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Lamellar surgeries with SMILE-derived lenticules

Sri Ganesh, Sheetal Brar*, Riya Chopra

Abstract:

PURPOSE: Lamellar surgeries with SMILE lenticules are an evolving field of refractive surgery. This chapter intends to discuss the reported clinical results of using SMILE derived lenticules in terms of feasibility, safety and predictability; or the potential management of hyperopia, keratoconus, SMILE ectasia and presbyopia.

MATERIALS AND METHODS: Donor SMILE lenticules were prepared under microscope tocreate doughnut shaped lenticules. For hyperopia, this tissue was then inserted into afemtosecond laser enabled pocket created using VisuMax FS Laser at a depth of 160µm. For ectasia induced by keratoconus and post refractive procedure (SMILE), 0.23% riboflavin dye was instilled into the interface and then lenticule was inserted followed by exposure to UV-A radiation with total energy of 6.3 J.

RESULTS: Spherical equivalent (S.E.) of within ± 0.5 D was observed in 50% (n=21) eyes and within 1 D was seen in 71% eyes treated for hyperopia. A significant increase in the K mean anterior, central corneal thickness, Q-value and corneal aberrations was seen 2 weeks post-op. Clinical improvement in terms of S.E. and uncorrected distance visual acuity in eyes treated for ectasia after keratoconus and post refractive procedure (SMILE) was seen.

CONCLUSION: With the ample availability of SMILE- derived lenticules, researchers are exploring the possibility of using this tissue for the treatment of various refractive and corneal conditions.

Keywords:

Ectasia, hyperopia, lenticule, SMILE

Nethradhama Eye Hospital, Bengaluru, Karnataka, India

***Address for correspondence:**
Dr. Sheetal Brar,
Nethradhama Eye Hospital, Bengaluru, Karnataka, India.
E-mail: brar_sheetal@yahoo.co.in

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Introduction

In 1949, José Ignacio Barraquer laid the groundwork for the use of natural corneal tissue to change the refractive properties of the eye.[1,2] Subsequently, Pradhan *et al.*, in 2013, published a case report showing the feasibility of use of a myopic SMILE lenticule for the correction of aphakia.[3] Many researchers successfully reported the use of SMILE lenticules for the management of conditions such as high hyperopia, keratoconus, presbyopia, and sealing corneal defects and post-SMILE ectasia.[4-10] SMILE lenticules were used as the newer techniques to correct ectasias.[11-13]

This manuscript aims at discussing the feasibility of SMILE-derived lenticules for the potential management of hyperopia, keratoconus, SMILE ectasia, presbyopia, and reporting the clinical outcomes.

Method

Lamellar surgery with SMILE lenticules for hyperopia

We recently concluded a retrospective study of eligible patients, who underwent FILI for the correction of moderate to high hyperopia from July 2013 to October 2020. The study was approved by the local ethics committee of the Nethradhama Superspeciality Eye Hospital Institute under the certificate number: CTRI/2014/04/004536, the patient consent is waived by Institutional Review Board. FILI was performed on 42 eyes of

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25 patients. The mean follow-up was 68 ± 17.28 months (12–84 months) [Table 1].

In the technique of femtosecond intrastromal lenticule implantation (FILI), published by our group in 2014, the cornea was made steeper by addition of a SMILE lenticule of known thickness and power, into a pocket created in the recipient's cornea using a femtosecond laser.[4] For FILI, the donor SMILE lenticules used were either cryopreserved or fresh.

A 3-mm corneal trephine was then used to punch the center of the lenticule under the microscope resulting in a donut-shaped tissue. This tissue was then inserted into a femtosecond laser-enabled pocket created using VisuMax FS Laser at a depth of 160 µm.[4] The postoperative medication regimen consisted of topical 0.3% ofloxacin (Exocin; Allergan, Inc) four times per day for 3 days, 0.1% prednisolone acetate eye drops (Pred Forte; Allergan, Inc) four times per day for 4 weeks (tapering weekly), and lubricants four to six times per day for 4 weeks or more.

Statistical analysis

SPSS software for Windows version 17.0.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. All values were expressed as mean ± standard deviation. The data were checked for normality before subjecting to analysis. Independent sample *t*-test was used for intergroup comparison and paired *t*-test was used for intragroup comparison of means. P = 0.05 or less was considered statistically significant.

