Journal of Ophthalmology

Advancements in Refractive Surgery

Lead Guest Editor: Sheetal Brar
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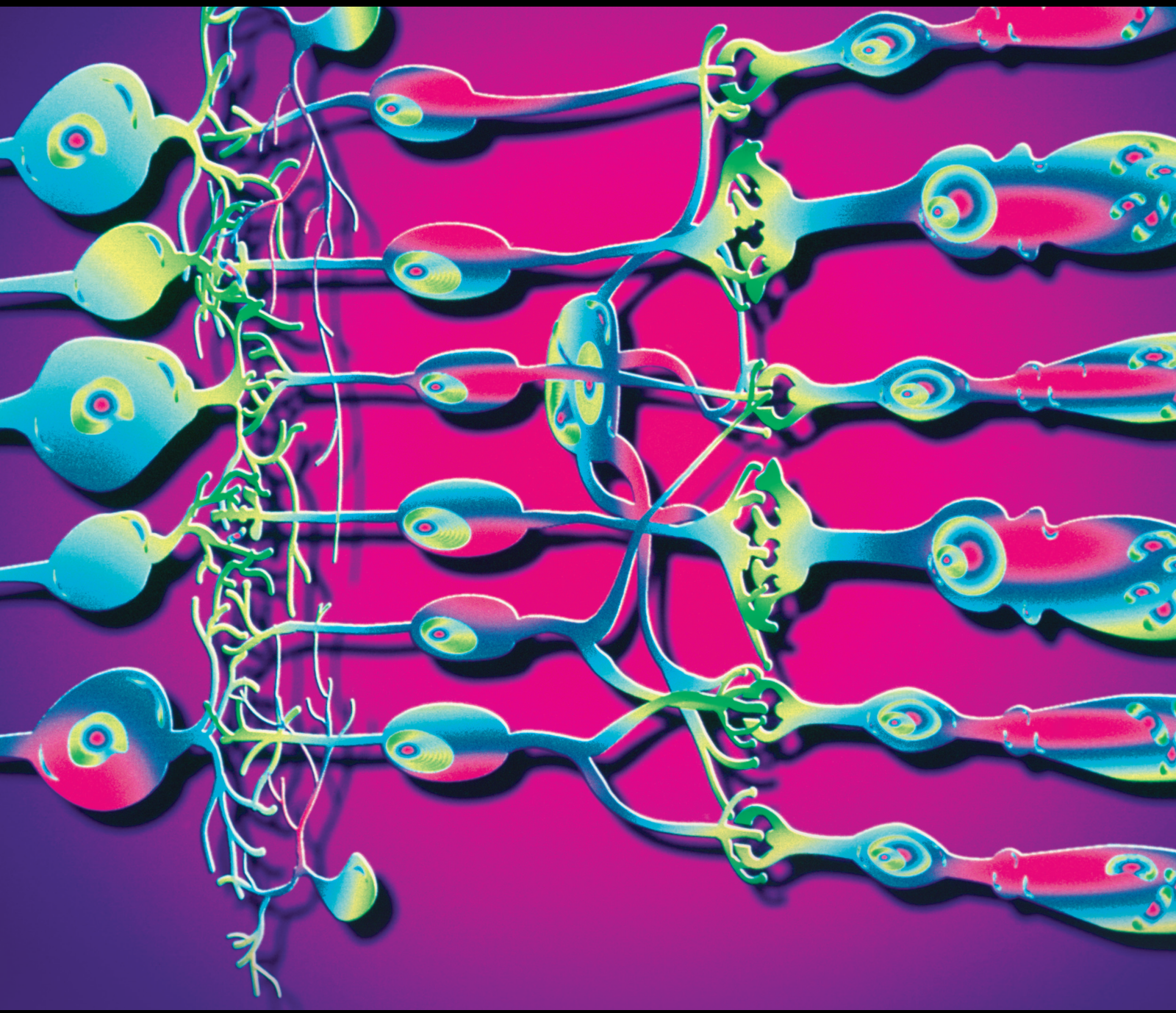

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Research Article

Comparison of Long-Term Outcomes and Refractive Stability following SMILE versus SMILE Combined with Accelerated Cross-Linking (SMILE XTRA)

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Purpose. To compare the long-term safety, efficacy, predictability, and refractive stability following SMILE versus SMILE combined with accelerated cross-linking (SMILE XTRA), and to specifically study the regression patterns following the two procedures. *Methods*. This retrospective study included 54 eyes of SMILE and 54 eyes of SMILE XTRA treated for normal and borderline cases of myopia/myopic astigmatism, respectively, based on certain predefined topographic features and risk factors. Patients in both the groups were matched for age and refractive error. The mean postoperative follow-up for the SMILE group was 22.18 ± 10.41 months and the SMILE XTRA group was 21.81 ± 10.19 months. *Results*. At the end of follow-up, the mean sphere, cylinder, and SE reduced to −0.03, −0.09, and −0.08 D in the SMILE group and −0.06, −0.15, and −0.13 D in the SMILE XTRA group. 96% and 93% eyes remained within ±0.50 D in SMILE and SMILE XTRA groups, respectively, and 94% eyes maintained an UDVA of 20/20 or better in the SMILE as well as SMILE XTRA groups. Safety and efficacy indices for the SMILE group were 1.03 and 1.00. For the SMILE XTRA group, the safety and efficacy indices were 1.00 and 0.99. No eye in either group had postoperative ectasia or enhancement performed for significant residual refractive error. *Conclusion*. Both the SMILE and SMILE XTRA groups exhibited comparable visual outcomes, safety, and efficacy. Contrary to the belief, combination of prophylactic CXL with SMILE did not result in a hyperopic shift in the long term. No eye in either group encountered postoperative ectasia; however, further follow-up is suggested to establish the long-term effects on refractive and corneal stability following SMILE XTRA, as all the eyes treated in this group were borderline.

1. Introduction

Despite the potential advantages of SMILE over femtosecond laser-assisted in situ keratomileusis (FS-LASIK) and photorefractive keratectomy (PRK), the procedure is characterized by a steeper learning curve, during which intraoperative complications may occur. Suction loss, black spots, dense opaque bubble layer, lenticule tears, incision tears, and inability to find the lenticule are some of the intraoperative complications of SMILE that were reported earlier. [1–5].

SMILE was proposed to be biomechanically more stable compared to LASIK and PRK [6]. However, ectasia was shown to occur even after SMILE, with most of these cases having borderline or abnormal preoperative topography [7]. Therefore, preoperative evaluation for a corneal refractive surgery has received significant attention in the recent years. Various risk scoring systems and tomographic indices combined with biomechanics have come into existence to help a refractive surgeon identify corneas at risk [8–12]. Along with these advanced screening systems, a new form of refractive surgery, i.e., combined collagen cross-linking (CXL) with the primary corneal refractive surgery has emerged in the recent years, aiming at improving postoperative corneal biomechanical stability, thereby preventing the risk of future keractasia [12–14]. This was based on the proven evidence that CXL lead to halting of progression and corneal stabilization of keratoconic corneas [15–20]. Newer CXL protocols [21–23],including the STARE-X protocol [21]and use of SafeCross® riboflavin solution chemically boosted corneal cross-linking [22], demonstrated effective

results in halting keratoconus progression in 2-year follow-up and improving DLD by a factor of 20%, without adverse events for corneal endothelium, respectively. Since there is enough evidence to support that CXL can stabilize keratoconus, it was proposed that prophylactic CXL when combined with various corneal refractive surgeries may prevent the risk of future keractasia in borderline eyes.

This class of refractive surgeries, popularly known as "XTRA procedures," can be combined with PRK, LASIK, and SMILE and is typically performed in cases where the topographic/tomographic indices or the clinical history is suggestive of "at risk" corneas.

However, many refractive surgeons are reserved to combine corneal refractive procedures with cross-linking due to reasons such as potential risk of haze, overcorrection, or hyperopic outcome due to progressive flattening as a result of cross-linking, additional cost, and lack of knowledge and experience, etc. However, evidence is growing that a refractive surgery with simultaneous cross-linking is safe and effective in preventing ectasia without any significant side effects [24–28]. Especially, when combined with SMILE, it was shown to be beneficial in preventing ectasia when used to treat borderline corneas [29]. However, there is a paucity of long-term data on the efficacy and stability of SMILE XTRA when compared to SMILE. The present retrospective study was thus conducted with the aim of comparing the long-term safety, efficacy, predictability, and refractive stability following SMILE versus SMILE XTRA and to specifically study the regression patterns following the two procedures.

2. Methods

The present retrospective study was approved by institutional ethics committee of Nethradhama Super Speciality Eye Hospital, Bangalore, and adhered to the tenets of Declaration of Helsinki. Data were collected from electronic medical records of all patients who had refractive surgery performed for correction of myopia or myopic astigmatism with SMILE or SMILE XTRA procedure from January 2017 to December 2018. Only those patients who had a minimum follow-up of 12 months were included in the study.

Preoperative evaluation was performed using the combined corneal tomography (OCULUS Pentacam® HR, Wetzlar, Germany) and biomechanics (Corvis ST, Oculus). Based on the tomographic and biomechanical evaluation and patient's age, refractive error, and additional risk factors, eyes were categorized into "normal" or "borderline" based on the following criteria [27]:

(1) Corneal thickness <480 microns

(2) Residual bed thickness between 250 and 280 microns

(3) Refractive Error >−6.00 D spherical equivalent (SE)

(4) Pentacam criteria: Belin Ambrosio display final *D*-value >1.65

(5) Corvis-ST criteria: Corvis Biomechanical Index (CBI) >0.5 and Tomographic Biomechanical Index (TBI) >0.29

(6) Additional risk factors = age <30 years, family history of keratoconus, or history of eye rubbing

If none of the above criteria were present, eyes were classified as "normal", whereas if 3 or more of the above criteria were present, eyes were classified as "borderline" for SMILE surgery. All eyes in the "normal" group underwent a routine SMILE procedure, whereas in the "borderline" group, some eyes underwent SMILE XTRA and some eyes underwent only SMILE. The decision regarding the procedure in the "borderline" eyes was influenced by factors such as additional cost, surgeon's intuition, and patient's willingness. Patients who did not undergo SMILE XTRA due to any reason were strictly advised against eye rubbing and were called for 6-monthly follow-ups. They were also asked to report earlier if they noticed any drop/change in their vision. Only eyes with a minimum follow-up of 12 months were included in the study.

2.1. Surgical Procedure. During treatment planning, a similar nomogram (10% overcorrection) was used for both the SMILE and SMILE XTRA groups.

As regards the surgical procedures, all procedures were performed by 2 experienced SMILE surgeons (SG and SB). SMILE was performed with the VisuMax FS laser (Carl Zeiss Meditec, Jena, Germany) using the following parameters: a cap thickness of 100–120 microns, an optical zone of 6-7 mm, energy cut index between 28 and 32 (140–160 nJ), and a superior access incision of 2-3 mm.

For SMILE XTRA, the surgical steps were as follows: (1) SMILE performed following the standard protocol (described above); (2) 0.22% riboflavin in saline (Vibex XTRA, Avedro, Waltham, MA) or 0.23% riboflavin (Peschke L, Huenenberg, Switzerland) injected into the interface and allowed to diffuse for 60 s, followed by irrigation of the interface with balanced salt solution; and (3) UV-A irradiation through the cap using a power of 45 mW/cm^2 for 75 s, delivering a total energy 3.4 J/cm^2.

Postoperative medication regimen consisted of topical 0.3% ofloxacin (Exocin®, Allergan, Irvine, U.S.A.) 4 times/day for 3 days after SMILE and 7 days after SMILE XTRA, 0.1% prednisolone acetate eye drops (Pred Forte®, Allergan, Irvine, U.S.A.) 4 times/day for 4 weeks (tapering weekly), and lubricants 4 times/day for 4 weeks or more following both procedures.

2.2. Statistical Analysis. Microsoft excel statistical tool pack was used to analyze the data and perform the statistical analysis. Data were checked for normality before subjecting to statistical tests. Based on the results of normality tests, parametric or nonparametric tests were applied. Intergroup comparisons were performed using the independent *t*-tests and intragroup comparisons were performed using the paired *t*-tests. A p value of 0.05 or less was considered statistically significant.

3. Results

A total of 108 eyes from 54 patients ($n = 27$ patients in the SMILE group, and $n = 27$ patients in the SMILE XTRA group) undergoing a bilateral refractive surgery for myopia or myopic astigmatism correction were included in study. Both groups were comparable with respect to preoperative age, sphere, cylinder, SE, and corneal astigmatism; however, the SMILE XTRA group had a significantly thinner central pachymetry and steeper keratometry (both K1 and K2) (Table 1). Regarding the intraoperative treatment parameters, there was no significant difference between the two groups in terms of actual refraction treated (after application of a 10% nomogram), cap thickness, optical zone, and residual bed thickness. However, the maximum and minimum lenticule thickness (LT) values were significantly lower for the SMILE XTRA group (LT, max = $87.48 \pm 21.70\,\mu$, min = $13.65 \pm 6.42\,\mu$) compared to the SMILE group (LT, max = $96.53 \pm 22.90\,\mu$, min = $16.85 \pm 8.25\,\mu$) (Table 1).

The mean follow-up in the SMILE group was 22.18 ± 10.41 (range 12–54) months and in the SMILE XTRA group was 21.81 ± 9.19 (range 12–52) months, $p = 0.45$.

3.1. Visual and Refractive Results. At the end of the mean follow-up, the % age of eyes seeing 20/20 or better was 94% ($n = 51$) in the SMILE group as well as in the SMILE XTRA group (Figure 1).

No significant difference in the mean postoperative UDVA was observed between both the groups ($p = 0.56$) (Table 2).

The efficacy index (postoperative UDVA/preoperative CDVA) was 1.00 and 0.99 for the SMILE and SMILE XTRA groups, respectively.

As regards the safety, 95% eyes ($n = 51$) in the SMILE group had postoperative CDVA same or better, compared to 93% ($n = 50$) in the SMILE XTRA group. No eye in either group had loss of 2 lines or more (Figure 2).

The safety index (postoperative CDVA/preoperative CDVA) was 1.03 and 1.00 for the SMILE and SMILE XTRA groups, respectively.

Ninety-six percent ($n = 52$) eyes in the SMILE group and 93% ($n = 50$) eyes in the SMILE XTRA group had postoperative SE predictability between ±0.5 D. All eyes in the SMILE group were within ±1.00 D, whereas all eyes in the SMILE XTRA group were within ±1.50 D (Figures 3 and 4).

The mean residual SE at the end of the mean follow-up was -0.08 ± 0.18 D in the SMILE group versus -0.13 ± 0.3 D in the SMILE XTRA group; however, the difference was not statistically significant ($p = 0.34$) (Table 2).

In terms of cylinder correction, 96% eyes ($n = 52$) in the SMILE group versus 93% eyes ($n = 50$) in the SMILE XTRA group were within ±0.50 D, and all eyes in both the groups were within ±1.00 D of cylinder correction (Figure 5).

4. Stability

In the SMILE group, the mean postoperative SE at 2 weeks was -0.006 ± 0.05 D which increased to -0.08 ± 0.18 D at the mean follow-up. On the other hand, in the SMILE XTRA group, the mean SE increased from -0.002 ± 0.01 D at 2 weeks to -0.13 ± 0.33 D at the end of the mean follow-up (Figure 6). The change in SE in both the groups compared to 2 weeks was found to be statistically significant (Tables 3 and 4).

Mean regression in the SMILE group was 0.08 D, which was less, compared to the SMILE XTRA group (0.13 D), the difference between the two groups, however, was not statistically significant ($p = 0.34$).

5. Long-Term Complications

All eyes in the SMILE group had a clear interface, while 4 eyes in the SMILE XTRA group had evidence of mild interface haze (grade 0-1) at the last follow-up. However, no patient complained of any visual disturbances due to this. When asked about the spectacle independence and quality of vision through a subjective questionnaire, the mean score of overall satisfaction (out of 100) was 98.2% in the SMILE group, and 95.4% in the SMILE XTRA group (Table 5).

6. Discussion

Inspired by the reports of safety and efficacy of LASIK XTRA, in 2015, we explored SMILE XTRA as a potential treatment option for borderline cases [29]. However, our initial cases of SMILE XTRA were reserved for selected cases of keratoconus suspect corneas. It may be argued that why SMILE XTRA was not performed in the borderline eyes, other than those who were keratoconus suspects, as the primary procedure when ectasia was anticipated. Multiple reasons influenced our decision making. First, there were some cases where topography was slightly borderline, but corneal thickness and residual bed thickness were relatively good. Considering the perceived biomechanical advantage of SMILE (no vertical cut), over LASIK; no flap-related complications and with proper counseling, one may be tempted to treat such cases. Other reasons were increased cost and theoretical risk of haze development, due to which, this option we reserved only for eyes which were indeed at risk of ectasia.

The current literature on SMILE XTRA suggests that combined SMILE and prophylactic accelerated cross-linking does not affect the safety and efficacy of the procedure [30]. In 2015, we published the first outcomes of SMILE XTRA in a prospective case series of 40 eyes of 20 myopic patients with moderate to high risk of ectasia (Randleman Scoring ≥3). The safety and efficacy indices observed in our study were 1.29 and 1.04 at the end of 1 year. CDVA remained stable and no complications such as keratitis, ectasia, regression, or endothelial decompensation were observed [29]. Two eyes that developed Grade 2 corneal haze, resolved within 3 months following treatment with topical steroids. It may be noteworthy to mention that the mild CXL related anterior stromal haze that accompanies the procedure is not visually significant and does not lead to reduction in CDVA. As seen from our data, the safety profile of both SMILE and SMILE XTRA was similar in both groups with no eye losing

Table 1: Patient demographics and preoperative data.

Parameter (mean ± SD)	SMILE ($n = 54$)	SMILE XTRA ($n = 54$)	p value
Total no. of eyes	54	54	—
Total no. of patients	27	27	—
Male: female	11 : 16	12 : 15	—
Age (years)	25.96 ± 2.71	25.85 ± 4.06	0.90
Sphere (D)	−4.24 ± 1.84	−4.036 ± 1.94	0.56
Cylinder (D)	−0.71 ± 0.68	−0.95 ± 1.06	0.17
SE (D)	−4.61 ± 1.98	−4.41 ± 1.89	0.57
CDVA (logMAR)	−0.06 ± 0.04	−0.06 ± 0.05	0.85
K1 (D)	42.67 ± 1.4	43.68 ± 1.77	≤0.001
K2 (D)	43.68 ± 1.41	44.87 ± 1.54	≤0.001
Astigmatism (D)	1.02 ± 0.55	1.19 ± 0.73	0.19
CCT (μ)	527.88 ± 29.47	515.29 ± 26.45	0.02
Thinnest pachymetry (μ)	523.83 ± 29.48	510.27 ± 26.84	0.01
VisuMax diagnostic and treatment data			
Sphere (D)	−4.43 ± 1.9	−4.23 ± 2.01	0.58
Cylinder (D)	−0.80 ± 0.68	−0.95 ± 1.1	0.39
Cap thickness (μ)	120 ± 0	120 ± 0	1.00
Optical zone (μ)	6.36 ± 0.30	6.27 ± 0.29	0.14
Minimum lenticule thickness (μ)	16.85 ± 8.25	13.65 ± 6.42	0.02
Maximum lenticule thickness (μ)	96.53 ± 22.90	87.48 ± 21.70	0.03
RST (μ)	314.13 ± 31.30	303.75 ± 30.65	0.08

UDVA: uncorrected distance visual acuity; D: diopter; SE: spherical equivalent; CDVA: corrected distance visual acuity; K: keratometry; CCT: central corneal thickness; RST: residual stromal thickness.

