes. Other complications included side cut tears in 2.5%, dark spots in 1.5%, and suction loss in 0.5%, highlighting the range of issues that can arise during these procedures. Notably, no cases of cap tear or retained lenticule were reported.

Discussion

To our knowledge, only a few studies have been reported on the safety, efficacy, and predictability of KLEx using Visumax 800.[7,8,17,18] As KLEx procedures are evolving, it is imperative that we publish the initial study on the refractive outcomes of KLEx procedures. This is the first-of-its-kind study from Western India, and the initial results with a 3-month follow-up period have been promising.

This study demonstrates the visual and refractive outcomes of the 2-MHz femtosecond laser system in myopic eyes with sphere up to −10D and astigmatism up to −3D. We found that 90.4% of the eyes achieved 20/20 UDVA vision or better after surgery. Correlation between attempted SEQ and achieved SEQ was 0.9636, implying high predictability. Our study demonstrated extremely high accuracy, with 100% of eyes achieving SEQ ± 1.00D of the intended target and 91.9% of eyes within 0.5D of the intended target SEQ. The present study results also confirm the refractive stability with minimal clinically and statistically insignificant changes (−0.04D relative to the intended target) over 3 months of follow-up.

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Reinstein et al[7] published the first report on the clinical outcomes of Visumax 800. Our results are in line with their results. There were a few differences, however. Our study had a larger sample size. Secondly, the efficacy was higher in our study (64% vs 90.4% of eyes achieving UDVA same or better than CDVA). This difference is due to a better understanding of the energy optimization when we started the procedure (2024 vs 2023). As mentioned, our energy optimization settled at much lower levels, 120–125 nj (vs 155nj), which might explain better efficacy.[19] Third, the accuracy of SEQ and refractive astigmatism showed that our results tend to have better outcomes for achieving ± 0.5D, though ± 1.00D results were quite similar. However, the mean refractive astigmatism angle of error within 15° of the intended correction was achieved in 73.5% of eyes in our study as compared to 81%. Safety was demonstrated as only 5.1% of eyes lost one line of CDVA, and no eyes lost two or more lines of CDVA. We noted that most of these eyes were in the initial case series.[20] We attribute this to the energy optimization process necessary to avoid creating OBL while maintaining easy dissection for better postoperative visual outcomes.[21,22] One patient who had an epithelial defect had 1 line loss of CDVA due to epithelial remodeling. We have been following the remodeling process on Anterior segment optical coherence tomography (AS-OCT), and longer follow-up may provide a final visual outcome for that patient. One patient had dark spots leading to difficult dissection, causing three lines of loss of UDVA. The CDVA of the same patient had a loss of one line. This is due to the known fact that difficult dissection and dark spots can reduce visual outcomes.[14]

Amar Saad et al[8] published similar clinical outcomes. They reported 93% of eyes achieved UDVA of 20/20 or better. Postoperative spherical equivalent refraction was within ± 0.50D in 91% of eyes and within ± 1.00 D in 99% of eyes. Safety was demonstrated as only 11% of eyes lost one line of CDVA and no eyes lost two or more lines of CDVA.

Dark spots, OBL, difficult lenticule extraction and side-cut tears were typically seen during the first few cases of starting the KLEx procedures at the centre. These can be attributed to energy optimisation protocol and the operating surgeon's initial learning curve.[23] In a previous study of KLEx using VisuMax 500, the incidence of suction loss was 0.5%, with 65% of the cases occurring after 10 seconds of creating the lenticule interface. Therefore, one may expect a 65% reduction in the incidence of suction loss using the Visumax 800.[24] The docking time and overall surgical time have been shown to be significantly shorter with Visumax 800 as compared to VisuMax 500.[25] We had one eye suction loss owing to sudden movements by the patient during the incision creation. Suction loss protocol was followed, and the procedure was abandoned.

This study has a few limitations. First, the short follow-up duration of 3 months limits our ability to assess long-term safety and treatment stability fully. Second, the relatively small sample size may restrict the generalisability of our findings, intraoperative safety outcomes and the ability to conduct robust subgroup analyses. Finally, different laser energy settings during energy optimisation protocol meant the overall results may differ if energy settings are kept consistent with minor energy level variations. Future studies with longer follow-up periods, larger sample sizes, data on aberrations and OSDI, and consistent laser energy settings are needed to confirm and expand upon our initial findings and better understand the KLEx procedure.

Conclusion

This study confirms the efficacy of the KLEx procedure in achieving satisfactory visual outcomes, solidifying its potential to become the dominant refractive surgery technique. Building upon the success of over 10 million procedures performed worldwide using VisuMax platforms, this research contributes valuable data on the clinical outcomes of the latest KLEx procedure.[26] In our future studies, we will explore the long-term stability, safety, and patient related outcome measures (PROM), further enhancing our understanding of KLEx and its overall impact on patient's quality of life.

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Disclosure

The authors report no conflicts of interest in this work.

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