Results

Efficacy and safety

At 68 months, the mean efficacy index was 0.86 ± 0.19 (0.39–1.0). The postoperative mean uncorrected distant visual acuity (UDVA) was 0.25 ± 0.22 (−0.12–0.6) LogMAR. Cumulative UDVA of 20/20 or better and 20/40 or better was seen in 38% (n = 16) and 81% (n = 34) of eyes, respectively [Figure 1a]. The mean safety index was 1.17 ± 0.39 (0.63–2.54). Thirty-six percent (n = 15) of eyes gained one or more lines, 45% (n = 19) had no change, whereas 19% (n = 8) eyes lost one line of corrected distant visual acuity (CDVA) [Figure 1b and Table 2].

Spherical equivalent, astigmatism accuracy, and stability

The accuracy of spherical equivalent (SE) refraction within ± 0.5 D was observed in 50% (n = 21) eyes; however, 71% (n = 30) of all the treated eyes were within ± 1.00 D of SE correction. 64% (n = 29) of eyes were within 0.5 D of astigmatism, while 88 (n = 37) eyes were within ± 1.00 D of astigmatism [Figure 1e]. The mean residual refraction at 2 weeks postoperative was 0.64 ± 1.05 D, which showed a nonsignificant increase to 0.66 ± 1.17 D at 68 months postoperative, P = 0.95 [Figure 1f].