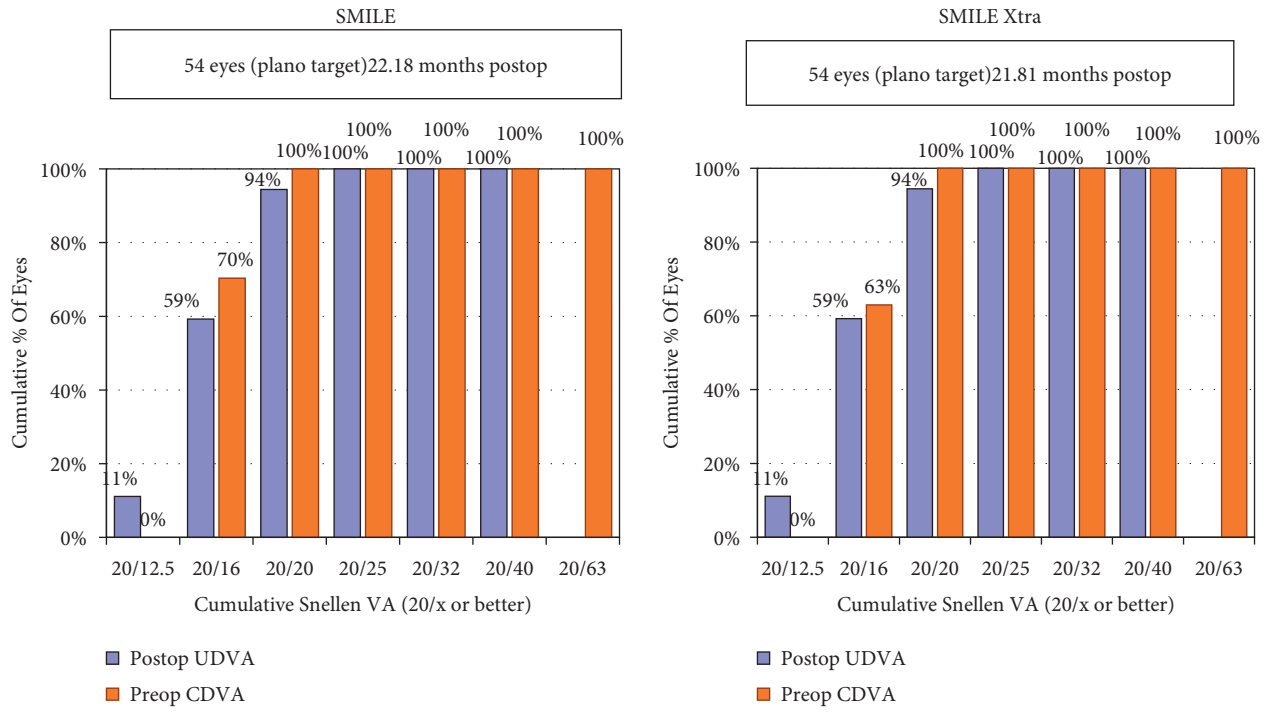

Figure 1: Cumulative histogram for binocular uncorrected distance visual acuity (UDVA).

more than 1 line of CDVA in either group. Osman et al. [28] in their retrospective comparison study observed a similar efficacy index in both the SMILE XTRA group (1.09) and SMILE group (1.12) at 2-year follow-up, suggesting that CXL did not have a significant impact on the uncorrected visual acuity when combined with SMILE. They also observed a high safety index of 1.29 with SMILE XTRA in their study. Besides the above studies on borderline corneas, a study by Graue-Hernandez et al. evaluated the safety and efficacy of SMILE XTRA on 15

Table 2: Postoperative data at mean follow-up.

Parameter (mean ± SD)	SMILE ($n = 54$)	SMILE XTRA ($n = 54$)	p value
Longest follow-up (months)	22.18 ± 10.41	21.81 ± 9.19	0.89
UDVA (logMAR)	−0.05 ± 0.07	−0.06 ± 0.08	0.56
Sphere (D)	−0.037 ± 0.14	−0.060 ± 0.25	0.55
Cylinder (D)	−0.09 ± 0.20	−0.14 ± 0.28	0.28
SE (D)	−0.08 ± 0.18	−0.13 ± 0.33	0.34
CDVA (logMAR)	−0.08 ± 0.06	−0.09 ± 0.05	0.37
K1 (D)	39.63 ± 1.61	40.50 ± 2.03	0.007
K2 (D)	40.44 ± 1.62	41.44 ± 2.02	0.005
Corneal astigmatism (D)	0.82 ± 0.39	0.84 ± 0.40	0.90
CCT (μ)	455.33 ± 29.57	442.85 ± 26.65	0.02
Thinnest pachymetry (μ)	453.01 ± 29.23	440.35 ± 25.97	0.01

UDVA: uncorrected distance visual acuity; D: diopter; SE: spherical equivalent; CDVA: corrected distance visual acuity; K: keratometry; CCT: central corneal thickness.

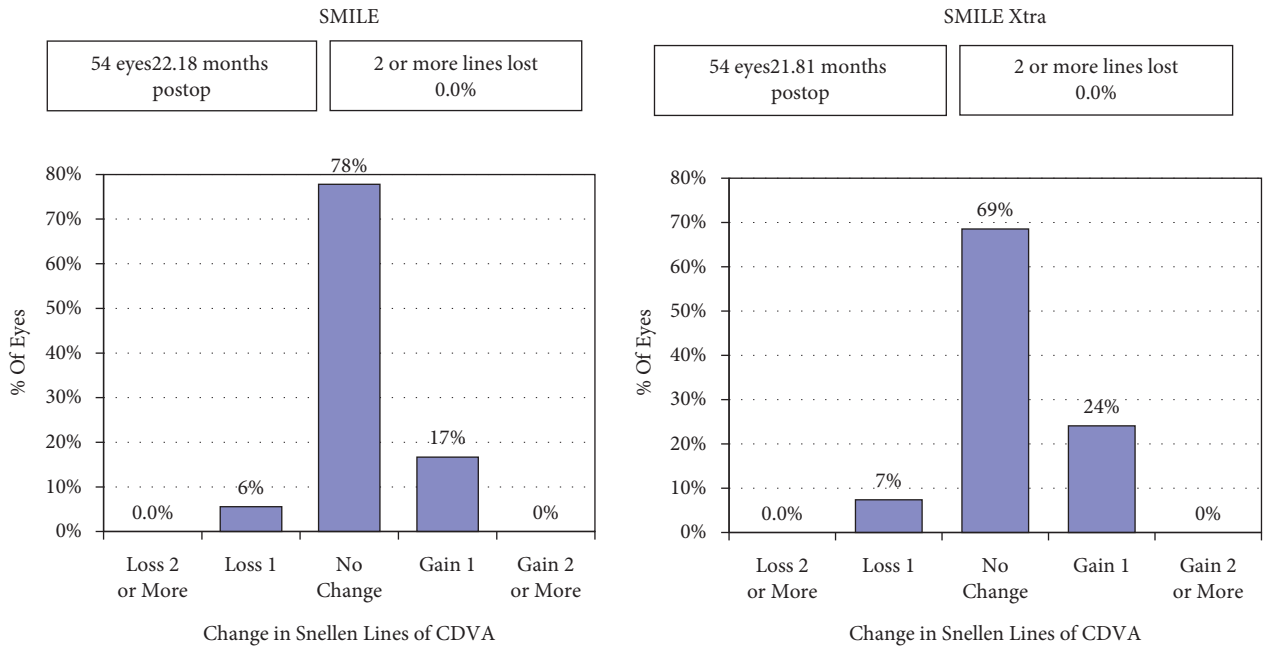

Figure 2: Histogram showing the change in the Snellen lines of corrected distance visual acuity (CDVA).

forme fruste keratoconus eyes. Their results suggested that SMILE combined with accelerated cross-linking was safe and effective in stabilizing these eyes over a follow-up ranging from 12 to 24 months [31].

The protocol of SMILE XTRA used in our series appears to be effective for preventing ectasia in susceptible eyes, as all eyes remained stable by the end of the follow-up. Recent studies, however, report using different riboflavin concentration, soak time, UV-A irradiation power, and duration to perform combined SMILE and accelerated cross-linking However, none of the eyes which underwent SMILE XTRA in the previously published studies progressed to ectasia. The present study, with a follow-up ranging from 1 to 4 years in both the groups, provides a substantial anecdotal evidence regarding the potentially enhanced stability provided by the simultaneous accelerated CXL, as no eye progressed to ectasia in this series.

Studies have found that collagen cross-linking results in [28, 30, 31] progressive corneal flattening over many years after the procedure [32, 33]. This is one of the main reasons why most refractive surgeons do not prefer simultaneous prophylactic cross linking along with a refractive surgery, as it may potentially lead to a hyperopic result and changes in the refractive outcome. However, we did not observe a significant difference in the mean regression between the two procedures, at almost the same post-op mean follow-up period of 21 months. Even though the same nomogram (10% over correction) was applied to both groups, the mean regression in the SMILE XTRA group was slightly higher compared to the SMILE group (0.13 D vs 0.08 D), although the difference was not significant. This may suggest that the UV protocol used in the study may be just sufficient to prevent ectasia. The cylinder in the SMILE XTRA group at the mean follow-up was higher compared to the SMILE

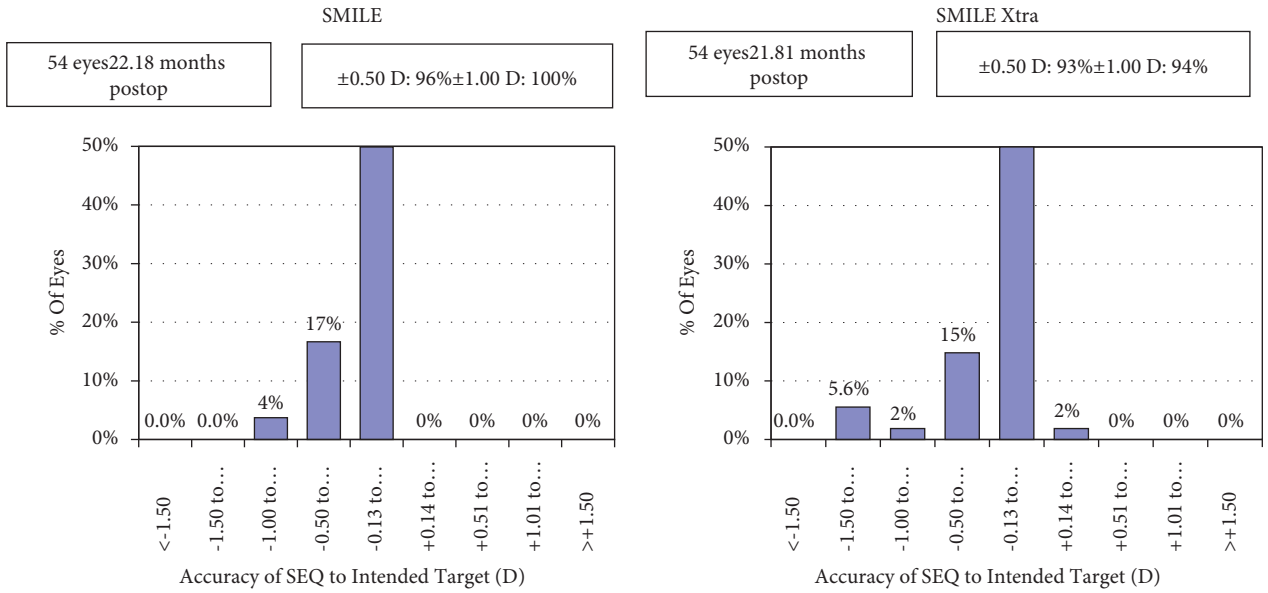

Figure 3: Histogram showing the accuracy to the intended spherical equivalent refraction.

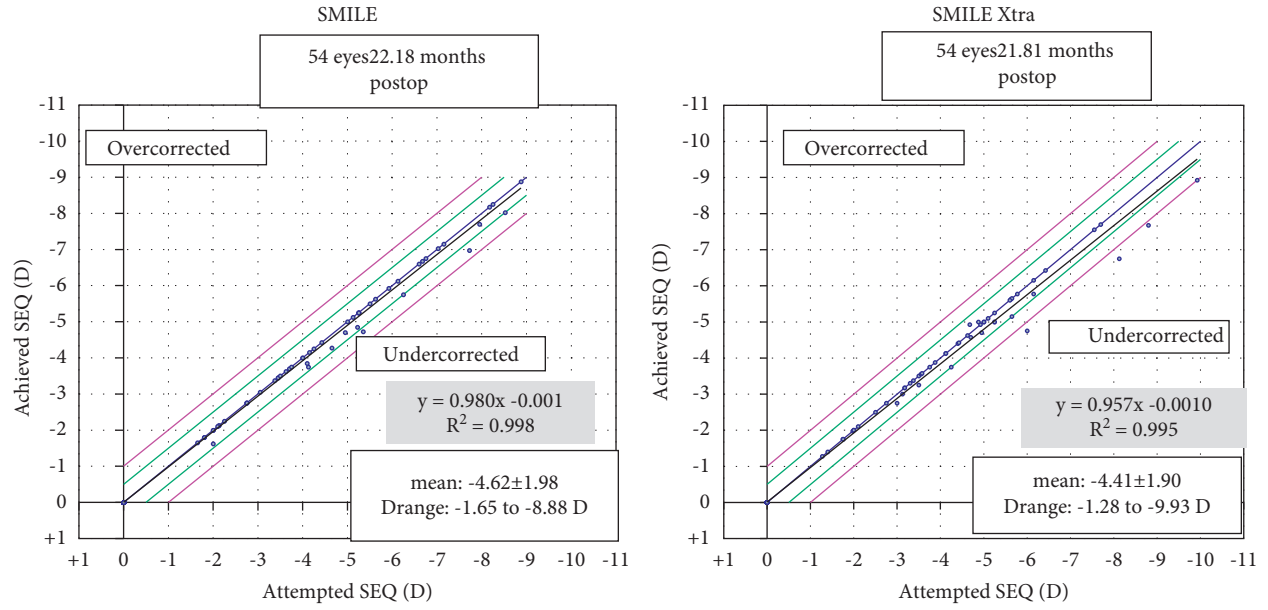

Figure 4: Spherical equivalent refraction predictability.

group (although nonstatistically significant), which may suggest that probably we need a longer follow-up to observe these eyes, which may potentially result into ectasia, since they all were borderline eyes to start with. On the other hand, this result may also be interpreted that possibly, it is the accelerated cross-linking which is just holding an ectasia, which may otherwise have become evident by now. The good stability and minimal regression in the SMILE group at the long term, may suggest that SMILE itself may be a stable procedure in a majority of cases and XTRA may only be reserved for suspect cases where the risk of ectasia is higher. This is also evident from the long-term studies recently published on SMILE, wherein a minimal regression of -0.35 ± 0.66 diopters over the 10-year period was observed following SMILE [34].

Nevertheless, our study adds to the existing knowledge on the refractive surgery and simultaneous accelerated cross-linking, especially related to the SMILE XTRA procedure by observing no ectasia, any significant haze or any hyperopic over correction in the borderline eyes treated and followed up for a mean duration of 21 months and longest duration of 4 years. However, since all these eyes were borderline and "at risk" for postoperative ectasia, they definitely call for even longer and closer follow-ups, as the prophylactic CXL may just be delaying the onset of ectasia, which may occur over subsequent course of time. Thus, the

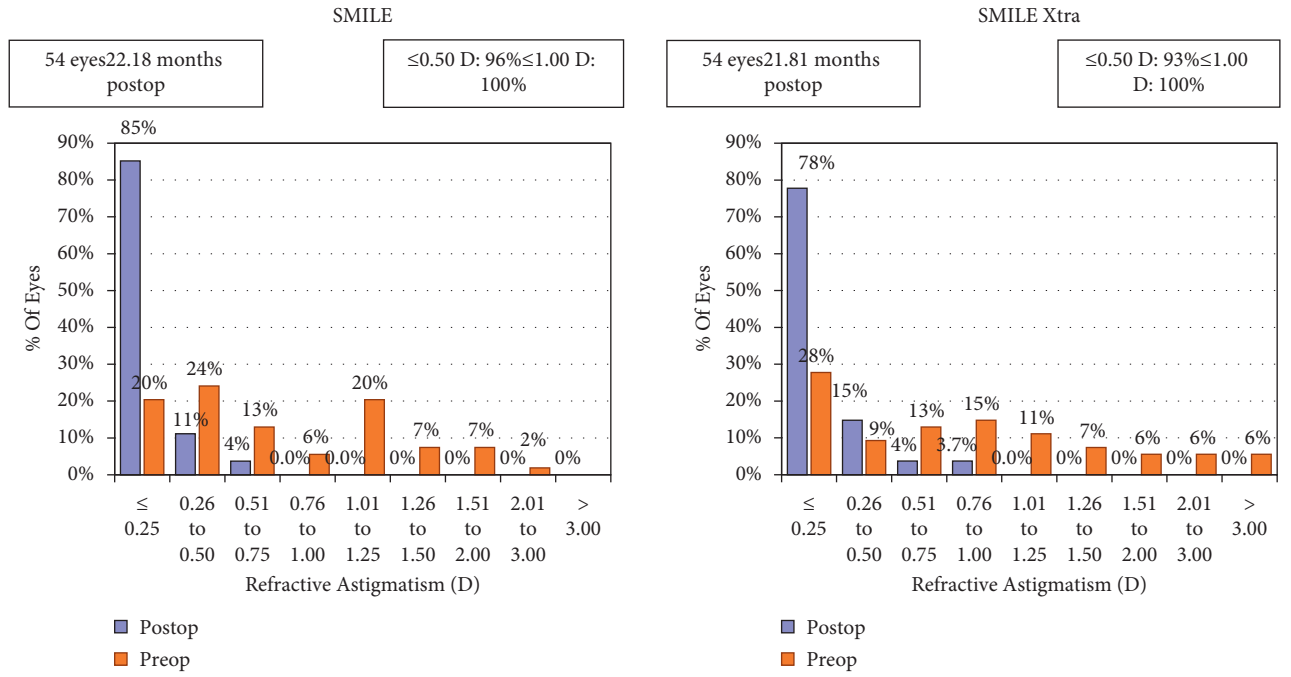

Figure 5: Histogram showing change in refractive astigmatism.

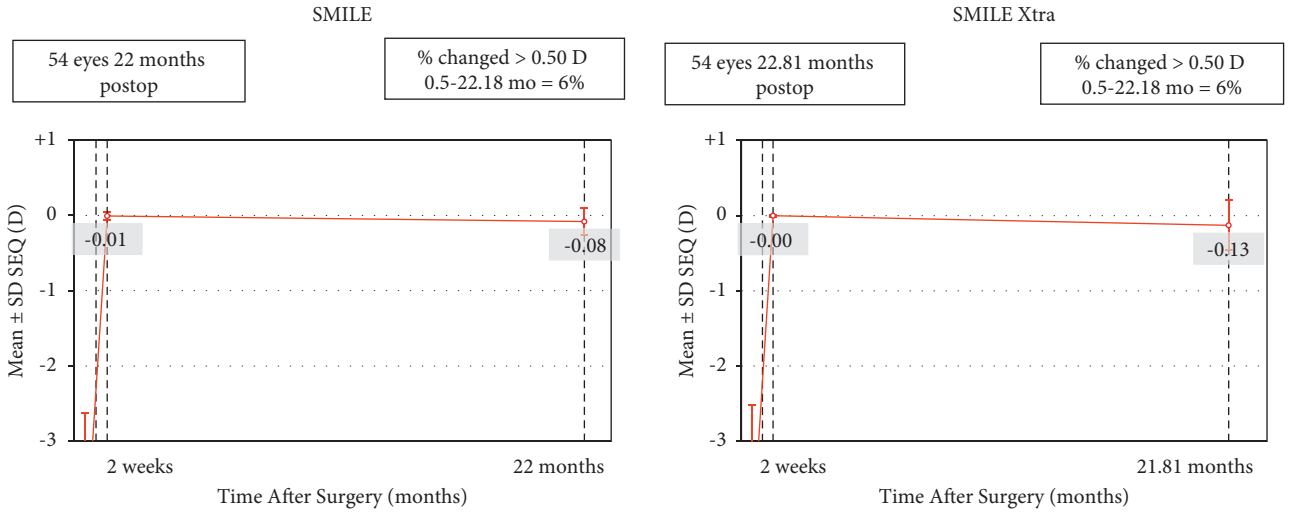

Figure 6: Stability of spherical equivalent refraction.

Table 3: Visual and refractive parameters 2 weeks post-op versus mean follow-up in the SMILE group.

Parameter (mean ± SD)	Post-op 2 weeks	Last follow-up	p value
UDVA (logMAR)	−0.07 ± 0.04	−0.05 ± 0.07	0.23
Sphere (D)	−0.00 ± 0.03	−0.037 ± 0.14	0.10
Cylinder (D)	−0.00 ± 0.05	−0.09 ± 0.20	0.002
SE (D)	−0.00 ± 0.05	−0.08 ± 0.18	0.003
CDVA (logMAR)	−0.08 ± 0.05	−0.08 ± 0.06	1.00
K1 (D)	39.58 ± 1.72	39.63 ± 1.61	0.88
K2 (D)	40.36 ± 1.71	40.44 ± 1.62	0.79
Corneal astigmatism (D)	0.77 ± 0.39	0.82 ± 0.39	0.46
CCT (μ)	449.31 ± 30.32	455.33 ± 29.57	0.29
Thinnest pachymetry (μ)	446.83 ± 29.77	453.01 ± 29.23	0.27

UDVA: uncorrected distance visual acuity; D: diopter; SE: spherical equivalent; CDVA: corrected distance visual acuity; K: keratometry; CCT: central corneal thickness.

Table 4: Visual and refractive parameters 2 weeks post-op versus mean follow-up in the SMILE XTRA group.

Parameter (mean ± SD)	Post-op 2 weeks	Last follow-up	p value
UDVA (logMAR)	−0.08 ± 0.13	−0.06 ± 0.08	0.24
Sphere (D)	0.00 ± 0.00	−0.062 ± 0.25	0.08
Cylinder (D)	−0.00 ± 0.03	−0.15 ± 0.28	≤0.001
SE (D)	−0.00 ± 0.01	−0.13 ± 0.33	0.005
CDVA (logMAR)	−0.08 ± 0.13	−0.07 ± 0.06	0.63
K1 (D)	40.34 ± 2.00	40.50 ± 2.03	0.67
K2 (D)	41.10 ± 2.06	41.44 ± 2.02	0.38
Corneal astigmatism (D)	0.79 ± 0.34	0.84 ± 0.40	0.49
CCT (μ)	435.20 ± 23.96	442.85 ± 26.65	0.11
Thinnest pachymetry (μ)	433.87 ± 24.88	440.35 ± 25.97	0.19

UDVA: uncorrected distance visual acuity; D: diopter; SE: spherical equivalent; CDVA: corrected distance visual acuity; K: keratometry; CCT: central corneal thickness.

Table 5: Questionnaire and mean scores for evaluation of spectacle independence, patient satisfaction, and quality of vision.

What is your level of spectacle independence after surgery?			
(a) Totally dependent on spectacles for all work (0–3.99)	(b) Partially dependent for certain work (4–7.99) SMILE = 9.4 SMILE XTRA = 9.0	(c) Completely independent of spectacles (8–10)	
Do you experience any dysphotopsia symptoms such as glare or halos? If yes, grade the same as per the following			
(a) Minimal/nil and occasional (0–3.99)	(b) Moderate and frequent (4–7.99) SMILE = 2.2 SMILE XTRA = 3.5	(c) Severe and persistent (8–10)	
Do you experience any dry eye symptoms? If yes, grade the same as per the following			
(a) Minimal/nil and occasional (0–3.99)	(b) Moderate and frequent (4–7.99) SMILE = 2.4 SMILE XTRA = 3.8	(c) Severe and persistent (8–10)	
How would you grade the quality of your vision after surgery?			
(a) Poor (0–2.99)	(b) Good (3–4.99) SMILE = 9.1 SMILE XTRA = 8.2	(c) Very good (5–7.99)	(d) Excellent (8–10)
How would you grade your overall satisfaction after the procedure?			
(a) Not satisfied at all (0–30.99)	(b) Somehow satisfied (31–60.99) SMILE = 98.2% SMILE XTRA = 95.4%	(c) Moderately satisfied (61–89.99	(d) Fully satisfied (90–100)

No eye in either group progressed to ectasia or required an enhancement procedure for significant residual refractive error during the course of the study.

long-term safety, efficacy, stability, and effects on corneal stabilization following SMILE XTRA when used to treat borderline corneas, still remain to be established.

Data Availability

The data can be made available on request from the institutional ethics committee in-charge of Nethradhama Super Speciality Eye Hospital, Bangalore, Dr. Sandhya who can be contacted at sandhyakrish@gmail.com.

Conflicts of Interest

Dr. Sri Ganesh and Dr. Sheetal Brar are consultants to Carl Zeiss Meditec; however, other authors have no financial or proprietary interest in a product, method, or material described herein.

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Research Article

Corneal Epithelial Removal with a Newly Designed Epithelial Brush

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This study aimed to evaluate and compare the effectiveness of a newly developed epithelial removal brush with conventional methods in a rabbit model of corneal epithelial defects. The corneal epithelia of thirty-seven rabbits were removed by three different methods including blades (blade group), newly developed epithelial brushes (Ocu group), and conventional rotating brushes (Amo group). The defect area was measured with light microscopy immediately and at 4, 18, 24, and 50 hours after removal. Corneas were obtained immediately and at 24 and 50 hours and subjected to hematoxylin and eosin (H&E) and immunofluorescence staining using proliferating cell nuclear antigen (PCNA) and phosphorylated heat shock protein 27 (pHSP27) antibodies. The residual stromal surface was observed by scanning electron microscopy (SEM). In the Ocu group, epithelia were significantly recovered at 18, 24, and 50 hours compared with immediately after removal, and in the blade and Amo groups, epithelia were significantly recovered only at 50 hours after epithelial removal. The expression levels of PCNA and pHSP27 did not differ among three groups. There was significantly more inflammatory cell infiltration in the blade group than in the other groups. SEM showed a more regular and uniform residual stromal surface in the Ocu group than in the other groups. The newly developed epithelial brush showed better polishing ability and led to earlier significant epithelial recovery and a more regular and uniform stromal surface than conventional methods in this rabbit model of epithelial defects. Accumulation of clinical data is expected to expand the scope of application of new brushes for laser surface ablation.

1. Introduction

Laser refractive surgery is a technique that has been widely used for approximately 40 years to correct refractive error and is performed with an excimer laser to ablate the cornea to deform the corneal structure. Laser in situ keratomileusis (LASIK) is a method of flap formation and ablation of the underlying stroma and is often associated with decreased postoperative pain and rapid visual acuity recovery, but there is a risk of flap-related complications [1, 2]. Laser surface ablation techniques including photorefractive keratectomy (PRK), laser-assisted subepithelial keratectomy (LASEK), and epi-LASIK (epithelial LASIK) have the advantage of maintaining the biomechanical strength of the cornea compared with LASIK, but they also have disadvantages such as increased time to recovery of visual acuity, subepithelial clouding, and myopic regression [3].

The first step of surface ablation is removal of the corneal epithelium. Keeping the corneal stromal surface as smooth as possible without damage is essential to prevent postoperative complications including pain and corneal haze by facilitating rapid epithelial healing [4–6]. Therefore, the use of an epithelial removal technique that leaves a smooth

stromal surface is clinically important, and mechanical removal using a blunt spatula or rotating brush and removal with alcohol or an excimer laser are commonly performed [7, 8]. The rotating brush effectively removes the corneal epithelium while minimizing damage to Bowman's membrane and allows more rapid healing of epithelial defects with less postoperative haze than blunt mechanical debridement [7, 9–11].

The Occubrush® epithelial brush (Occutech, Gyeonggi-do, Korea) is a recently developed corneal epithelial brush that facilitates accurate epithelial removal due to its uniform center and curvature structure. The aim of our study was to evaluate the effectiveness and safety of this newly developed epithelial brush and compare it with the widely used rotating brush and sharp blade in a rabbit model of corneal epithelial defects.

2. Methods

2.1. Animals. Thirty-seven New Zealand white rabbits, each weighing between 2.5 and 3.0 kg, were used in this study. They were kept in standard rabbit cages with good environmental control. All experimental procedures conformed to the guidelines in the Association for Research in Vision and Ophthalmology (ARVO) Statement for the Use of Animals in Ophthalmic and Vision Research (ARVO Animal Policy). This study was conducted in strict accordance with adherence to the relevant national and international guidelines regarding animal handling as mandated by the Institutional Animal Care and Use Committee of the University of Ulsan College of Medicine. This committee reviewed and approved the animal study protocol (2019-13-247).

All interventions were performed under anesthesia, and all efforts were made to minimize suffering. All rabbits were anesthetized with an intramuscular injection of a mixture of tiletamine and zolazepam (Zoletil®50; Virbac Corp., Carros Cedex, France) and xylazine (Rompun; Bayer AG, Leverkusen, Germany). Then, topical anesthesia was given with 0.5% proparacaine hydrochloride (Alcaine®; Alcon Laboratories, Fort Worth, TX). The rabbits were randomly divided into three groups according to the epithelial removal method. The polishing ability and scanning electron microscopy findings were blindly evaluated by one practitioner (JYK) who was blinded to the group assignment. In the blade group, the corneal epithelium of approximately 6 mm from the periphery to the center was quickly and gently removed by mechanical debridement using a sharp scalpel blade (#15, Kiato plus blade, MDSS GmbH, Hannover, Germany), and the removed site was washed with normal saline. In the Ocu and Amo groups, the corneal epithelium was removed at room temperature (RT) using the newly developed epithelial brush (Occubrush, product photo is attached in Supplementary Materials) and a rotating brush (Amoils epithelial scrubber; Innovative Excimer Solutions, Inc., Toronto, Canada), respectively. Removal of the corneal epithelium was performed for approximately 10 seconds, and the diameter of the removed epithelium was approximately 6 mm.

2.2. Comparison of Polishing Ability and Wound Healing in a Rabbit Model. Thirty-six rabbits were divided into the three groups mentioned above with twelve rabbits (24 eyes) per group to compare the polishing ability of each technique and wound healing in each group. One untreated rabbit was included as a control. To compare the polishing ability of each technique, the corneal epithelium was observed with a light microscope immediately after removal. After epithelial removal, wound healing was observed with a light microscope under cobalt blue light following instillation of 2% sodium fluorescein (Bausch and Lomb, Inc., Rochester, NY), and photographs were taken immediately after epithelial removal and at 4, 18, 24, and 50 hours after epithelial removal. The area of the epithelial defect in the photographs taken was calculated using ImageJ software (version 1.62f; available at https://rsbweb.nih.gov/ij/; developed by Wayne Rasband, National Institutes of Health, Bethesda, MD).

2.3. Immunofluorescence and Hematoxylin and Eosin (H&E) Staining. Three rabbits in each group were sacrificed immediately and 24 and 50 hours after removal. Both eyes were enucleated and fixed for 24 hours in neutral-buffered formalin (3.7% formaldehyde). The cornea was obtained from each eye by making a stab incision through the pars plana and cutting circumferentially with scissors. The separated cornea was embedded into a paraffin block, and the processed tissue was sectioned into 4 μm thick sections and mounted on slides. After deparaffinization, the slides were heated in 0.01 M sodium citrate buffer solution (pH 6.0) at 90–100°C for 30 minutes for antigen retrieval. The tissues were then blocked with 0.1% bovine serum albumin (BSA) and 5% donkey serum (Jackson ImmunoResearch Laboratories Inc., West Grove, PA) at RT for 30 minutes. The slides were washed three times for 10 minutes each and incubated with primary antibodies for proliferating cell nuclear antigen (PCNA; 1:200, NB500-106; Novus Biologicals, Inc., Centennial, CO) and phosphorylated heat shock protein 27 (pHSP27; 1:200, ab5581; Abcam, Inc., Cambridge, MA) overnight at 4°C. They were incubated with the secondary antibodies (1:1000) at RT for 1 hour. The slides were washed three times for 10 minutes each and stained with 4′-6-diamidino-2-phenylindole (DAPI) (Vector Laboratories, Inc., Burlingame, CA) for 5 minutes to counterstain the cell nuclei. After dehydration, the slides were mounted in fluorescence mounting medium and examined using an LSM780 confocal microscope (Carl Zeiss Meditec AG, Jena, Germany). The remaining sections were subsequently used to confirm the infiltration of inflammatory cells in the cornea by H&E staining.

2.4. Scanning Electron Microscopy (SEM). A total of nine rabbits with three rabbits per group were assigned to observe the residual stromal surface using SEM. All rabbits were sacrificed immediately after epithelial removal, all right eyes were enucleated, and the anterior segment including the cornea was obtained from each eye. The separated cornea was prefixed with 1% paraformaldehyde and 1% glutaraldehyde in 0.1 M cacodylate buffer (pH 7.4) for 24 hours at

4°C, postfixed with 2% osmium tetroxide in 0.1 M cacodylate buffer at RT, and dehydrated with progressive concentrations of ethanol. The dehydrated sample was replaced with ethanol and isoamylacetate, and the tissue sample substituted with pure isoamylacetate was once again dried with a critical point dryer. The sample was coated with platinum (Au) using an ion coater and examined with a scanning electron microscope (S-4500; Hitachi, Inc., Tokyo, Japan).

2.5. Statistical Analysis. The Wilcoxon signed-rank test was used to compare the area of the epithelial defect according to the time after epithelial removal in each group. The Kruskal–Wallis test was used to compare the proportion of the epithelial defect area immediately after epithelial removal and at each time point between groups. Statistical significance was set at $P < 0.05$. All statistical analyses were performed using SPSS version 21.0 software (IBM SPSS Inc., Chicago, IL).

3. Results

3.1. Polishing Ability. Light microscopic images taken immediately after epithelial removal and under cobalt blue light after fluorescence staining showed irregular and rough borders of the epithelial defects in the blade group (Figure 1). However, in the Ocu and Amo groups, 50 μm or more of the corneal epithelial layer was completely removed, revealing excellent polishing ability of these methods. The Ocu group showed regular and clear borders of the epithelial defects, and the epithelium was removed in a precise circular shape. The Amo group also showed clean borders of the epithelial defects, but the epithelium was removed in a more oval than circular shape.

3.2. Epithelial Wound Healing. The ratio of the epithelial defect area at each time point (4, 18, 24, and 50 hours) after epithelial removal to the epithelial defect area immediately after epithelial removal was calculated (Table 1). In the blade and Amo groups, the ratio significantly decreased only at 50 hours after epithelial removal. However, in the Ocu group, the ratio significantly decreased at 18, 24, and 50 hours (all $P < 0.05$). There were no significant differences among the three groups at 4, 18, and 24 hours. At 50 hours, only Ocu and Amo groups exhibited complete epithelial healing.

3.3. Immunofluorescence for PCNA and pHSP27. PCNA staining was performed at 24 and 50 hours after epithelial removal in the blade, Ocu, and Amo groups and in untreated controls (Figure 2). In untreated controls, there was more PCNA expression in the peripheral cornea close to the limbus where stem cells were located than in the central cornea. At 24 hours, PCNA was not expressed in the central cornea in three groups, indicating that the central corneal epithelia had not yet recovered. However, there was increased PCNA expression in the peripheral cornea where wound healing had occurred in three groups, and there was no difference in the expression levels among the three groups. At 50 hours after epithelial removal in the blade group, the epithelial defect remained in the central cornea; however, in the Ocu and Amo groups, the epithelia were completely healed, and PCNA was expressed in the central cornea, with no significantly different expression between the two groups. There was no difference in the PCNA expression among the three groups in the peripheral cornea at 50 hours.

At 24 and 50 hours after epithelial removal in three groups, pHSP27 expression was investigated (Figure 3). At 24 hours, pHSP27 was not expressed in the central cornea, indicating that the central corneal epithelia had not yet recovered. However, pHSP27 was expressed in the peripheral cornea where wound healing had occurred in the three groups, and there was no difference in the expression levels among three groups. At 50 hours after epithelial removal in the blade group, the epithelial defect remained in the central cornea; however, in the Ocu and Amo groups, the epithelia were completely healed, and pHSP27 expression was found in the central cornea, with no significantly different expression between the two groups. There was no difference in pHSP27 expression among the three groups in the peripheral cornea at 50 hours.

3.4. H&E Staining. H&E staining was performed in the three groups (Figure 4). Corneal epithelia were not present in the central cornea immediately after epithelial removal in all groups. At 24 hours, no inflammatory cell infiltration was observed in the central cornea in all groups, but the blade group had significantly more infiltration in the peripheral cornea where wound healing had occurred than the Ocu and Amo groups ($P < 0.05$). At 50 hours, the epithelial defect remained in the central cornea in the blade group, but in the Ocu and Amo groups, the epithelial defects had completely healed. No inflammatory cell infiltration was observed in all groups at 50 hours.

3.5. SEM. SEM images at 50x and 100x magnification were obtained in the three groups (Figure 5). In the blade group, several grooves measuring from 10 to 20 μm were observed, and the residual stromal surface was rougher and more irregular than in the other groups. However, in the Ocu and Amo groups, flat, regular, and uniform residual stromal surfaces were found. There was more regularity of the residual stromal surface in the Ocu group than in the Amo group.

4. Discussion

The newly developed epithelial brush was designed to be different from the conventional brush in its microscopic structure to increase the accuracy of epithelial removal. In the manufacturing process, a jig suitable for the corneal curvature was used to reduce decentralization and to adhere to the cornea at a constant pressure when removing the epithelium. In addition, the noncontact processing method

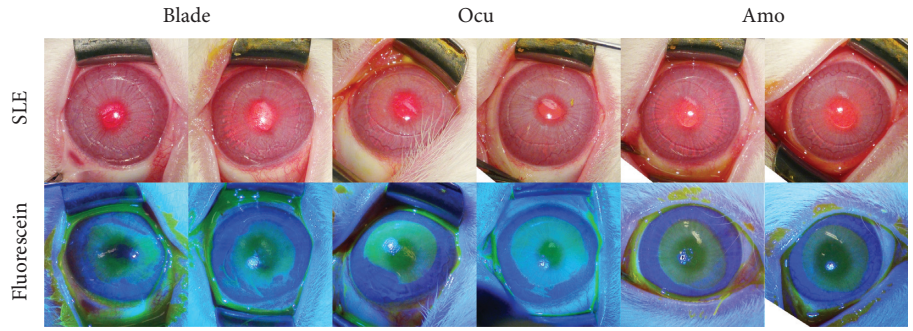

Figure 1: Light microscopic images taken immediately after epithelial removal before and after fluorescence staining in the three groups.

Table 1: Ratio of the epithelial defect area at each time point after epithelial removal to the epithelial defect area immediately after epithelial removal.

Time	Blade group	Ocu group	Amo group	P value[†]
4 hours	0.99 ± 0.06	1.02 ± 0.05	0.93 ± 0.10	0.30
18 hours	0.88 ± 0.08	$0.86 \pm 0.05^{*}$	0.79 ± 0.14	0.58
24 hours	0.76 ± 0.11	$0.65 \pm 0.04^{*}$	0.71 ± 0.08	0.28
50 hours	$0.09 \pm 0.05^{*}$	Completely Healed	Completely Healed	NA[‡]

[*] Statistically significant difference in the epithelial defect area between immediately after epithelial removal and at each time point. [†] Kruskal–Wallis test. [‡]P value could not be obtained due to the complete healing of the epithelial defect in the Ocu and Amo groups.

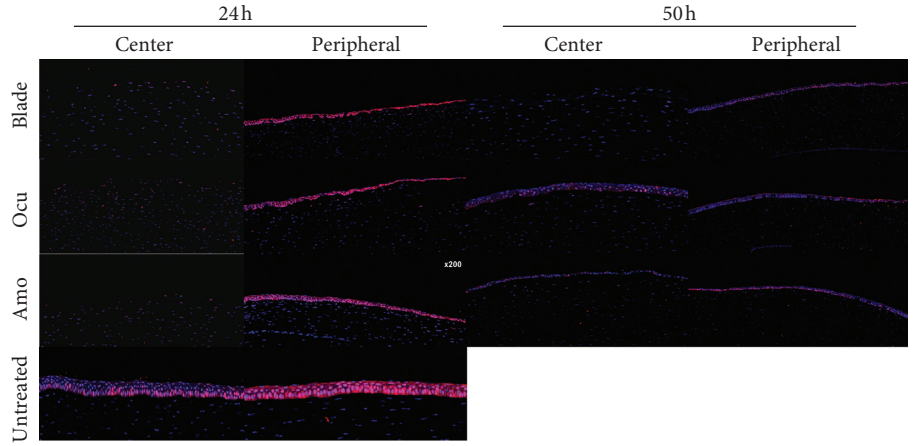

Figure 2: Proliferating cell nuclear antigen (PCNA) staining at 24 and 50 hours after epithelial removal in the three groups and an untreated control.

using vibrations and air can reduce the occurrence of foreign bodies on the brush surface.

In this study, three different methods of epithelial removal for laser surface ablation were evaluated. When the newly developed epithelial brush was used, the epithelium was removed with regular, circular, and clean margins. This method led to earlier significant recovery and a smoother surface than the other epithelial removal methods. Overall, the Ocu group showed better results than the blade group and showed similar or better results than the Amo group. In the Ocu and Amo groups, staining for PCNA and pHSP27, indicators of epithelial proliferation and migration, occurred only in the peripheral cornea at 24 hours and in the central cornea at 50 hours. Furthermore, less inflammatory cell infiltration was exhibited in these groups than the Blade group. To the best of our knowledge, only comparative studies of clinical outcomes according to the epithelial removal method and studies of changes at the cellular level after general PRK have been conducted [4, 12–16]. This study is meaningful in that the differences in wound healing at the cellular level were compared according to the epithelial removal method.