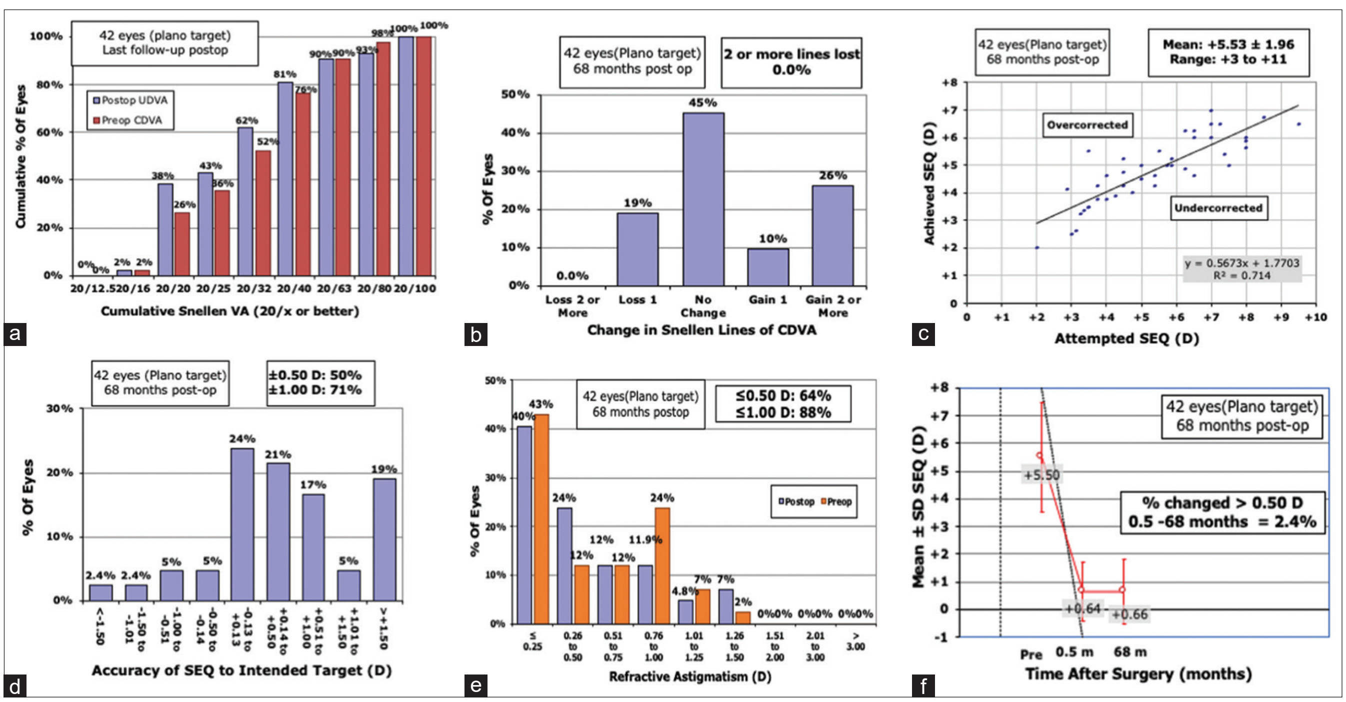

Figure 1: (a-f) JRS standard graphs for n = 42 eyes treated with femtosecond intrastromal lenticule implantation in the series. 1 (a) shows cumulative Snellens Visual acuity,1(b) shows change in Snellens line corrected distance visual acuity of enrolled patients. (c) shows mean Attempted spherical equivalent as + 5.53) ± 1.96 (d) shows 71% of the eyes with 1D accuracy of spherical equivalent to indented target. (e) refractive astigmatism, 1(f) Time after surgery in months

There was a significant increase in the K mean anterior, central corneal thickness, Q-value, and corneal HOAs, 2 weeks postoperative compared to the preoperative values, $P < 0.05$, [Table 3].

Figures 2 and 3, respectively, show the 2-weeks versus preoperative difference maps of both eyes of a 29-year-old male, who underwent FILI for high hyperopia of +6.5 D and +7.0 D in the right and left eyes, respectively, which showed an increase in K1, K2, and thinnest pachymetry. Figures 4 and 5, respectively, show the difference maps of both eyes of the same patient at a long follow-up of 5.8 years versus 2 weeks post-FILI. Figure 6a and b shows clinical photographs of both eyes of the same patient at 2 weeks postoperative, showing the implanted lenticule with well-defined borders. However, at 5.8 years postoperative follow-up, [Figure 6c and d], the borders of the lenticules are merged with the surrounding host tissue. Figure 7 demonstrates the corresponding AS-OCT scans with clear and well-centered lenticules *in situ*.

Table 1: Preoperative demographic data of the recipient and donor eyes

Parameter	Mean±SD
Recipient details	
Age (years)	27.04±5.33
UDVA (LogMAR)	1.03±0.39
CDVA (LogMAR)	0.22±0.23
Sphere (diopter)	5.24±1.96
Cylinder (diopter)	0.51±0.48
SE (diopter)	5.50±1.96
CCT (μm)	550.02±29.68
Km anterior (diopter)	43.72±1.55
Km posterior (diopter)	−6.30±0.26
Q-value	−0.34±0.09
HOA (RMS)	0.398±0.15
Donor details	
Age (years)	28±5.33
SE treated (diopter)	−6.03±1.99
Optical zone (μm)	6.50±0.28
Lenticule thickness (μm)	114±25.70
Length of cryopreservation (days)	61±103.61

UDVA=Uncorrected distant visual acuity, CDVA=Corrected distant visual acuity, SE=Spherical equivalent, RMS=Root mean square, CCT=Central corneal thickness, HOA=Higher order aberration, SD=Standard deviation, LogMAR=Logarithm of the minimum angle of resolution

Table 4 depicts the visual and refractive outcomes of these eyes following enhancement with bowman membrane relaxation (BMR).

Complications

Four eyes of two patients underwent explantation of the lenticule due to suspected stromal rejection. For one patient, the lenticules were exchanged with fresh lenticules. Figure 8 shows the dilated clinical pictures of the left eye of this patient at 1.5 years postoperative, showing interface haze due to diffuse lenticular scarring. For the second patient, lenticules were explanted after 3 years of the FILI procedure, following which hyperopic LASIK was performed, 2 months later.

Discussion

In this study, we evaluated the long-term clinical outcomes of FILI for the treatment of moderate to high hyperopia in 42 eyes. Our study shows reduction of SE from +5.54 D to +0.64 D at 2 weeks and +0.66 D

Table 2: Visual and refractive results postfemtosecond intrastromal lenticule implantation (*n*=42 eyes) at 2 weeks and 68 months postoperative