When the polishing ability was compared immediately after epithelial removal, as expected based on the results of a previous clinical study, the most irregular and unclear margins of the epithelial defect were exhibited in the blade group [7]. The Ocu and Amo groups exhibited sufficiently regular and clean margins, but the Ocu group exhibited a rounder shape of the removed epithelium than the other groups. The Amoils rotating brush consists of a disposable

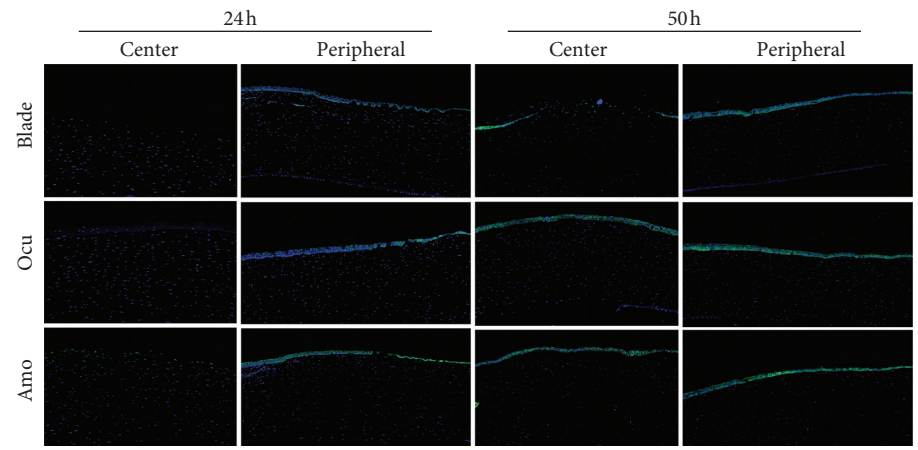

Figure 3: Phosphorylated heat shock protein 27 (pHSP27) staining at 24 and 50 hours after epithelial removal in the three groups.

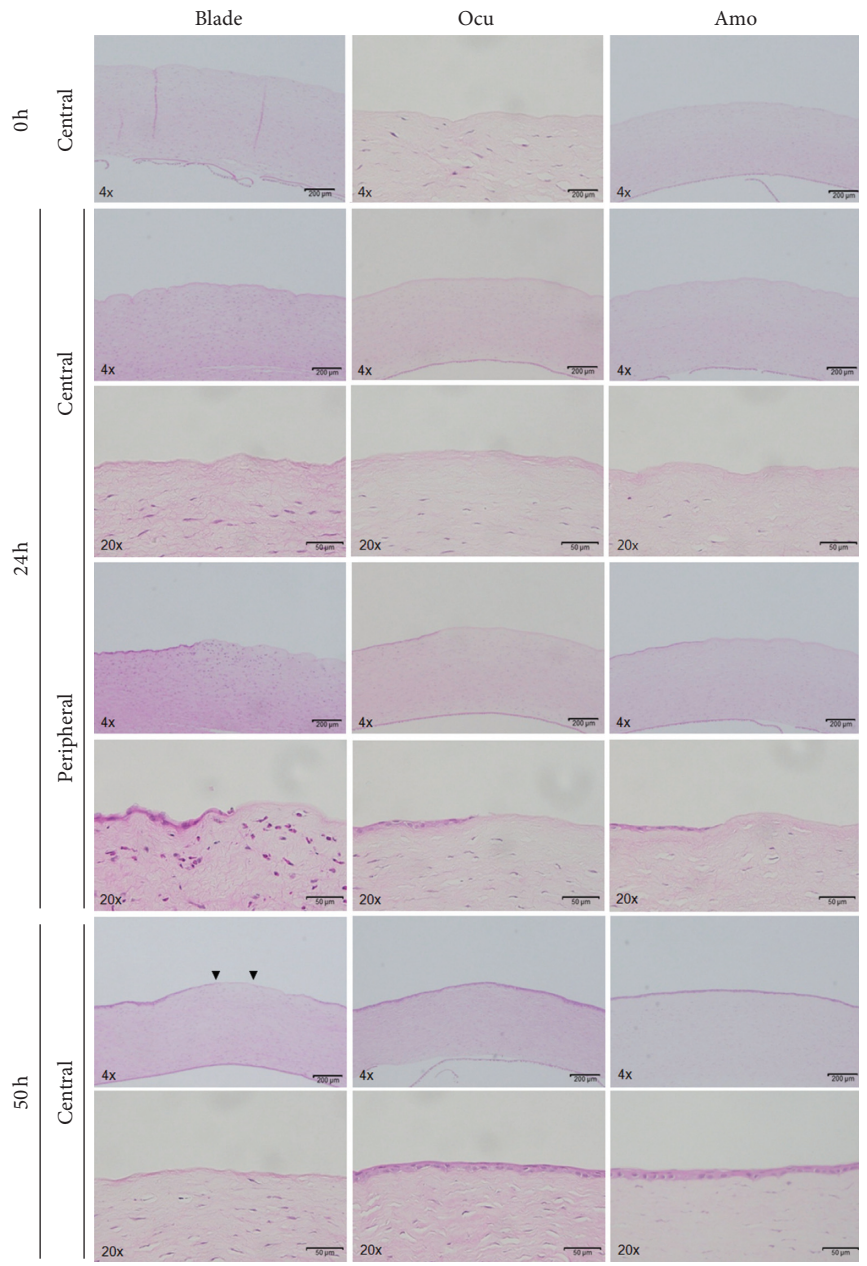

Figure 4: Hematoxylin and eosin staining immediately and at 24 and 50 hours after epithelial removal in the three groups.

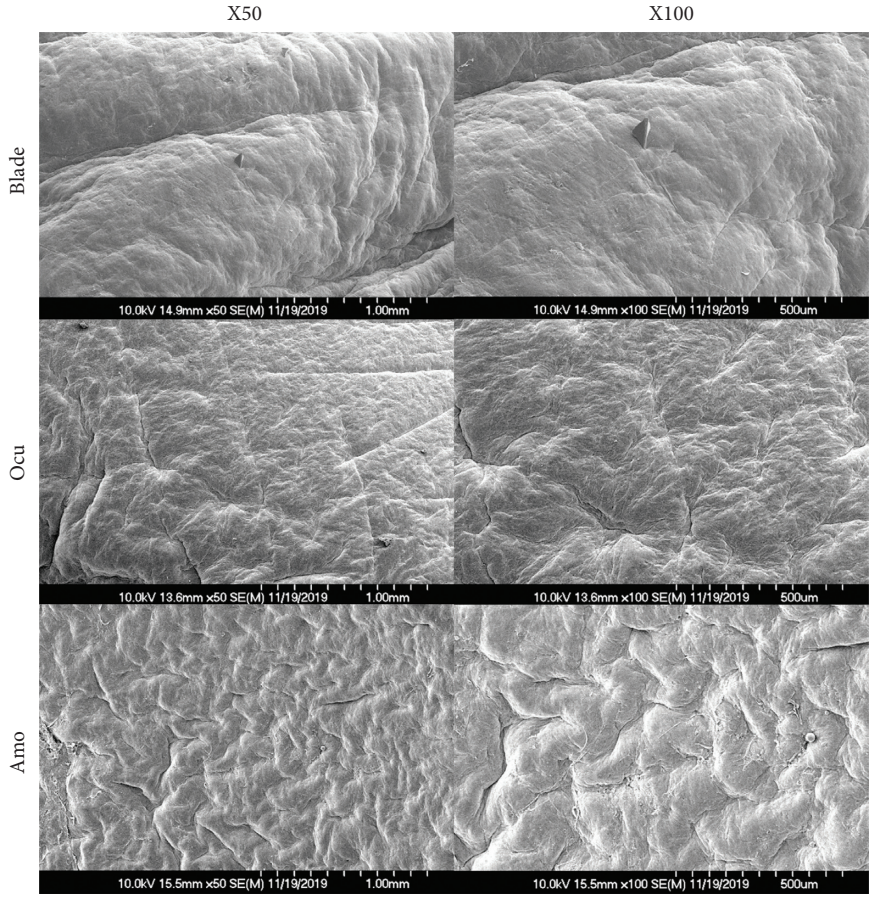

Figure 5: Residual stromal surfaces investigated by scanning electron microscopy (SEM) in the three groups (50x and 100x magnification).

circular brush and a handle with a motor that rotates it, which may lead to an oval shape of the removed epithelium due to fine movement and irregular contact of the rotating head [17]. Although the area was not large, unintended areas of the epithelium could be removed in the Amo group. The newly developed epithelial brush used a jig suitable for the corneal curvature to prevent decentralization during the manufacturing process. As a result, the new brush was uniformly adhered to the ocular surface, and the corneal epithelium was precisely removed in a circular shape.

In previous studies that observed the corneal surface with SEM after epithelial removal, the residual stromal surface after epithelial removal with a brush was smoother without grooves than after mechanical removal with a spatula, and there were few remaining epithelial cells [7, 18]. Similarly, in this study, the residual stromal surfaces on SEM images of the blade and Amo groups were comparable with previous results using a sharp blade and rotating brush, respectively [18]. The newly developed epithelial brush uses a noncontact processing method using vibrations and air to reduce the occurrence of foreign bodies on the brush surface. The Ocu group exhibited an overall uniform residual stromal surface due to decreased foreign body generation and to the structural suitability of the newly developed epithelial brush.

When comparing the epithelial defect area over time, the ratio of epithelial defects significantly decreased at 18 hours after removal in the Ocu group, but significantly decreased at 50 hours in the other groups. This result can be attributed to the more uniform and flatter residual surface in the Ocu group than in the Amo group as revealed with SEM as well as to the superior polishing ability in the Ocu group. However, there was no significant difference between the Amo and Ocu group at any time point, and this result needs to be confirmed by comparing wound healing after laser refractive surgery in a clinical setting. In a previous clinical study, complete healing was observed in 64% of patients treated using a brush 3 days after PRK and in 36% of patients treated using a blunt scraper [7]. The postoperative uncorrected visual acuity was also better, and corneal haze occurred less frequently in the brush group than in the scraped group [7]. In a relatively recent clinical study, complete healing was observed in both the brush and crescent knife groups during 5 days after PRK, and the results of the present study are comparable with those of this previous study [15].

PCNA is naturally expressed in proliferating cells, and pHSP27 is involved in epithelial migration and apoptosis [19–21]. Both PCNA and pHSP27 were expressed only in the peripheral cornea in all groups at 24 hours after epithelial removal and in the central cornea in the Ocu and Amo groups at 50 hours but only in the peripheral cornea in the blade group at this time point. In experiment on the wound healing process after refractive surgery, proliferation and migration of residual keratocytes after apoptosis begin from 12 to 24 hours and markedly diminish approximately after 1

week [4, 22]. Our results at 24 and 50 hours are consistent with those from previous reports, and in the blade group, the wound healing process may have been slower than in the other groups due to irregular wound margins and residual stromal surface.

Inflammatory cell infiltration begins from 8 to 12 hours after injury and penetrates through the broken blood-aqueous barrier [4]. After phagocytosis of apoptotic cell bodies and other residual cell fragments, these cells disappear after epithelial closure [14]. Other previous study reported that mechanical removal upregulates the expression of inflammatory cytokines compared to ethanol removal [23]. Our H&E staining results are consistent with these reports. In the blade group, significantly more inflammatory cell infiltration was observed around the margins than in other groups; this finding may be related to the poor polishing ability of this technique. In the Ocu and Amo groups, after wound healing was completed at 50 hours after removal, no inflammatory cells were observed.

Using the conventional brush, the uncorrected distant visual acuity showed 20/20 or more in more than 95% of cases 12 months after PRK, and a difference of 0.12 diopters from the intended spherical equivalent which was satisfactory [24, 25]. Even though our findings showed the newly developed brush had less inflammation and more regular epithelial defects, post-LASEK refractive outcomes might be quite unrelated to these factors. Further clinical trials need to be carried out to determine whether the newly developed brush can provide additional improvement in visual acuity and refractive outcomes compared to the conventional brush through the uniform residual stromal surface and rapid epithelial recovery.

5. Conclusion

In conclusion, due to its structural originality and specificity, the newly developed epithelial brush showed better polishing ability and led to earlier significant epithelial recovery and a more regular and uniform residual stromal surface than the conventional rotating brush in this rabbit model of epithelial defects. We also observed the wound healing process at the cellular level according to the epithelial removal method. Our study is meaningful in accumulating data for clinical research, and it is necessary to confirm the clinical relevance of this experimental results through clinical research. In addition, clinical studies comparing the refractive outcomes and intraoperative or postoperative pain associated with this new method with those of other epithelial removal methods are expected to expand the scope of application.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare no conflicts of interest.

Authors' Contributions

Ho Seok Chung and Seung Hwan Moon contributed equally to this work.

Acknowledgments

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Supplementary Materials

Supplementary Figure 1. A product photo of the newly developed epithelial brush (Occubrush). (*Supplementary Materials*)

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Research Article

Functional Outcomes and Reading Speeds following PRESBYOND LBV Using Nonlinear Aspheric Ablation Profiles Combined with Micro-Monovision

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Purpose. To report the functional outcomes and reading speeds following PRESBYOND laser blended vision (LBV) using nonlinear aspheric ablation profiles with micro-monovision with the Carl Zeiss Meditec MEL 90 platform. *Methods*. Data have been collected retrospectively for all patients who underwent PRESBYOND LBV using the MEL 90 excimer laser. Postoperative binocular uncorrected distance and near visual acuity, stereo-acuity, contrast sensitivity, and reading performance were compared with pre-op values measured with patient's progressive glasses. Mean follow-up was 6 ± 1.2 months. *Results*. Sixty eyes of 30 patients (mean age 50.47 ± 6.43 years) were included. Of these, 18 patients were hyperopic and 12 patients were myopic with mean SE of 1.28 ± 1.38 D and -2.84 ± 1.86 D, respectively. At 6 months, the mean binocular UDVA was $\geq -0.03 \pm 0.06$ log MAR and the mean binocular UNVA was $\geq 0.22 \pm 0.04$ log MAR. The uncorrected reading speeds (words per minute) at the preferred reading distance of 46.17 cm, 60 cm, and 80 cm were significantly better (p value <0.01), whereas the smallest letter size and reading acuities were comparable to the preoperative values ($p > 0.05$ for all distances). Uncorrected contrast sensitivity log values showed mild reduction; however, this was not statistically significant for any spatial frequency. There was a significant reduction in post uncorrected stereopsis to 89.67 arc sec, compared with pre-op corrected stereopsis (50.67 arc sec); however, it recovered fully with near correction (53.33 arc sec, $p > 0.05$ compared with pre). *Conclusion*. PRESBYOND LBV resulted in significantly better reading speeds and satisfactory functional visual outcomes, without a permanent change in stereo-acuity and contrast sensitivity 6 months postoperatively.

1. Introduction

The PRESBYOND LBV procedure performed with MEL 90 excimer laser and the CRS-Master successfully combines monovision with extended depth of field achieved by the aspheric laser ablation profile combined with a micro-monovision (−1.50 D) protocol to treat presbyopia. Using this protocol, the intended postoperative refraction is plano for the dominant eye and in the range of −1.00 to −1.50 D for the nondominant eye [1]. Various studies have demonstrated that the procedure was safe and effective across all types of ametropia [1–5].

However, the complete assessment of vision-related abilities should consider visual function (the performance of components of the visual system) and functional vision (visual task-related ability) [6]. Typical visual function tests include assessment of visual acuity, contrast sensitivity, visual fields, tests for binocular vision, colour, depth, and motion perception etc. These properties represent an aspect of visual function, each of which may impact an individual's level of functional vision [7] and thus patient satisfaction after a presbyopia correction surgery.

The goal of functional vision assessment after surgical treatment of presbyopia therefore should be to measure the visual task-related ability under real-world scenarios. Through this study, we aim to evaluate the various visual functions such as distance and near visual acuity, contrast sensitivity, and stereopsis following PRESBYOND LBV. Reading performance, as the visual task-related ability, was also assessed, which has not been described earlier in the context of this procedure.

2. Material and Methods

The study was approved by the Institutional Ethics Committee of Nethradhama Eye Hospital and involved retrospective review of electronic medical records of the patients who had undergone PRESBYOND LBV for correction of presbyopia from June 2015 till June 2018. Exclusion criteria were corrected distance visual acuity (CDVA) worse than 20/25 in either eye, previous refractive surgery, corneal and/or lens opacities that may affect vision, optic disc or retinal pathologies, acute or chronic systemic disease, or any kind of immunosuppressive disorder. Only patients whose complete records were available and who had a follow-up of 6 months after surgery were included.

A complete ophthalmic examination was performed for all patients prior to surgery, which included anterior and posterior segment evaluation; dilated refraction; corneal topography with ATLAS topographer (Carl Zeiss Meditec, Jena, Germany) and Pentacam HR (Oculus); and dry eye assessment with Schirmer's I, II, and tear film breakup time (TBUT). Apart from the above, reading performance using Salzburg Reading Desk (SRD), stereo-acuity measurement using the Titmus-C circles (Stereo Optical Co, Chicago, USA), contrast sensitivity using the CSV-1000 chart, and defocus curve testing with defocusing lenses from +2.00 to −3.00 D were also assessed binocularly, with the patients wearing their progressive spectacles.

The reading performance for near and intermediate was evaluated using the Salzburg Reading Desk camera "Version B.5.1." This device consists of a reading desk with a high-resolution monitor and a laptop where the operating software is displayed. Two infrared video cameras continuously measure the reading distance by stereo photometry. The reading speed and time are recorded with a microphone, incorporated into the SRD monitor. Log-scaled Colenbrander sentences are presented on the monitor in progressively smaller print sizes. A sentence is accepted if it can be read with a minimum speed of 80 words per minute, as this was found to be the minimum threshold for recreational reading in healthy eyes [8, 9].

The reading performance was assessed binocularly before surgery, using patient's own progressive glasses, which were appropriate and improved to the patient's best corrected vision. For near, patients were asked to choose their preferred distance, while for the intermediate, reading performance was evaluated at a fixed distance of 60 cm and 80 cm. Furthermore, the smallest log-scaled print size that could be read effectively (>80 words per minute) was assessed. For near, the letter size ranged from 0.16 to 0.8, while for the intermediate distance, it ranged from 0.16 to 2.0, where 0.16 being the largest and 0.8 and 2.0 being the smallest letter size presented on the monitor of the SRD version evaluated in the current study.

Preoperative refractive workup, verification of the eye dominance, micro-monovision assessment, and anisometropia tolerance were performed as per a standard protocol published earlier [10]. Wavefront aberrometry (WASCA Analyzer; Carl Zeiss Meditec, Jena, Germany) was used to measure the ocular wavefront aberrations in scotopic condition, and data at a diameter of 6 mm were analyzed.

All surgical procedures were performed by two experienced refractive surgeons (SG and SB) using the VisuMax femtosecond laser and MEL 90 excimer laser (both Carl Zeiss Meditec, Jena, Germany). The CRS-Master software platform (both Carl Zeiss Meditec) was used to design the aspheric ablation profile using the ocular wavefront data obtained by the WASCA aberrometer, which was then exported for treatment with the MEL 90 excimer laser. The surgical procedure was similar to that of a standard femtosecond LASIK treatment. Flaps were created with the VisuMax femtosecond laser using a 100–120 μm flap thickness. Stromal aspheric ablation was performed using the MEL 90 excimer laser with a 6.45 ± 0.19 (Range: 6.00–6.80) mm optical zone and 2.2 mm transition zone.

Postoperatively, patients were followed up at day 1, 2 weeks, 3 months, and 6 months. On all follow-up visits, measurement of uncorrected distance and near visual acuity (UDVA and UNVA), CDVA, manifest refraction, and a patient questionnaire regarding their satisfaction following the procedure were obtained. On all visits from 2 weeks onwards, reading performance, stereo-acuity, contrast sensitivity, and defocus curve testing were repeated binocularly without correction to evaluate functional outcomes.

Statistical analysis was performed using the SPSS statistical package (version 17.0; SPSS, Inc., Chicago, IL). Data were checked for normality before subjecting to analysis. If the data were normally distributed, paired Student's *t*-tests were performed to compare the mean values of UDVA, UNVA, CDVA, UIVA, contrast sensitivity, stereo-acuity, and reading performance-related parameters. If the data distribution was not normal, the Wilcoxon signed-rank test was used. A p value less than 0.05 was considered statistically significant.

3. Results

A total of 30 patients with mean age of 50.47 ± 6.43 years (range 41–64 years), who underwent bilateral treatment with PRESBYOND LBV for myopia ($n = 12$ patients) or hyperopia ($n = 18$ patients), with or without astigmatism were included in the study. Table 1 shows the preoperative demographic details of all the patients included in the study. The mean preoperative manifest spherical equivalent (SE) of the dominant eyes was -0.30 ± 2.45 D (range: −7.25 to +4.00 D), and that of the nondominant eyes was -0.47 ± 2.70 D (range: −5.75 to +3.625 D). Mean follow-up was 6.00 ± 1.2 months.

3.1. Visual and Refractive Outcomes. Eighty-three percent ($n = 25$) patients achieved a binocular cumulative uncorrected distance visual acuity of 20/20 or better, while all patients had a binocular UDVA of 20/25 or better (Figure 1).

Additionally, all patients achieved binocular cumulative uncorrected near visual acuity of 0.3 log MAR, and 73% patients could read 0.2 log MAR or better binocularly (Figure 2).

The mean post-op SE refraction of the dominant eyes was -0.03 ± 0.29 D (range: −0.5 to +0.62 D) and that of the nondominant eyes was -1.26 ± 0.40 D (range: −2.25 to −0.75 D), Table 2.

Ninety-seven ($n = 29$) percent dominant eyes were within ±0.50 D, and all eyes were within ±1.00 D of SE predictability. Of the nondominant eyes, 66.7% ($n = 20$) were within −1.00 to −1.50 D of SE predictability (range −0.75 to −2.25 D) (Figure 3).

Ninety-seven ($n = 29$) percent of dominant eyes and 100% of nondominant eyes were within a refractive astigmatism of ±0.5 D (Figure 4).

3.2. Reading Performance. The preferred reading distance increased from 41.8 ± 4.87 cm pre-op to 46.16 ± 5.40 cm postsurgery, which was statistically significant ($p = 0.01$).

The reading speeds at the near preferred distance, 60 cm, and 80 cm showed significant improvement, compared with the pre-op values recorded with patient's progressive glasses. The reading speed at 60 cm was significantly better than the reading speed at 80 cm (Table 2, Figure 5).

There was, however, no significant difference for the post-op uncorrected reading acuity and smallest letter read (with a minimum reading speed of 80 wpm) at the preferred reading distance, 60 cm, and 80 cm versus their pre-op corrected values (Table 2, Figure 5).

3.3. Stereopsis. The mean postoperative binocular uncorrected stereopsis (89.67 ± 35.95 arc sec) was significantly lower than the preoperative corrected value of 50.67 ± 17.20 arc sec ($p = 0.01$). However, with near correction, the stereo-acuity improved to 53.33 ± 16.25 arc sec, which was comparable with the preoperative values ($p = 0.53$).

3.4. Subgroup Analysis. Subgroup analysis was done between two groups for patients aged "less than 55 years" and "55 years and above," with regard to binocular visual outcomes, reading performance in terms of reading acuity, letter size and reading speed, and stereopsis. No significant change was found between groups for any of the analyzed parameter (Table 3).

3.5. Contrast Sensitivity. A mild drop in the contrast sensitivity was observed at 6 months for post uncorrected log values at all spatial frequencies, which was not significantly different from the pre-op corrected values (p value >0.05 for all spatial frequencies) (Figure 6).

3.6. Defocus Curve. Binocular defocus curves were plotted with distance correction from +2.00 to −4.00 D. The curve showed a single peak at 0.00 D, corresponding to a visual acuity of −0.1 log MAR, followed by a gradual decline. A mean visual acuity of 0 log MAR or better was observed within the defocus range of +0.50 to −1.00 D, and a full range of functional vision, i.e., 0.2 log MAR(20/30) or better was achieved from +0.50 to −2.00 D of defocus (Figure 7).

3.7. Safety and Complications. Twenty percent (12) eyes gained one or more lines, 8% (5) eyes lost one line, while 72% (43) eyes did not show any change in CDVA at 6 months post-op (Figure 8).

The loss in one line of CDVA in 5 eyes could be explained by higher induced aberrations in hyperopic eyes, post-op LASIK-induced dry eye, loss in contrast, etc. This was, however, not clinically significant as binocular evaluation showed good outcomes for distance vision.

None of the eyes had any short- or long-term complications such as diffuse lamellar keratitis, infection, flap wrinkles, dislocation, and epithelial ingrowth. No eye in this cohort required enhancement for distance or near vision at the end of 6-month follow-up.

3.8. Patient Satisfaction Scores. Table 4 shows the subjective questionnaire used to assess patient satisfaction following PRESBYOND LBV at 6 months. The mean satisfaction scores for distance, intermediate and near were 97.97 ± 2.13, 99.36 ± 0.64 and 96.84 ± 2.36 respectively. Twenty-eight (93.3%) patients were satisfied for distance, while 26 (86.6%) patients were satisfied for near vision. All patients had 100% satisfaction for intermediate vision related activities. No patient complained of severe glare or haloes. However, two (6.6%) patients reported grade 1 (mild) dysphotopsia at the end of 6 months follow-up.

4. Discussion

As earlier described, laser blended vision (LBV) involves a combination of controlled induced corneal spherical aberrations and a micro-monovision protocol, aiming at a micro-monovision targeting mild myopia of −1.50 D or less for the near eye, irrespective of the age [10]. In addition, the optimized aspheric ablation profile is intended to increase the depth of field of each eye, resulting in creation of a blend zone to enable continuous distance to intermediate to near vision between the two eyes. Due to the above factors, PRESBYOND LBV appears to be advantageous over traditional LASIK monovision, which was found to be associated with side effects such as poor intermediate vision, reduced contrast sensitivity, loss of stereopsis, and increased photic phenomena and longer adaptation time; all factors potentially reducing patient satisfaction [11, 12]. The main aim of this study was to evaluate the functional aspects of vision and reading speeds following PRESBYOND LBV, of which data are limited in the literature.

Castro et al. simulated the anisocoria generated by corneal inlays using a small aperture contact lens and demonstrated a significant deterioration of stereo-acuity for near and intermediate distances [13]. Also, studies with LASIK monovision demonstrated that in a proportion of these patients, stereo-acuity is lost and that once lost, it does not recover [11, 14, 15]. Our results were similar to those of Reinstein et al., who found that although postoperative uncorrected stereo-acuity was lower than preoperative near-corrected stereo-acuity after LBV, a functional level of stereo-acuity was maintained postoperatively; 68% of patients had stereo-acuity of 100 sec or better and 93% had stereo-acuity of 200 sec or better [16].

In our series, all patients had stereo-acuity of 140 sec or better, while 70% (21) patients had stereo-acuity of 60 sec or

Table 1: Patient demographics and preoperative data.

Patient demographics	
Total no. of eyes	60
Total no. of patients	30
Male: female	14 : 16
Age (years)	50.47 ± 6.43
Binocular UDVA (log MAR)	0.48 ± 0.39
Binocular CDVA (log MAR)	−0.01 ± 0.06
Binocular DCNVA (log MAR)	0.23 ± 0.06
K mean (D)	43.89 ± 1.38
CCT (μ)	529.93 ± 34.10
Optical zone (mm)	6.45 ± 0.19
Flap thickness (μ)	118.33 ± 8.89
Ablation depth (μ)	49.3 ± 26.57
Post-op RST (μ)	356.30 ± 43.97
Z (4, 0)	−0.23 ± 0.28

Visual acuity and refraction		
Parameter (mean ± SD)	Dominant eyes ($n = 30$)	Nondominant eyes ($n = 30$)
Sphere (D)	−0.075 ± 1.72	−0.25 ± 2.40
Cylinder (D)	−0.24 ± 0.80	−0.41 ± 0.91
SE (D)	−0.19 ± 1.93	−0.47 ± 2.70
UDVA (log MAR)	0.48 ± 0.39	0.62 ± 0.41
CDVA (log MAR)	−0.01 ± 0.06	−0.01 ± 0.08
DCNVA (log MAR)	0.23 ± 0.06	0.22 ± 0.05

D: dioptre, SE = spherical equivalent, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, DCNVA = distance corrected near visual acuity, K = keratometry, CCT = central corneal thickness, and RST = residual stromal thickness.

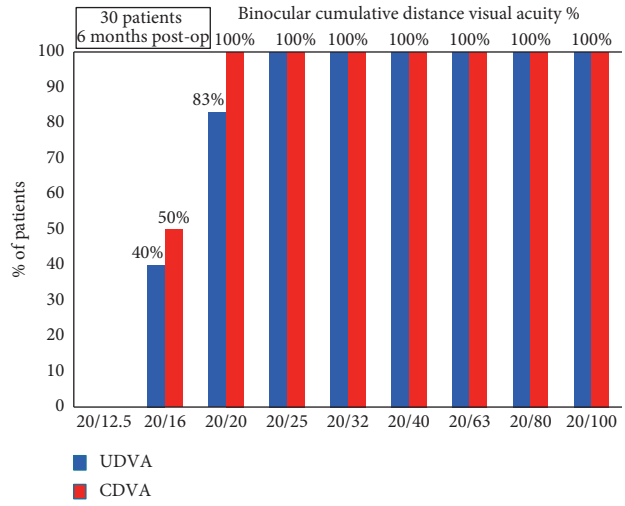

Figure 1: Cumulative histogram for binocular UDVA and CDVA at 6 months post-op.

better. Near-correction restored preoperative near-corrected stereo-acuity in all the patients, suggesting that PRESBYOND LBV did not lead to irreversible loss of stereo-acuity.

Uthoff et al. investigated the outcomes of simultaneous correction of presbyopia and ametropia by a PresbyMAX (bi-aspheric cornea modulation) technique, based on the creation of a central hyper positive area for near vision and leaving the pericentral cornea for far vision [17]. In a series of 60 eyes of 30 patients, they reported up to 13% eyes losing 2 lines of CDVA. On the other hand, our study involving the similar number of eyes showed better safety, as only 8% eyes lost 1 line and no eye lost more than 2 lines of CDVA. This may suggest that procedures based on creating corneal multifocality for presbyopia treatment may result in drop in distance visual acuity, which is more than PRESBYOND LBV, probably due to higher induced aberrations and worsening of contrast sensitivity.

Studies evaluating the results of peripheral PresbyLASIK algorithm [18] and hybrid techniques [15] (based on targeting a postsurgical corneal asphericity) reported a reduction in postoperative contrast sensitivity for all spatial frequencies. However, Zhang et al. who evaluated contrast sensitivity following PRESBYOND LBV found that, compared in logarithmic scale, the change in binocular contrast sensitivity from the preoperative values in mesopic and photopic conditions was not significantly different at any

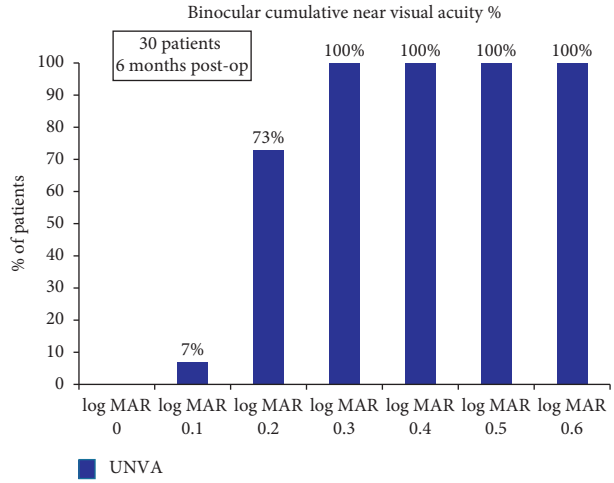

Figure 2: Cumulative histogram for binocular UNVA at 6 months post-op.

Table 2: Visual acuity outcomes and reading performance at 6 months postoperatively.

Parameter	Dominant eyes ($n = 30$)	Nondominant eyes ($n = 30$)	
Sphere (D)	0.02 ± 0.23	−1.20 ± 0.36	
Cylinder (D)	−0.09 ± 0.31	−0.11 ± 0.19	
SE (D)	−0.03 ± 0.29	−1.26 ± 0.40	
UDVA (log MAR)	−0.03 ± 0.67	0.39 ± 0.19	
CDVA (log MAR)	−0.04 ± 0.54	−0.03 ± 0.05	
	Binocular visual acuity (log MAR)		
Parameter	Uncorrected	Distance corrected	p value
Distance	−0.032 ± 0.06	−0.06 ± 0.05	0.06
Near	0.22 ± 0.04	0.4 ± 0.11	0.01
	Reading performance		
Reading acuity (log MAR) (mean ± SD)	Pre corrected	Post uncorrected	p value
40 cm	0.043 ± 0.12	0.031 ± 0.11	0.70
60 cm	0.049 ± 0.17	0.046 ± 0.06	0.92
80 cm	0.117 ± 0.04	0.101 ± 0.05	0.21
Letter size (log scale) (mean ± SD)			
40 cm	0.71 ± 0.12	0.74 ± 0.08	0.36
60 cm	0.91 ± 0.21	0.97 ± 0.16	0.19
80 cm	0.92 ± 0.17	0.95 ± 0.26	0.60
Reading speed (WPM) (mean ± SD)			
40 cm	150.56 ± 7.3	164.03 ± 18.62	0.01
60 cm	162.67 ± 6.38	174.16 ± 9.55	0.01
80 cm	154.36 ± 7.29	165.63 ± 18.06	0.01
Reading performance at intermediate distance (60 cm versus 80 cm) at 6 months post-op			
Reading acuity (log MAR)		0.52	
Letter size		0.16	
Reading speeds (WPM)		0.02	

frequency. The change of AULCSF was not significant either, changing from 1.38 to 1.41 and 1.42 to 1.43 in mesopic and photopic conditions [19]. Our results were similar to those of Zhang et al. wherein we did not observe any significant difference between the pre-op corrected versus post-op uncorrected contrast sensitivity values at any spatial frequency at 6 months.

Charman [20] suggested that, extended binocular depth of focus for presbyopia treatments can be achieved by aiming for residual higher-order aberrations (HOAs). Although, in the present study, we did not analyse change in aberrations, in a previously published paper, we calculated the same based on the experiments performed by Yi et al. [21] according to which the theoretical depth of focus achieved was up to 1.55 D in hyperopic and 0.48 D in the myopic eyes. This could be reflected in the defocus curve, which was charted +2.00 to −4.00 D. It could be inferred that PRESBYOND LBV resulted in a functional vision [22] of 0.2 log MAR (20/32) or better from +0.50 to −2.00 D, suggesting a theoretical depth of defocus of 2.50 D.

Reading is one of the most vital and common skills for engaging, communicating and interpreting ideas. Any visual

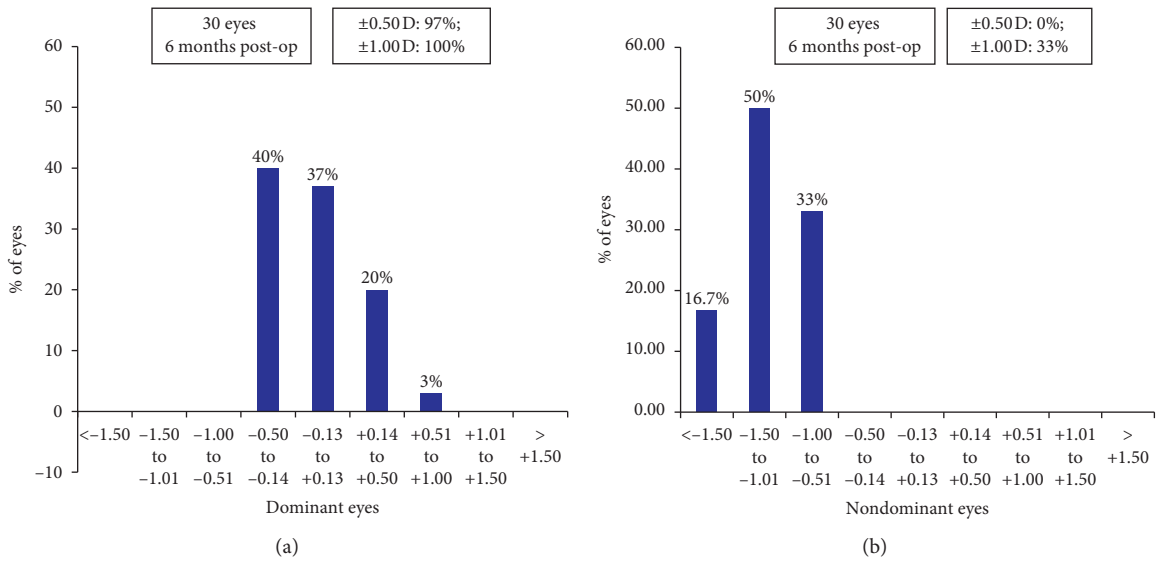

Figure 3: Histogram showing the accuracy to the intended spherical equivalent refraction for (a) dominant and (b) nondominant eyes at 6 months post-op.

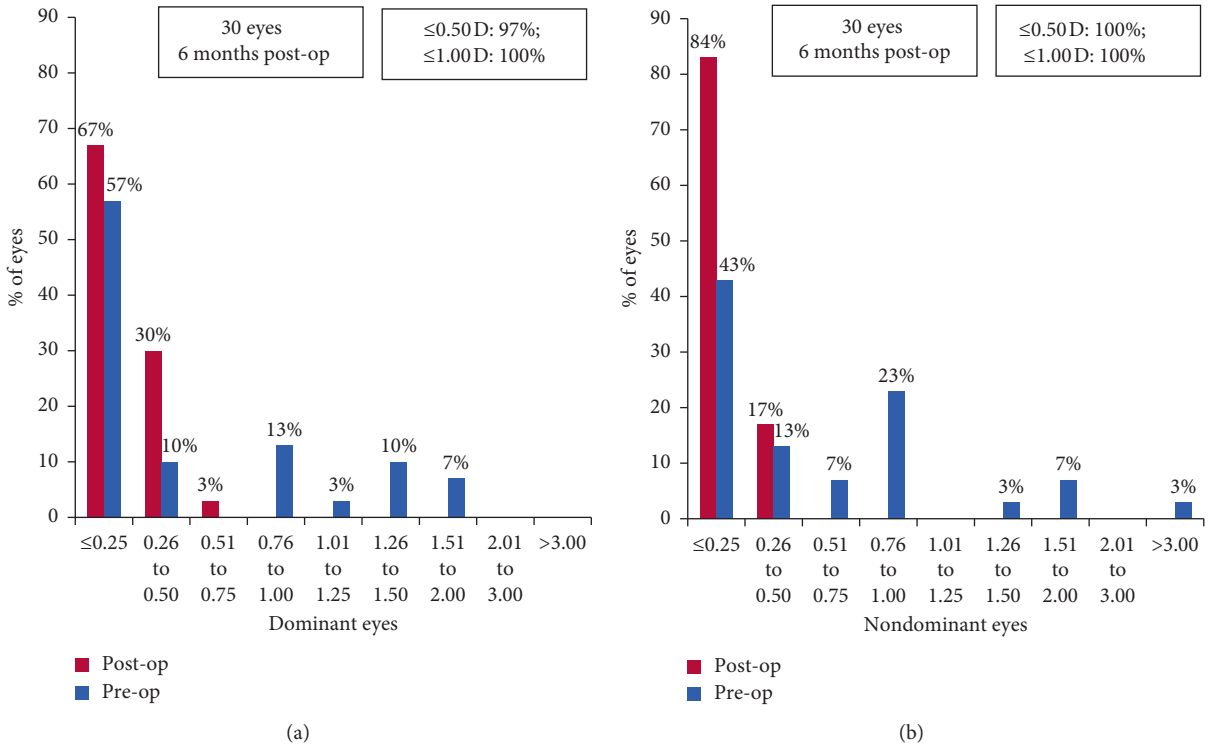

Figure 4: Histogram showing change in refractive astigmatism for (a) dominant and (b) nondominant eyes at 6 months postoperatively.

loss that affects reading ability will have a disproportionate impact on a patient's quality of life. Reading speed more closely aligns with task performance than visual acuity metrics [23]. In this study, reading performance at near was evaluated at the patients preferred distance, as it was suggested that reading distance could vary considerably depending upon the posture, body size, habits, illumination, type of spectacles, and other factors [9]. However, for intermediate, fixed distances of 60 and 80 cm were selected, as the "blend zone" created in the this range following PRESBYOND LBV, is supposed to provide a continuous vision from distance through near. It was found that the reading speed at 60 cm was significantly better than 80 cm, reflecting the expected outcome of the treatment planning,

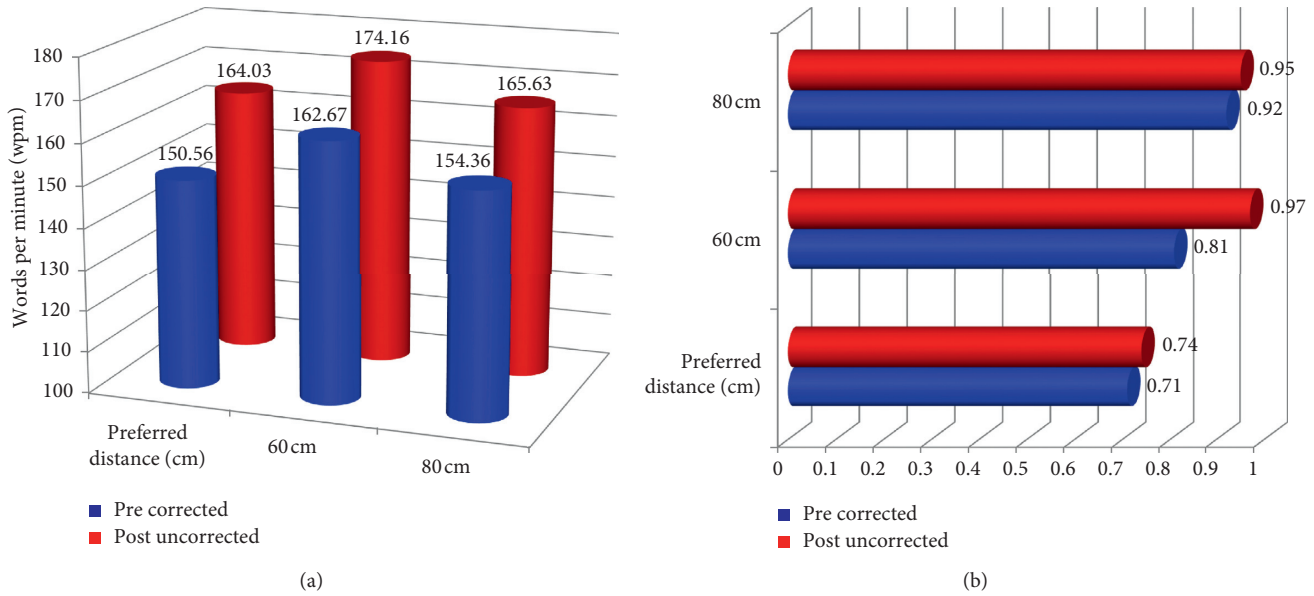

Figure 5: Binocular reading performance evaluated using SRD at preferred reading distance, 60 cm, and 80 cm. (a) Reading speed. (b) Letter size.