Parameter	Pre, mean±SD (range)	2 weeks, mean±SD (range)	*P* (pre vs. 2 week)	Last follow-up, mean±SD (range)	*P* (2-week vs. last follow-up)
UDVA (LogMAR)	1.03±0.39 (0.22–1.78)	0.21±0.23 (−0.10–0.80)	<0.001	0.25±0.23 (−0.10–0.60)	0.36
CDVA (LogMAR)	0.22±0.23 (−0.10–0.80)	0.19±0.20 (−0.10–0.70)	0.51	0.19±0.21 (−0.20–0.60)	0.88
Sphere (diopter)	5.24±1.96 (+3–+11)	0.57±0.82 (0–+2.25)	<0.001	0.56±0.94 (−1.50–+2.25)	0.95
Cylinder (diopter)	0.51±0.48 (0–+1.50)	0.14±0.65 (−1.50–+1.50)	<0.001	0.19±0.67 (−1.25–+1.50)	0.71
SE (diopter)	5.54±1.96 (+3–+11)	0.64±1.05 (−0.625–+4.50)	<0.001	0.66±1.18 (−2.00–+2.375)	0.95

UDVA=Uncorrected distant visual acuity, CDVA=Corrected distant visual acuity, SE=Spherical equivalent, LogMAR=Logarithm of the minimum angle of resolution, SD=Standard deviation

Table 3: Changes in Kmean anterior, Kmean posterior, central corneal thickness, *Q*-value and corneal higher order aberrations at 2 weeks and 68 months postoperative

Parameter	Pre, mean±SD (range)	2 weeks, mean±SD (range)	*P* (pre vs. 2 week)	Last follow-up, mean±SD (range)	*P* (2-week vs. last follow-up)
Kmean anterior (diopter)	43.72±1.55 (41.50–46.20)	47.45±1.75 (44.20–50.30)	<0.001	47.48±2.02 (44.30–50.90)	0.94
Kmean posterior (diopter)	−6.30±0.26 (−5.70–−6.80)	−6.13±0.34 (−5.37–−6.60)	0.02	−6.19±0.31 (−5.50–−6.70)	0.23
CCT (μm)	550.02±29.68 (494–596)	631.59±37.72 (546–717)	<0.001	625.76±41.69 (530–720)	0.50
Q-value	−0.34±0.09 (−0.13–−0.55)	−0.89±0.23 (−0.43–−1.69)	<0.001	−0.95±0.28 (−0.40–1.94)	0.29
HOA (RMS)	0.39±0.15 (0.07–0.97)	0.83±0.34 (0.13–1.62)	<0.001	0.96±0.34 (0.41–1.94)	0.10

HOA=Higher order aberration, CCT=Central corneal thickness, RMS=Root mean square, SD=Standard deviation

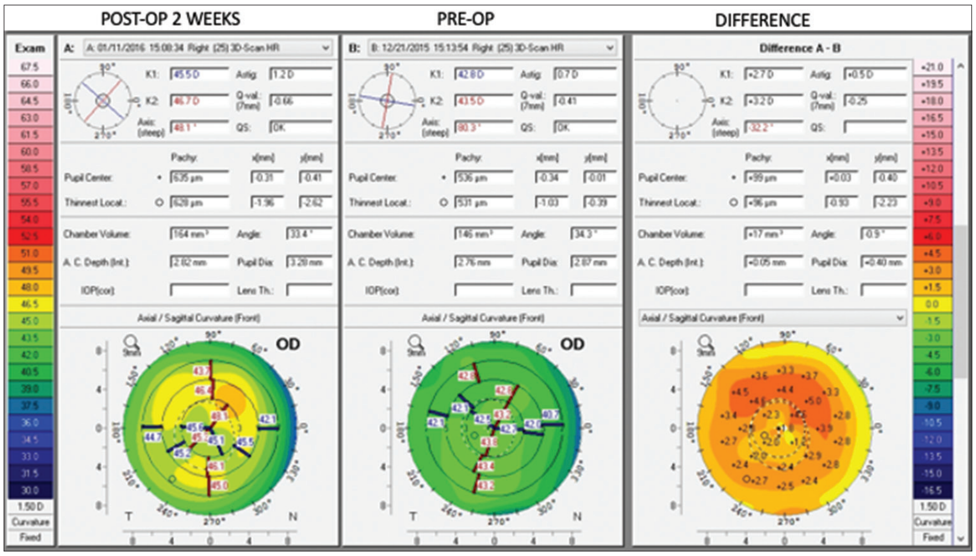

Figure 2: Two weeks versus preoperative difference maps of RE eye of a 29-year-old patient, who underwent femtosecond intrastromal lenticule implantation for hyperopic refractive error of + 6.5 D