Table 3: Subgroup analysis for patients aged "less than 55 years" and "55 years and above."

Parameter (mean ± SD)	Less than 55	55 and above	p value
Binocular visual acuity (log MAR)			
Distance uncorrected	−0.037 ± 0.06	−0.01 ± 0.07	0.46
Distance corrected	−0.06 ± 0.04	−0.04 ± 0.05	0.39
Near uncorrected	0.22 ± 0.03	0.24 ± 0.05	0.27
Near corrected	0.38 ± 0.10	0.45 ± 0.15	0.16
Reading performance			
Reading acuity (log MAR)	Less than 55	55 and above	p value
40 cm (pre corrected)	0.03 ± 0.11	0.06 ± 0.14	0.6
(Post uncorrected)	0.02 ± 0.11	0.04 ± 0.11	0.64
60 cm (pre corrected)	0.05 ± 0.15	0.04 ± 0.23	0.86
(Post uncorrected)	0.04 ± 0.06	0.04 ± 0.05	0.76
80 cm (pre corrected)	0.11 ± 0.05	0.12 ± 0.01	0.71
(Post uncorrected)	0.1 ± 0.05	0.10 ± 0.04	0.82
Letter size (log scale)			
40 cm (pre corrected)	0.71 ± 0.12	0.72 ± 0.11	0.97
(Post uncorrected)	0.74 ± 0.08	0.73 ± 0.08	0.77
60 cm (pre corrected)	0.11 ± 0.03	0.12 ± 0.03	0.82
(Post uncorrected)	0.97 ± 0.17	0.98 ± 0.14	0.92
80 cm (pre corrected)	0.94 ± 0.16	0.86 ± 0.20	0.28
(Post uncorrected)	0.96 ± 0.29	0.93 ± 0.20	0.96
Reading speed (WPM)			
40 cm (pre corrected)	150.45 ± 7.28	150.87 ± 7.82	0.89
(Post uncorrected)	165.09 ± 20.02	161.12 ± 14.85	0.61
60 cm (pre corrected)	162.72 ± 6.51	162.5 ± 6.41	0.93
(Post uncorrected)	173.90 ± 9.99	174.87 ± 8.80	0.81
80 cm (pre corrected)	154.04 ± 7.39	155.25 ± 7.42	0.69
(Post uncorrected)	166.63 ± 17.91	162.87 ± 19.44	0.62
Stereopsis			
Pre-op uncorrected	50 ± 17.18	52.5 ± 18.32	0.73
Post-op uncorrected	82.27 ± 36.40	96.25 ± 36.22	0.55
Post-op uncorrected	52.27 ± 16.59	56.25 ± 15.97	0.56

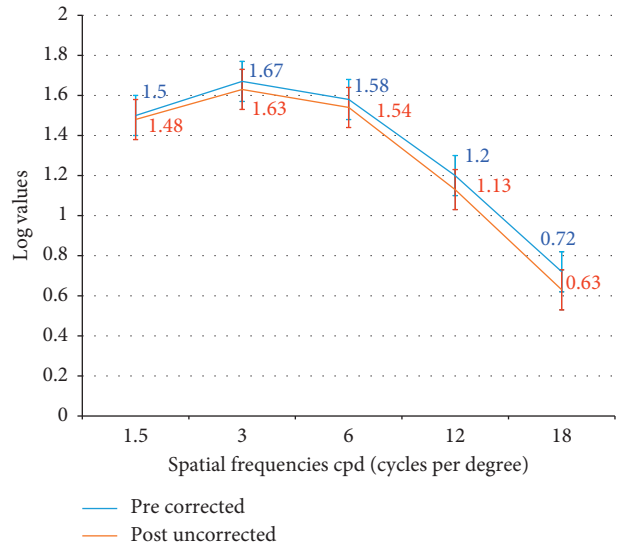

Figure 6: Contrast sensitivity (F.A.C.T) at 6 months post-op.

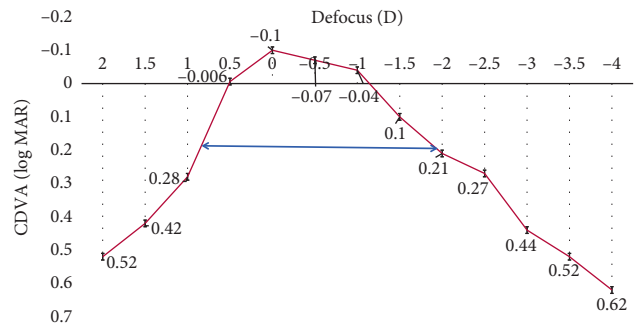

Figure 7: Defocus curve (distance corrected) at 6 months post-op.

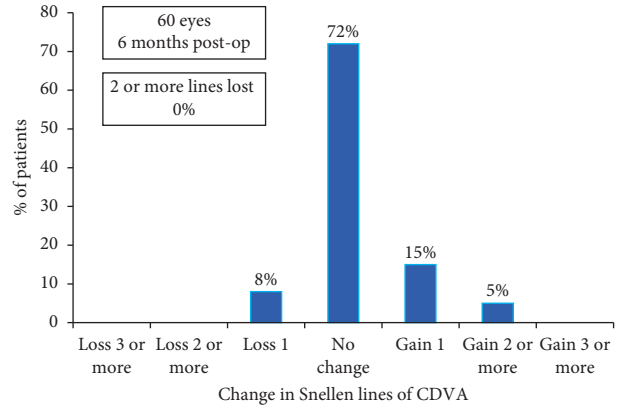

Figure 8: Histogram showing the change in Snellen lines of corrected distance visual acuity (CDVA).

wherein the average monovision target achieved at 6 months, was −1.26 D.

Reading speeds using the Salzburg reading desk have been evaluated earlier for various presbyopia-correcting modalities. Dexl et al. assessed reading performance following a small aperture corneal inlay at 2 years follow-up using SRD [24]. In their study, the mean uncorrected post-op reading speed was 146 ± 20 wpm, which was lower than the pre-op value of 153 ± 23 wpm, measured with reading addition at patient's preferred distance (39.5 cm). Another study evaluating the reading performance following Tecnis Symfony extended depth of focus IOL found that the average post-op binocular

Table 4: Postoperative patient satisfaction score and dysphotopsia grading.

Patient satisfaction score (mean ± SD)	
Distance vision	97.97 ± 2.13
Intermediate vision	99.36 ± 0.64
Near vision	96.84 ± 2.36
Postoperative spectacle independence [% of patients] (n = 30)	
Distance vision	93.33% (28)
Intermediate vision	100% (30)
Near vision	86.67% (26)
Postoperative dysphotopsia grading [% of patients] (n = 30)	
Grade 0 (nil)	93.33% (28)
Grade 1 (mild)	6.66% (2)
Grade 2 (moderate)	0% (0)
Grade 3 (severe)	0% (0)

Satisfaction questionnaire included scores ranging from 0 to 100, where 0 indicated not at all satisfied and 100 indicated completely satisfied, without the need of spectacles. Postoperative spectacle independence was evaluated as the percentage of patients who were completely free or did not feel the need of glasses for a particular distance. Dysphotopsia grading was done as per the following questionnaire: 0 = nil, no dysphotopsia symptoms experienced; 1 = mild, minimal dysphotopsia not affecting night vision and routine activities; 2 = moderate, dysphotopsia symptoms affecting night vision and routine activities, but manageable; 3 = severe, bothersome dysphotopsia, severe enough to interfere in routine activities.

reading speed at patient's preferred distance (41 cm) was 109 ± 33 wpm [25]. This appears to be markedly low compared with the reading speed achieved after PRESBYOND LBV in the present study, where in the post-op reading speed (164 ± 18 wpm) was significantly better than the pre-op value of 150 ± 7.29 wpm, measured with patient's progressive spectacles at a preferred distance chosen by the patient (46.16 cm). This may suggest that PRESBYOND LBV may result in better reading performance than procedures aiming at extending the depth of focus, achieved through means other than controlled induction of spherical aberrations, as utilized in PRESBYOND. This may, however, need further data for verification.

The significant improvement in post-op reading speeds seen in our study may be attributed to various factors. First and foremost, pre-op measurements were performed with patients own progressive spectacles, which may cause visual acuity drop-off, image distortion, and constant need to adapt their gaze and head movements to each lens design, causing patient discomfort [26]. These phenomena obviously improved after PRESBYOND LBV, which additionally also widened the field of vision, making reading a more comfortable task. Second, it could be due to the learning effect of repeating the test sentences by the patients [27].

In conclusion, PRESBYOND LBV effectively demonstrated improved visual and refractive results as well as functional outcomes at 6 months. The procedure delivered a wide range of functional vision, without any permanent change in contrast sensitivity or stereopsis, compared with the previously published presbyopia-correcting procedures. Reading speeds evaluated under standardized conditions were significantly better after surgery than patient's progressive glasses, indicating both subjective and objective improvement in everyday reading ability. To the best of our knowledge, this is the first study evaluating reading performance following PRESBYOND LBV. We believe this further enhances our understanding about the functional outcomes and reading ability after PRESBYOND LBV and how it affects the quality of life and patient satisfaction postoperatively.

Data Availability

The data can be made available on request from Dr Sandhya, Institutional Ethics Committee in-charge of Nethradhama Superspeciality Eye Hospital, Bangalore, who can be contacted at sandhyakrish@gmail.com.

Conflicts of Interest

Dr Sri Ganesh and Dr Sheetal Brar are consultants to Carl Zeiss Meditec.

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Research Article

One-Year Visual and Refractive Outcomes following LASIK for Myopia and Myopic Astigmatism with MEL 90 versus Schwind Amaris 750S Excimer Laser: A Comparative Study

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Purpose. To compare clinical outcomes following LASIK for myopia performed with MEL 90 vs. Schwind Amaris 750S excimer laser. *Methods*. Data were collected retrospectively for patients who underwent Femto-LASIK, using the MEL 90 and Schwind Amaris 750S excimer laser for correction of myopia and myopic astigmatism within the range of −1.00 to −10.00 D SE from January 2013 till June 2018. Outcomes were analysed at 12 months for safety, efficacy, enhancement rate, and long-term complications. *Results*. A total of 328 eyes of 328 patients were analysed. One hundred and sixty-three eyes were treated with Schwind Amaris and the remaining 165 eyes with the MEL 90 laser. Twelve months postoperatively, the mean UDVA, CDVA, residual SE, and cylinder in the Amaris group were −0.10 ± 0.09 logMAR, −0.14 ± 0.06 logMAR, −0.21 ± 0.22 D, −0.13 ± 0.18 D versus −0.05 ± 0.07 logMAR, −0.09 ± 0.08 logMAR, −0.23 ± 0.23 D, and −0.14 ± 0.21 D for the MEL 90 group (p values >0.05). For the Amaris group, safety and efficacy indices were 1.12 and 1.02, whereas for the MEL 90 group, these indices were 1.08 and 1.00, respectively. No eye in either group had any postop flap-related complications, infectious keratitis, diffuse lamellar keratitis, or keratectasia. Two eyes in the Amaris and 4 eyes in MEL 90 group required enhancement for the progression of myopia. *Conclusion*. At 12 months, both Schwind Amaris 750S and MEL 90 lasers demonstrated comparable clinical outcomes for myopic LASIK in a single surgeon setting.

1. Introduction

Laser in situ keratomileusis (LASIK) is one of the most widely performed laser vision correction surgery worldwide, clinical results of which have improved over the past decade due to significant advancements in techniques and technology. The introduction of femtosecond laser flap creation vastly reduced microkeratome-related complications and improved the safety and efficacy of LASIK [1, 2]. Newer generations of excimer laser machines have also contributed to improved results of LASIK in recent years, due to the use of scanning beams or flying spots, with smaller spot sizes and more efficient eye trackers [3, 4].

The MEL 90 excimer laser (Carl Zeiss Meditec, Jena, Germany) is an upgrade to its predecessor, the MEL 80, with advanced features such as faster pulse rate, compatibility with the new Triple-A ablation profile, and further improved dynamic flow cone for controlled atmosphere [5]. The safety and efficacy of MEL 90 laser have already been evaluated for the treatment of myopia, hyperopia, and mixed astigmatism [5–7]; however, no comparison study has been reported so far, comparing its outcomes with any of the existing excimer lasers.

The aim of this study was to evaluate and compare the visual and refractive results of myopic Femto-LASIK performed with the MEL 90 versus Schwind Amaris 750 excimer laser platforms; both the platforms are currently being claimed as the fastest excimer lasers [7–9]. We also wanted to test the hypothesis that a faster ablation rate might lead to better predictability in the outcomes.

2. Materials and Methods

This was a retrospective, comparative study of all patients who underwent Femto-LASIK for myopia or myopic astigmatism at Nethradhama Superspeciality Eye Hospital, Bangalore, between January 2015 and June 2018, using either

MEL 90 or Schwind Amaris 750s excimer laser system. Ethics committee approval was not deemed necessary due to the retrospective nature of the study. Data were retrieved from the electronic medical records and both groups were matched for age and preoperative refractive error.

All patients had undergone a complete preoperative ophthalmic evaluation including manifest and cycloplegic refraction, corneal topography with Pentacam Scheimpflug imaging (OCULUS, Optikgerate GmbH, Wetzlar, Germany) & Orbscan topographer (Orbscan IIz, Bausch & Lomb), slit lamp, dry eye evaluation, and indirect ophthalmoscopy for dilated fundus examination.

Inclusion criteria were as follows: (1) myopia or myopic astigmatism in the range of −1.00 to −10.00 D spherical equivalent (SE); (2) manifest cylinder up to −6.00 D; (3) stable refractive error for the past 12 months (change in SE of <0.5 D); (4) corrected distance visual acuity (CDVA) of 20/30 or better. Exclusion criteria were the usual ones followed for case selection for corneal LASIK surgery [8].

Following thorough counselling, informed consent was obtained from each patient. Patients had surgery with either of the two excimer lasers available at our center, MEL 90 or Schwind Amaris 750S. All surgeries were performed by a single, experienced, high volume refractive surgeon (SG) using a standard technique of Femto-LASIK.

2.1. Schwind Amaris 750S. The Schwind Amaris 750S laser (SCHWIND eye-tech-solutions GmbH & Co. KG, Kleinostheim, Germany) is a flying spot laser working at a true repetition rate of 750 Hz and produces a beam size of 0.54 mm FWHM (full width at half maximum) with a super-Gaussian ablative spot profile. High-speed eye-tracking (pupil and limbus tracker with cyclotorsional tracking) with a 1050 Hz acquisition rate is accomplished with a 3 ms latency time.

The Amaris 750S uses a dual-fluence concept. Approximately the first 80% of the ablation is performed with higher pulse energy, and the last 20% is completed with lower pulse energy to achieve a smooth ablation surface. Its Intelligent Thermal Effect Control prevents damage to the surrounding corneal tissue because the laser pulses are distributed in a thermally optimized, dynamically adapted way, giving each position on the cornea sufficient time to cool down before being hit by another laser pulse [8–10].

2.2. MEL 90. The MEL 90 (Carl Zeiss Meditec, Jena, Germany) uses a Triple-A ablation profile, which integrates the original MEL 80 Aberration Smart Ablation (ASA) profile for low myopic corrections and Tissue Saving Ablation (TSA) profile for high myopic corrections into a single profile, to reduce the ablation depth. The platform provides the option to operate at 250 Hz (the same frequency as the MEL 80) or 500 Hz, a feature known as "Flexiquence." The infrared eye tracker operates at 1,050 Hz, tracks the pupil border and the corneal limbus, and can be offset manually so that the treatment may be centered on the coaxially sighted corneal light reflex rather than to the entrance pupil center. The small 0.7 mm Gaussian flying spot and the nonrandom proprietary shot distribution pattern ensure that corneal heating is kept below the relevant threshold so that the 500 Hz pulse rate can be safely used continuously for the whole ablation to avoid overheating of the corneal surface [5, 6].

2.3. Treatment Planning. In the Schwind Amaris group, ablation calculation and treatment planning were done using an aspheric aberration neutral (Aberration-Free™) with the ORK-CAM software module, which enables automatic iris registration for cylinders.

In the MEL 90 group, for eyes with cylinder ≤1.00 D, the treatment was directly planned on the MEL 90 laser at 500 Hz pulse frequency using a Triple-A profile, which is an aspherically optimized ablation profile and allows for a wide range of spherocylindrical (SCA) corrections including eyes with higher and lower levels of ametropia, simplifying the treatment planning. However, in eyes with >1.00 D, Wavefront Supported Customized Ablation (WASCA) aberrometry was performed for iris registration and treatment plan using the CRS-Master software and imported into the laser. The treatment profile used for these eyes was Aberration Smart Ablation (ASA), and the laser pulse frequency used was 250 Hz, as the laser allows only a frequency of 250 Hz to be used for customized treatments.

2.4. Surgical Protocol. All treatments in both the groups were performed as bilateral simultaneous Femto-LASIK using the VisuMax femtosecond laser for flap creation at 110 microns. Scotopic pupil diameter, along with the amount of myopia being treated, was used to choose the optical zone within the pachymetric safety limits. No nomogram adjustments were used in either group. All cases underwent a fluency test daily prior to the procedure and were uneventful. No eye in either group had any intraoperative complications such as suction loss, dense opaque bubble layer, gas breakthrough, flap tears, etc., requiring postponing or abandoning of the procedure.

Postoperative medications were the same for all patients and included a combination of 0.5% moxifloxacin ophthalmic solution (Vigamox®; Alcon) and 0.1% prednisolone (Predforte®; Allergan) eyedrops in a tapering dose for 10 days and installation of preservative-free artificial tear supplements 4 times a day for a month.

2.5. Postoperative Evaluation. Patients were examined on postoperative day 1, 1 week, 1 month, 6 months, and 12 months after the procedure. Postoperative examinations included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) using a standard Snellen acuity chart at 6 m, manifest refraction, and slit lamp biomicroscopy.

Patients were observed for possible flap related complications including microfolds, epithelial ingrowth, interface haze, interface debris, infection, superficial punctate keratitis, and diffuse lamellar keratitis at each visit using a 6-grade classification system: trace, GD I-II (not visually significant), and GD III-V [11, 12].

Table 1: Preoperative baseline characteristics of both study groups.

Parameter (mean ± SD) (range)	Schwind Amaris 750S	MEL 90	p value
Age(years)	33.00 ± 6.50 (23 to 53)	35.20 ± 10.50 (21 to 65)	0.33
Sph (D)	−3.53 ± 2.04 (−1.00 to −8.75)	−3.63 ± 1.80 (−1.00 to −8.80)	0.37
Cyl (D)	−1.13 ± 1.15 (0.00 to −6.00)	−0.74 ± 0.70 (0.00 to −3.50)	0.27
SE (D)	−4.10 ± 1.87 (−1.00 to −11.75)	−3.98 ± 1.896 (−1.00 to −10.50)	0.17
CDVA (logMAR)	−0.17 ± 0.02 (−0.2 to 0.00)	−0.053 ± 0.087 (−0.20 to 0.10)	0.07
CCT (μm)	543 ± 28.6 (476 to 608)	536 + 32.4 (440 to 621)	0.31
Keratometry (D)	44.2 ± 2.3 (41.8–46.3)	43.7 ± 3.5(40.3–46.5)	0.43
Optical zone (mm)	6.50 ± 0.30 (6.10 to 7.00)	6.50 ± 0.20 (6.00 to 7.00)	1.00
Transition zone (mm)	1.20 ± 0.05 (1.00–1.50)	1.20 ± 0.03 (1.00–1.40)	0.80
RST(μm)	369.70 ± 37.55 (302 to 484)	358.20 ± 46.54 (306 to 463)	0.22
Pupil size (mm)	6.14 ± 0.4 (5.6 to 6.7)	6.03 ± 0.3 (5.8 to 6.8)	0.30
Flap thickness (μ)	110 ± 11 (90 to 130)	110 ± 8.2 (90 to 120)	0.06
Flap diameter (mm)	7.90 ± 1.04 (7.50 to 8.10)	7.81 ± 1.05 (7.50 to 8.10)	0.09
Ablation depth (μ)	73.37 ± 27.48 (24 to 169)	68.00 ± 30.00 (20 to 131)	0.80

SE: spherical equivalent; CDVA: corrected distance visual acuity; CCT: central corneal thickness; RST: residual stromal thickness; SD: standard deviation.

2.6. Statistical Analysis. All treatments in both groups were performed as bilateral simultaneous LASIK. However, one eye was selected randomly (using computer generated random numbers) from each patient for statistical analysis. Outcome analysis was performed according to the Standard Graphs for Reporting Refractive Surgery [13]. Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA) was used for data entry, and means and standard deviations were calculated for all parameters. Data were analysed using SPSS software (v 15; SPSS, Inc, Chicago, IL). Since the data was normally distributed, paired t-tests were used to calculate the statistical significance for comparison of postoperative parameters between the two study groups. A p value less than 0.05 was defined as statistically significant.

3. Results

Of the 328 eyes of 328 patients that underwent Femto-LASIK, 165 were treated with the MEL 90 and 163 with the Schwind Amaris 750S excimer laser. Of all patients, 56.8% were males and 43.2% were females. The mean follow-up duration of all patients from both groups was 12.2 ± 2.2 months (range 10.5 to 14.7 months). There were no statistically significant differences in preoperative manifest SE, cylinder, CDVA, keratometry, central corneal thickness, scotopic pupil size, intraoperative optical zone, mean flap thickness, ablation depth, and postoperative residual bed thickness) (RST) between the two groups (p values >0.05 or all parameters) (Table 1).

The postoperative mean UDVA for the Amaris group was −0.10 ± 0.09 logMAR (range: −0.20 to 0.20), while for the MEL 90 group, it was −0.05 ± 0.07 logMAR (range: −0.20 to 0.10) ($p = 0.24$). The accuracy of SE refraction within ±0.5 D was 96% eyes in the Amaris and 91% eyes in the MEL 90 group. However, all eyes in both the groups were within ±1.50 D of SE correction. The predictability curve gave a similar coefficient of determination values of 0.99 (Figures 1 and 2) and Table 2.

3.1. Safety. Safety index was defined as postoperative CDVA/preoperative CDVA. The mean safety indices of the Amaris and MEL 90 groups were 1.12 ± 0.16 (range 0.62 to 1.6) and 1.08 ± 0.15 (range 0.78 to 1.6), respectively ($p = 0.29$). Figure 3 shows the safety data of both the groups at 12 months. No eye lost more than 2 lines of CDVA in either of the groups (Figure 3).

3.2. Efficacy. Efficacy index was defined as postoperative UDVA/preoperative CDVA. The mean efficacy index of the Amaris group was 1.025 ± 0.10 (range 0.63 to 1.28), while that of the MEL 90 group was 1.00 ± 0.10 (range 0.5 to 1.25) ($p = 0.90$). The percentage of eyes having postop UDVA same or better than preop CDVA was 96% in the Amaris group, versus 93% in the MEL 90 group (Figure 4). 18% of eyes in MEL 90 and 22% eyes in the Amaris group had cumulative UDVA of 20/16 or better (Figure 5).

3.3. Subgroup Analysis of Eyes with High Myopia (−6 D and above). Both groups were comparable in terms of preop SE $p = 0.30$. At the end of mean follow-up, too, there was no significant difference between the postop SE of the two study groups ($p = 0.66$, −0.31 vs. −0.29 D for Schwind Amaris and MEL 90 groups, respectively). Similarly, postop UDVA, CDVA, Safety and Efficacy indices were comparable between the two groups ($p > 0.05$, for all parameters), Table 3.

3.4. Astigmatism Outcomes. The mean postoperative cylinder was −0.13 ± 0.18 D (range: −0.75 to 0.5 D) in the Amaris group and −0.14 ± 0.21 D (range: −1.00 to 0.00 D) in the MEL 90 group ($p = 0.79$). All eyes in both groups were within ±1.00 D of astigmatism (Figures 6 and 7). The angle of error (AE) graphs for both groups showed the majority of eyes (80% in the Amaris and 77% in MEL 90 group) having angle of error between −5 to +5 degrees (Figure 8).

3.5. Subgroup Analysis of High-Cylinder Eyes (>1 D). We also performed a subgroup analysis of eyes with preop cylinder >1 D in both the groups, which showed preop astigmatism to be comparable ($p = 0.13$). However, postop astigmatism was significantly lower in the Schwind Amaris group (−0.25 D) compared to the MEL 90 group (−0.39 D),

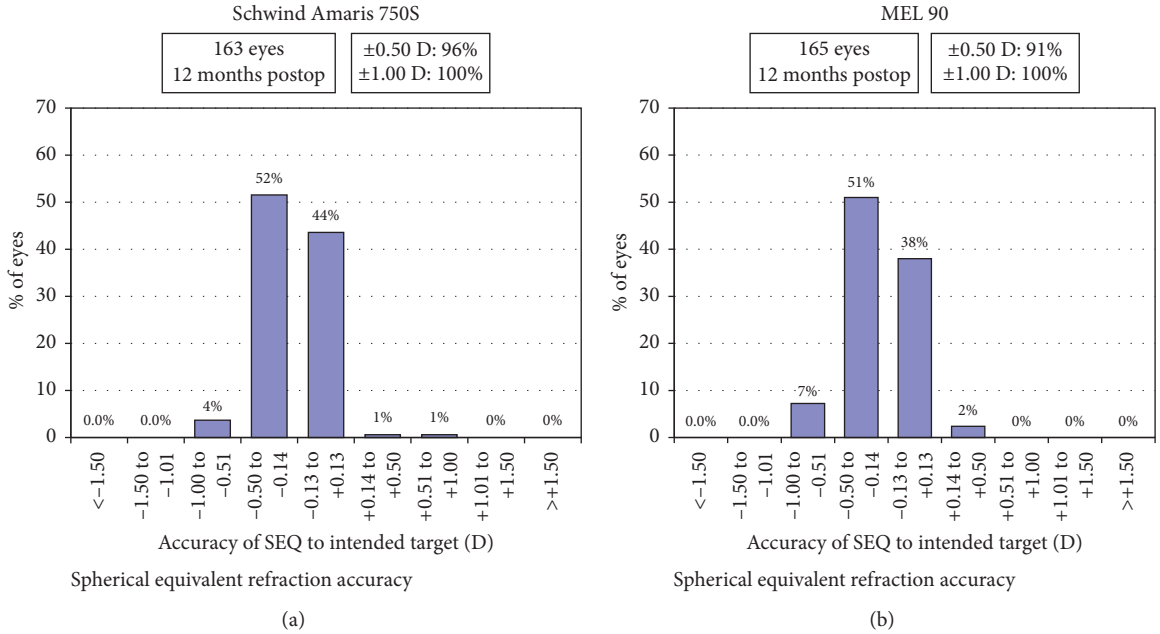

Figure 1: Spherical equivalent refraction accuracy of both groups at 12 months.

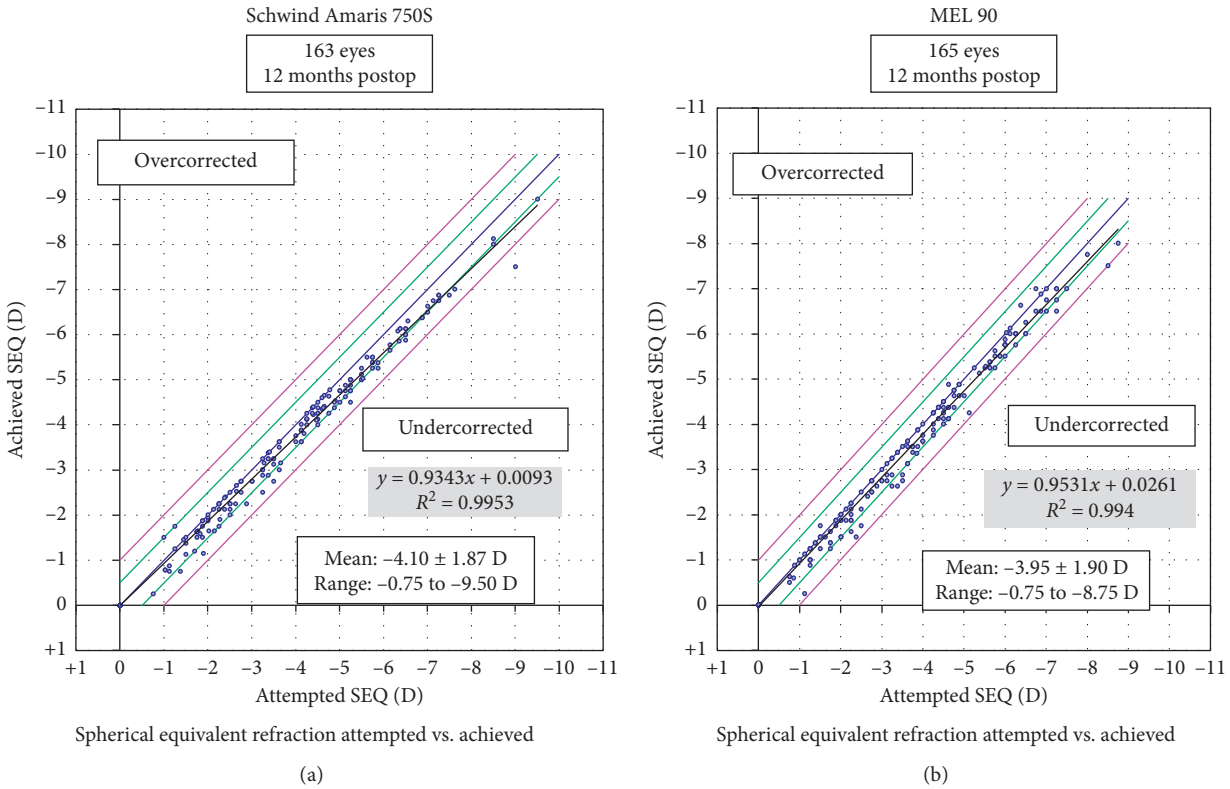

Figure 2: Attempted vs. achieved spherical equivalent refraction of both groups at 12 months.

($p = 0.01$). An undercorrection of 4% and 8% was observed in the Schwind Amaris and MEL 90 groups, respectively; however, the mean CI did not show any significant difference (Table 4).

3.6. Stability. Both groups showed good stability of refraction at 1 year, compared to 1 month and 6 months, with slight residual myopia of −0.23 D and −0.21 D in MEL 90 and Amaris group, respectively (Figure 9).

Table 2: The postoperative visual and refractive results obtained at 1 year for both study groups.

Parameter (mean ± SD) (range)	Schwind Amaris 750S	MEL 90	p value
Sphere (D)	−0.15 ± 0.20 (−0.75 to 1.25)	−0.15 ± 0.21 (−1.00 to 0.50)	1.00
Cylinder (D)	−0.13 ± 0.18 (−0.75 to 0.5)	−0.14 ± 0.21 (−1.00 to 0.00)	0.79
SE (D)	−0.21 ± 0.22 (−0.87 to 1.25)	−0.23 ± 0.23 (−1.00 to 0.25)	0.29
UDVA (logMAR)	−0.10 ± 0.09 (−0.2 to 0.2)	−0.05 ± 0.07 (−0.20 to 0.10)	0.24
CDVA (logMAR)	−0.14 ± 0.06 (−0.2 to 0)	−0.09 ± 0.08 (−0.20 to 0.00)	0.24
Safety index	1.12 ± 0.16 (0.62 to 1.6)	1.08 ± 0.15 (0.78 to 1.6)	0.29
Efficacy index	1.02 ± 0.10 (0.63 to 1.28)	1.00 ± 0.10 (0.5 to 1.25)	0.90
AOE (arithmetic)	0.29 ± 6.05 (−24 to 30)	0.37 ± 7.34 (−30 to 40)	0.96
AOE (absolute)	2.87 ± 5.33 (0 to 30)	3.22 ± 6.60 (0 to 40)	0.82
CI	0.95 ± 0.33 (0 to 2.02)	0.93 ± 0.26 (0.21 to 1.48)	0.80

SD: standard deviation; SE: spherical equivalent; UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; AOE: angle of error; CI: correction index.

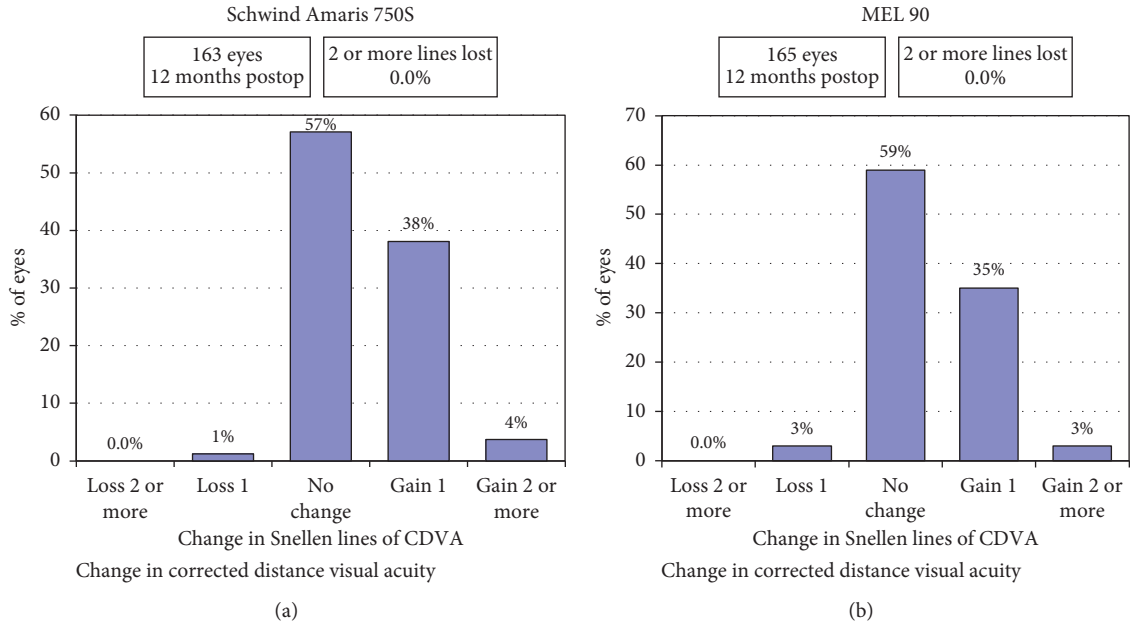

Figure 3: Safety (postop CDVA/preop CDVA) of both study groups at 12 months.

3.7. Long-Term Complications. No vision threatening long-term complications such as diffuse lamellar keratitis, infectious keratitis, flap-folds, dislocations, epithelial ingrowth or, postoperative ectasia occurred within one year of the surgery in either of the groups. Four eyes of 2 patients in the MEL 90 group and both eyes of one patient in the Amaris group required enhancement at the last follow-up for significant residual refractive error due to progression of their myopia.

4. Discussion

The advantages of fast repetition rates and short ablation time, such as better patient safety and comfort, minimum risk of corneal dehydration, and reduced time of patient's eye fixation, have been reported in various studies [7, 8]. In the present study, we compared MEL 90 and Schwind Amaris 750S, which are currently the two fastest excimer lasers available for safety, efficacy, and predictability of outcomes obtained following Femto-LASIK at 12 months [7–10, 14–16].

It is pertinent to emphasize that the present study is a single surgeon study using the same standardized procedure, comparing the Schwind Amaris 750S, an established laser, with a newly installed MEL 90 laser. The results of our study showed that the MEL 90 wavefront-optimized excimer treatment was performed equally with the Amaris 750S platform in terms of postoperative UCVA, predictability, and safety and efficacy indices when aspherically optimized ablation profiles were used for MEL 90 except if cylinder over 1D was present.

The shorter treatment times with both lasers could be one of the main factors contributing to the comparable refractive predictability, as longer ablation time results in stromal bed drying, potentially affecting the treatment result. Although the Schwind Amaris® operates at a higher frequency of 750 Hz, the intraoperative time taken to correct the same degree of myopia is slightly longer than MEL 90. It

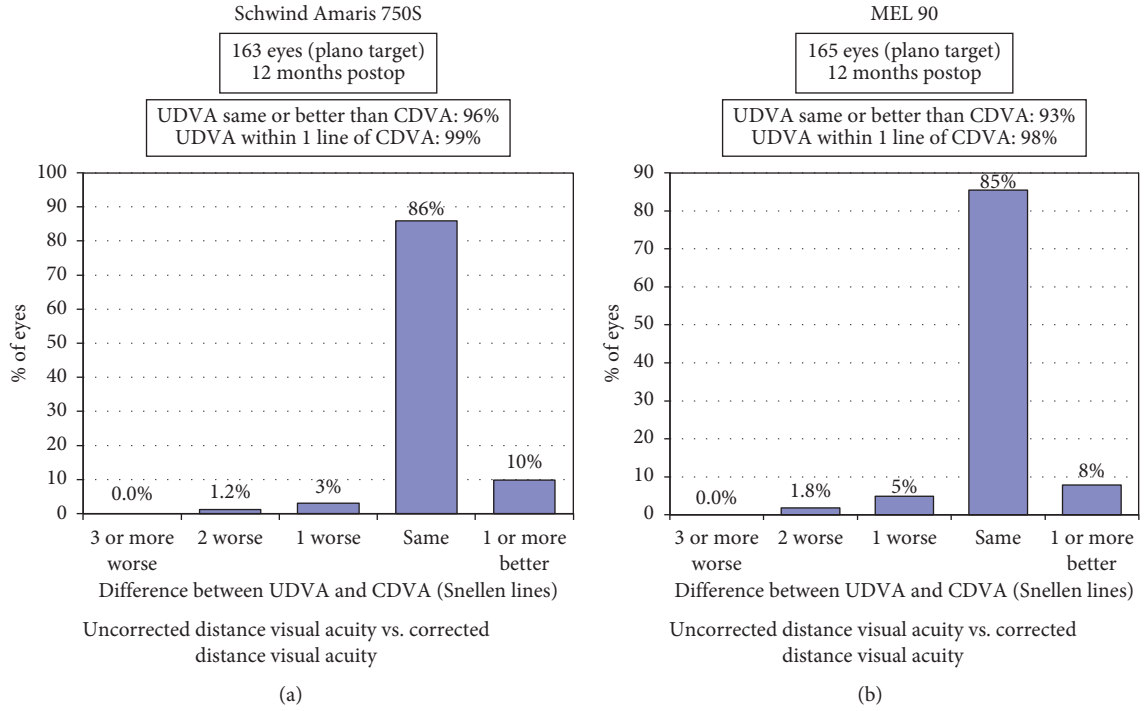

Figure 4: Uncorrected visual acuity vs. corrected visual acuity for both study groups at 12 months.