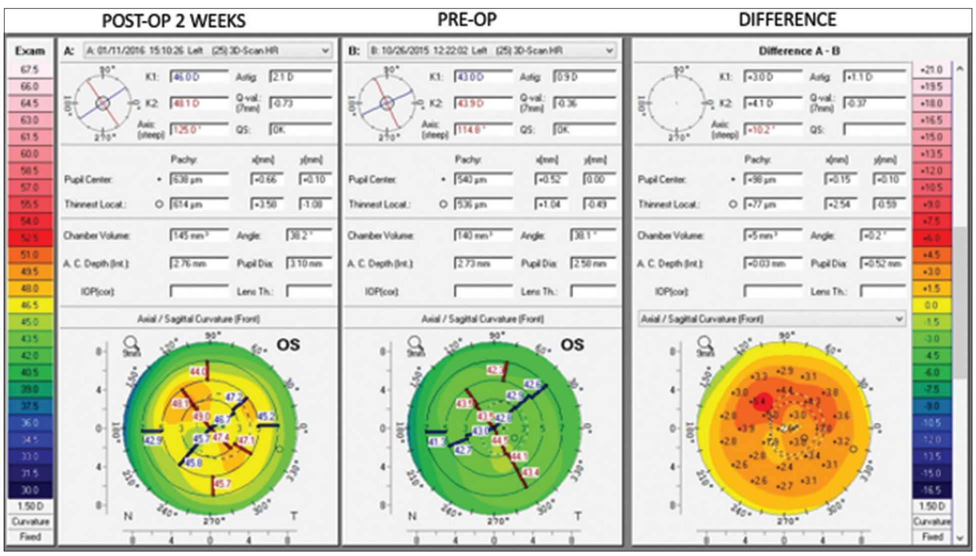

Figure 3: Two weeks versus preoperative difference maps of LE of a 29-year-old patient, who underwent femtosecond intrastromal lenticule implantation for hyperopic refractive error of + 7.0 D

at 5.6 years. Dave *et al*. reported the mean SE in their study reduced from +3.74 D to +0.84 D at a comparable follow-up of 5 years.[14] This may support the previously proposed mechanisms described in relation with tissue addition, such as lesser epithelial response, induced aberrations, and better biomechanical stability, favoring this technique over excimer laser procedures for treating higher degrees of hyperopia.[4,15] Pradhan *et al*. reported a relative change in SE from +5.61 D to −0.19 D at 12 months of follow-up.[16]

Liu *et al*. recently reported their 2 years clinical experience of treating 14 eyes with implantation of allogenic SMILE lenticule for moderate to high hyperopia.[15] However, Liu *et al*. noted a slight overcorrection, as the preop SE reduced from + 5.53 D to-0.60 D at 2 years postoperative. This may be explained by the fact that the depth of the femto laser pocket at which the donor lenticule was implanted in their study was set at 100 µm as compared to 160 µm in our study, which may have maximized the refractive effect by mainly changing the anterior corneal curvature, without significantly influencing the posterior curvature. Moshirfar *et al*. reported a case of high hyperopia of + 6.00D/ 1.00D @ 40 degrees which was managed with Lenticule Intrastromal Keratoplasty (LIKE) procedure using a thick corneal lenticule of 157 µm and implanted under a flap at a depth of 100 µm.[17] Damgaard *et al*. evaluated changes in corneal tomography after stromal lenticule implantation *ex vivo*, using a combination of two implantation depths