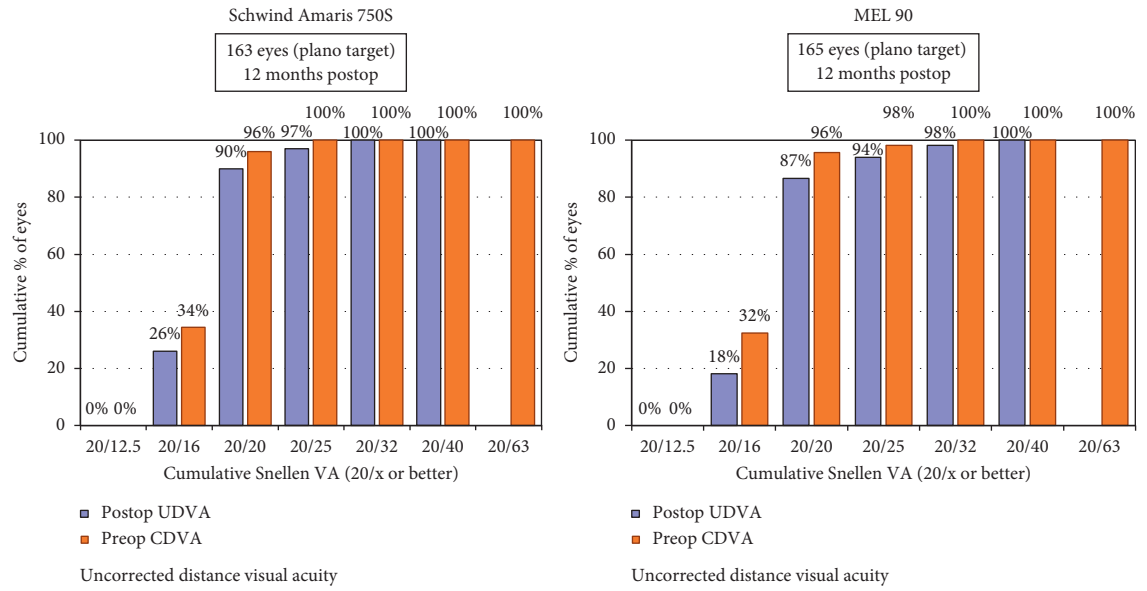

Figure 5: Cumulative uncorrected visual acuity of both study groups at 12 months.

Table 3: Subgroup analysis of eyes with high myopia (−6 D and above).

Parameter (mean ± SD) (range)	Schwind Amaris 750S ($n = 26$)	MEL 90 ($n = 31$)	p value
Preop SE	−6.19 ± 0.71 (−6.15 to −9.00)	−6.79 ± 0.70 (−6 to −8.75)	0.30
Postop SE	−0.31 ± 0.17 (0 to −0.625)	−0.29 ± 0.27 (−1.00 to 0.50)	0.66
Postop UDVA	−0.03 ± 0.09 (−0.2 to 0.20)	−0.03 ± 0.06 (0 to −0.20)	0.99
Postop CDVA	−0.11 ± 0.07 (0 to −0.20)	−0.08 ± 0.08 (0 to −0.20)	0.20
Safety index	1.18 ± 0.19 (1 to 1.60)	1.10 ± 0.18 (0.90 to 1.60)	0.11
Efficacy index	0.99 ± 0.09 (0.63 to 1.28)	0.99 ± 0.12 (0.625 to 1.25)	0.93

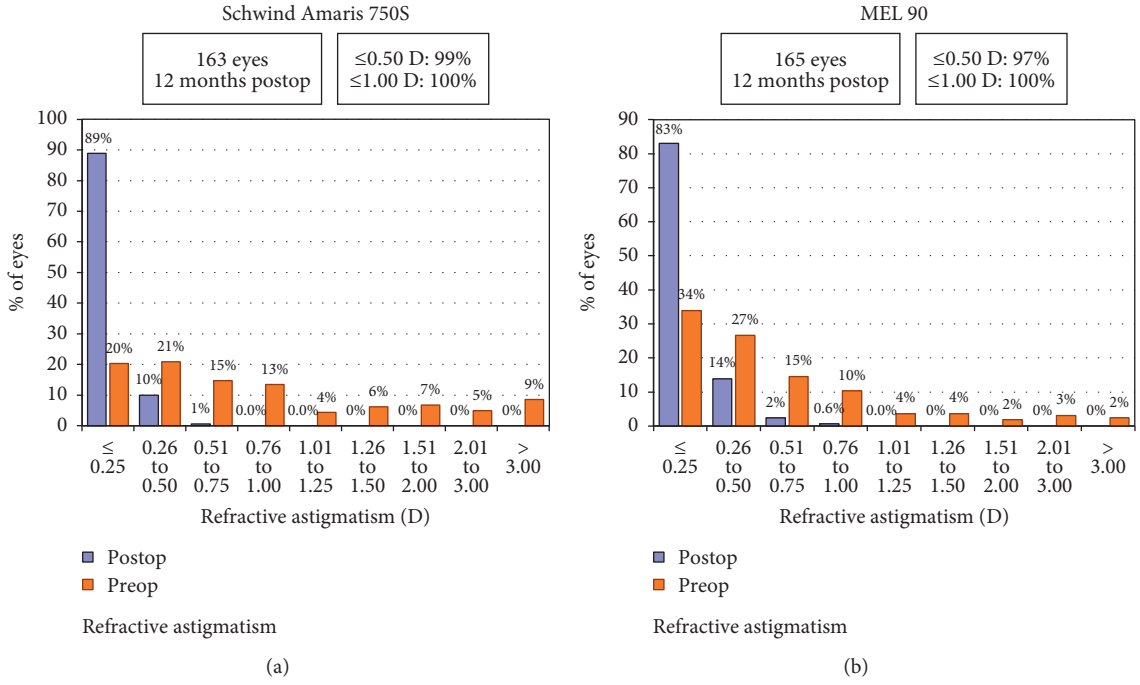

Figure 6: Refractive astigmatism distribution of both study groups at 12 months.

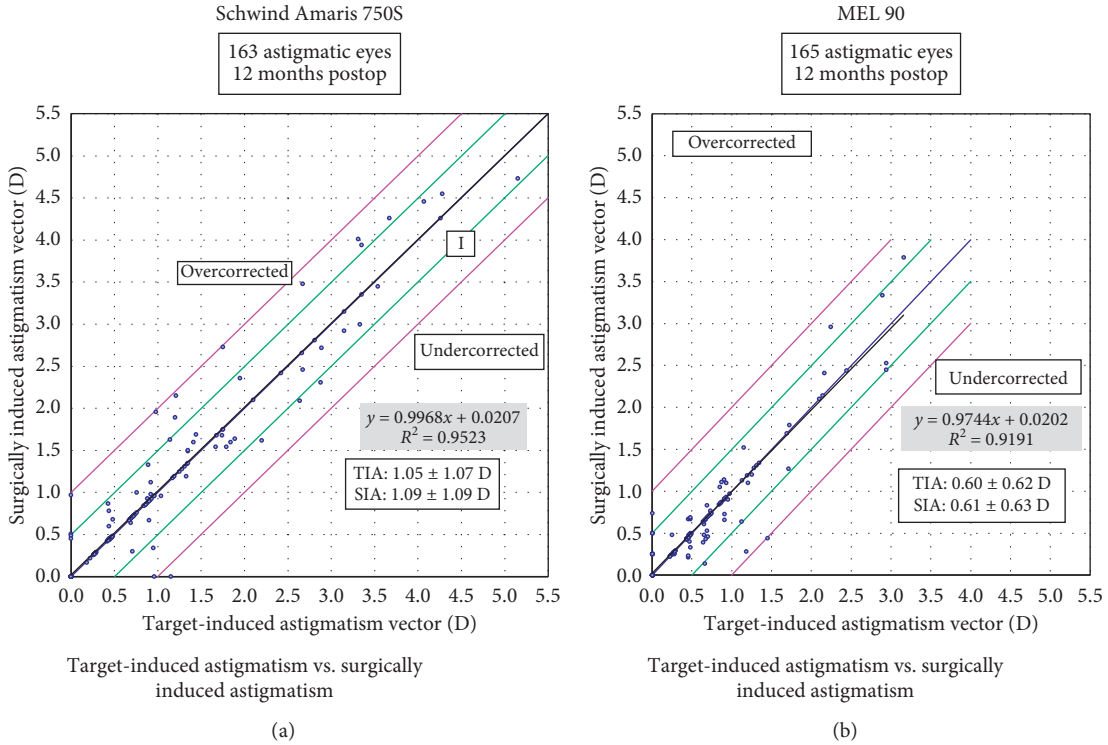

Figure 7: Target-induced astigmatism (TIA) vs. surgically induced astigmatism (SIA) for both study groups at 12 months.

typically takes 1.3 seconds for treatment of 1.00 D myopia at an optical zone of 6.0 mm for the MEL 90, while the Amaris 750S takes 1.5 seconds for the same [7–10, 14–16]. This may be because of the differences in the spot sizes of both lasers, which are larger in MEL 90 (0.70 mm) compared to Schwind Amaris 750S (0.54 mm). Due to this, it requires firing less number of pulses per square area with MEL 90, thus, theoretically making the treatment slightly faster than Amaris 750s for correcting the same degree of refractive error. This, however, may not make much difference practically while

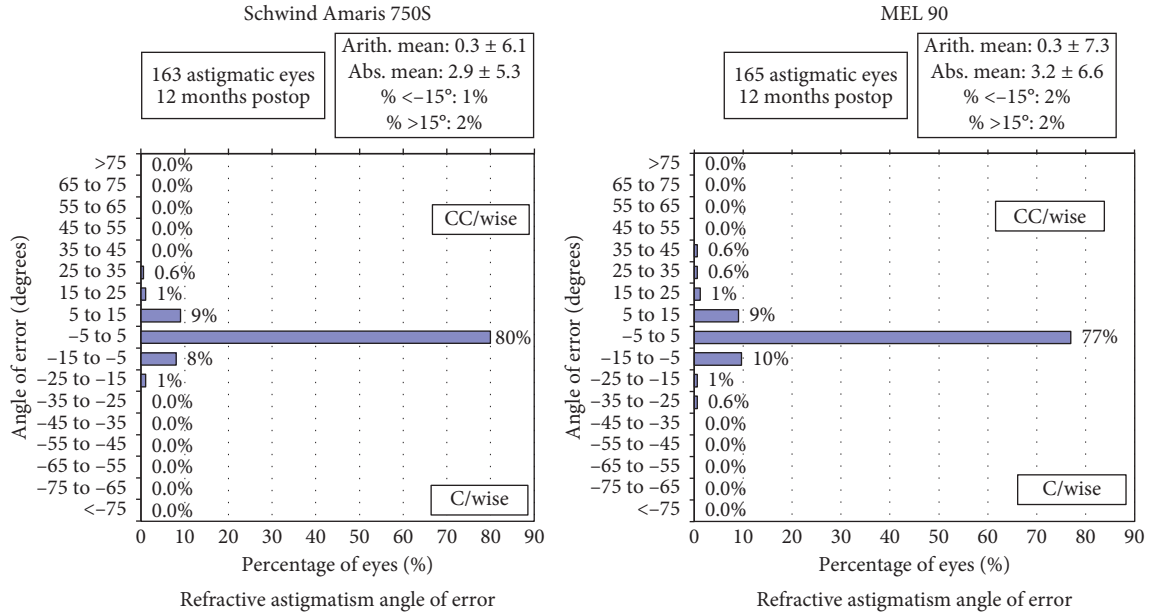

Figure 8: Refractive astigmatism angle or error distribution for both study groups at 12 months.

Table 4: Subgroup analysis of high-astigmatism eyes (1 D and above).

Parameter (mean ± SD) (range)	Schwind Amaris 750S ($n = 38$)	MEL 90 ($n = 25$)	p value
Preop cylinder	−2.34 ± 1.18 (−1.25 to −6.00)	−1.99 ± 0.75 (−1.25 to −3.50)	0.13
Postop cylinder	−0.25 ± 0.19 (0 to −0.75)	−0.39 ± 0.24 (0 to −1.00)	0.01*
TIA	2.15 ± 1.33 (0.46 to 5.58)	1.73 ± 0.75 (0.43 to 3.16)	0.11
SIA	2.07 ± 1.11 (0.44 to 5.16)	1.60 ± 0.87 (0.28 to 3.79)	0.08
AOE-absolute	3.71 ± 4.27 (0 to 16)	3.20 ± 4.66 (0 to 15)	0.66
AOE-arithmetic	−0.5 ± 5.66 (−16 to 15)	0.875 ± 5.62 (−10 to 15)	0.35
CI	0.96 ± 0.23 (0 to 1.77)	0.92 ± 0.24 (0.23 to 1.32)	0.48

*Independent t-test

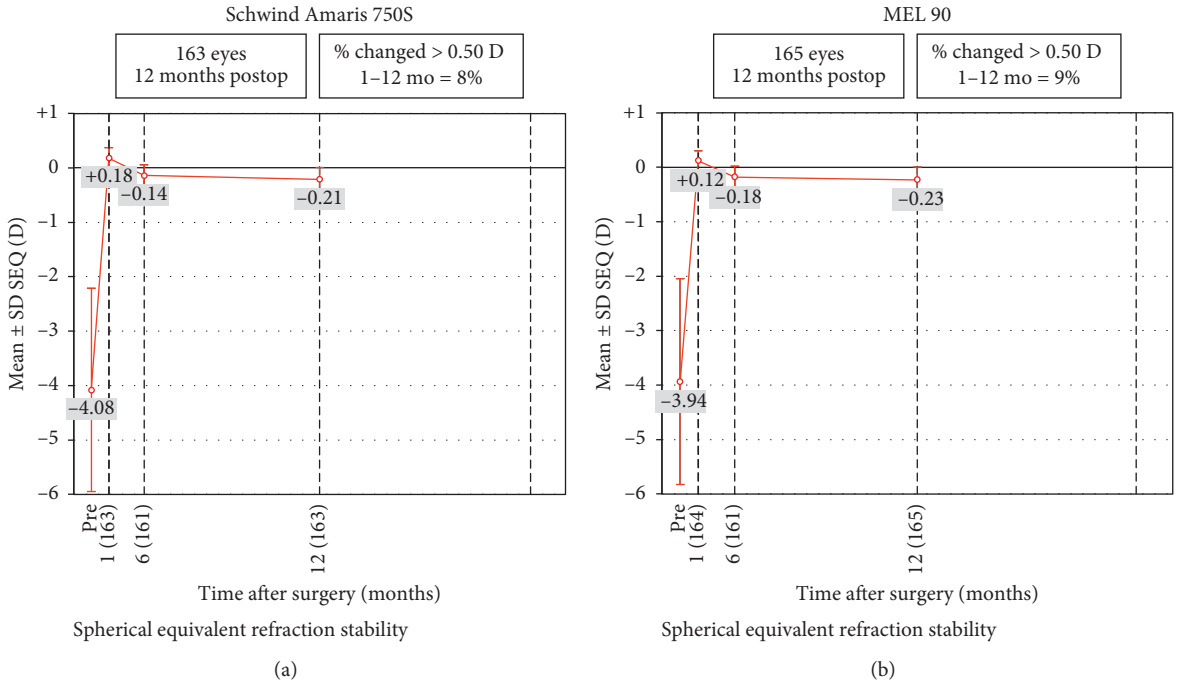

Figure 9: Stability of postoperative SE refraction at 1, 6, and 12 months for both study groups.

correcting low to moderate degrees of myopia, as was the case in our study.

The Amaris 750S uses a dual-fluence concept, wherein approximately the first 80% of the ablation is performed with higher pulse energy, and the last 20% is completed with lower pulse energy to achieve the smoothest possible ablation surface using a small spot size of 0.54 mm and a super-Gaussian beam profile while reducing the thermal damage to the stromal bed [14, 15]. The MEL 90, on the other hand, utilizes uniform fluence throughout the ablation. However, it does not lead to increased heat production again due to its spot size being wider, requiring fewer pulses per square area, hence reducing the overall energy delivered to the cornea. Furthermore, its improved dynamic flow cone regulates the atmosphere more efficiently, preventing excess heat generation [7, 8].

Another aspect on which the accuracy of outcomes depends is the efficiency of eye-tracking during laser treatment. The more perfectly the eye is centred and the laser spots are positioned, the more precise the results of the refractive treatment are. For customized treatments and whenever astigmatism is greater than 1.00 D, compensation for possible cyclorotation has been suggested in various studies to achieve the intended outcome [17, 18]. Published reports have quoted an advantage in astigmatism control by the Amaris 750S system, which offers advanced eye-tracking technology with iris registration and static plus dynamic cyclotorsion compensation, including the rotating movement of the eye during the laser treatment [9, 10, 16, 19].

The MEL 90, on the other hand, has a 240 Hz video based infrared eye tracker, which also operates at 1,050 Hz, with active x- and y-axis and passive z-axis tracking [7, 8]. This, combined with iris registration from WASCA, also offers compensation of static cyclotorsion, occurring when the patient moves from upright to supine position. Dynamic cyclotorsion compensation, however, is not available in the current version of the laser.

The present study, in fact, showed no significant difference in postoperative astigmatism between eyes treated with the Amaris 750S versus those treated with the MEL 90, as the mean residual astigmatism was similar (-0.13 ± 0.18 D in Amaris 750S and -0.14 ± 0.21 D in MEL 90 group, respectively, $p = 0.79$). This may suggest that good accuracy in astigmatism correction may still be achieved with a fast eye tracker and compensation of only static cyclotorsion, which forms for the major component of cyclotorsion [10]. However, subgroup analysis of high astigmatism eyes showed significantly lower postoperative astigmatism in the Schwind Amaris group, compared to the MEL 90 group, which may be attributed to the high-speed eye-tracking (pupil and limbus tracker with cyclotorsional tracking), as described earlier.

However, in a recently published study by Reinstein et al., they found a 12% overcorrection of astigmatism at 1 year for LASIK using the Triple-A ablation profile with the MEL 90 laser for mixed cylinder up to is −7.00 D, for which it was suggested that the results could be improved by the application of a nomogram [6]. Similarly, while evaluating outcomes of myopic LASIK with MEL 90 and triple-A profile, the same authors observed overcorrection of astigmatism at 3 months follow-up [7]. This is different from our results, wherein we observed an overall undercorrection of 7% (evident from a correction index of 0.93), which is expected at a follow-up period of 12 months. Also, we performed iris registration and compensation of cyclotorsional error for higher cylinders and used a frequency of 250 Hz for these eyes, which may also probably have influenced the results. However, from the clinical point of view, slight undercorrection is preferred above overcorrection.

It may be emphasized that 17/165 (10.3%) eyes requiring cyclotorsion compensation in MEL 90 group were treated with 250 Hz, whereas the rest were treated using 500 Hz frequency. This could have potentially influenced the cylinder accuracy and overall results, as stated above. However, the MEL 80 laser, using the repetition rate of 250 Hz has also been shown to provide excellent predictability in the previously published studies [20, 21], [22, 23], which may possibly explain the fairly comparable results with regard to astigmatism and overall accuracy between the two study groups. The mean UDVA in the Schwind Amaris treated eyes was better at one year postop. The difference, however, was not statistically significant.

To our knowledge, this is the first study comparing the outcomes of MEL 90® excimer laser with the Schwind Amaris® 750S for Femto-LASIK. The study demonstrated a tendency for slightly systematic better results with Amaris 750S, although in a nonsignificant manner. However, excellent safety and comparable results were observed in terms of postoperative UDVA, residual refraction, and efficacy with both lasers in a single surgeon setting, particularly applying to low astigmatism.

The retrospective and nonrandomized nature of this study may be a potential limitation. Therefore, a prospective, contralateral eye study with one eye of each patient assigned to each group would be more powerful for any further analysis of outcome measures. Nevertheless, the results reflect on the fact that newer and advanced technologies of excimer laser correction have certainly enhanced the overall safety and accuracy of outcomes with LASIK, resulting in better stability of outcomes and patient satisfaction.

Data Availability

The data can be made available upon request from Dr. Sandhya R, who is in charge of the Ethics Committee of Nethradhama Eye Hospital (sandhyakrish@gmail.com).

Conflicts of Interest

Dr. Sri Ganesh and Dr. Sheetal Brar are consultants to Carl Zeiss Meditec. The other authors declare that they have no conflicts of interest.

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