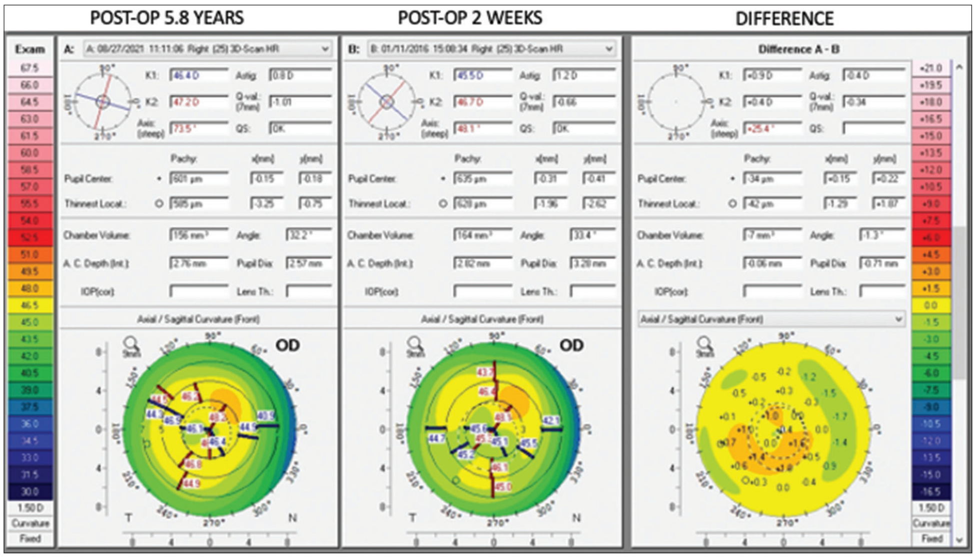

Figure 4: RE difference map of 5.8 years versus 2 weeks postfemtosecond intrastromal lenticule implantation of the same patient

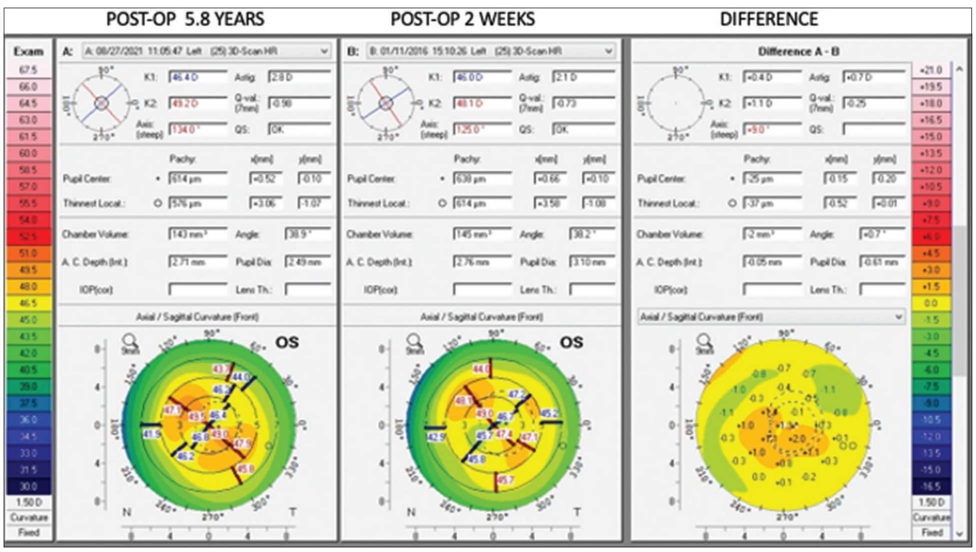

Figure 5: LE difference map of 5.8 years versus 2 weeks postfemtosecond intrastromal lenticule implantation of the same patient

(110 and 160 μm) and two lenticule thicknesses (95 μm = 4.00 D, 150 μm = 8.00 D).[18] For the front curvature, a 110 μm implantation depth induced significantly more steepening than a 160 μm depth in all groups.[19] These observations may suggest that a relatively superficial implantation of the lenticule may result in more pronounced anterior curvature changes.

Liu *et al*. observed a significant decrease in the anterior keratometry at 2 years when compared to 3 months values.[15] The much anterior placement of the lenticule (at 100 μm) may result in an acute and exaggerated changes in the corneal curvature making the cornea prone to regression due to resultant epithelial response.

Tissue additive procedures for high hyperopia may involve insertion of natural corneal tissue or SMILE lenticule under a LASIK flap (LIKE)[20] or inside a corneal pocket created using a femtosecond laser (FILI and s-LIKE).[4,9] The creation of a flap for tissue addition may pose various challenges such as increased risk of dry eye, diffuse lamellar keratitis, weakening of biomechanics, poor adhesion and dislocation of the flap edge, and epithelial ingrowth that may not be present when the tissue is implanted inside a pocket.[9]

In our study, 45% (19) of eyes had no change, 36% (15) eyes gained one line or more, and 19% (8) of eyes lost 1 line of CDVA. However, 4 eyes required lenticule explantation due to suspected stromal rejection diagnosed at a mean period of 2.25 years. A common factor in these 4 eyes was the use of a cryopreserved tissue. Cryopreservation process may alter the physical

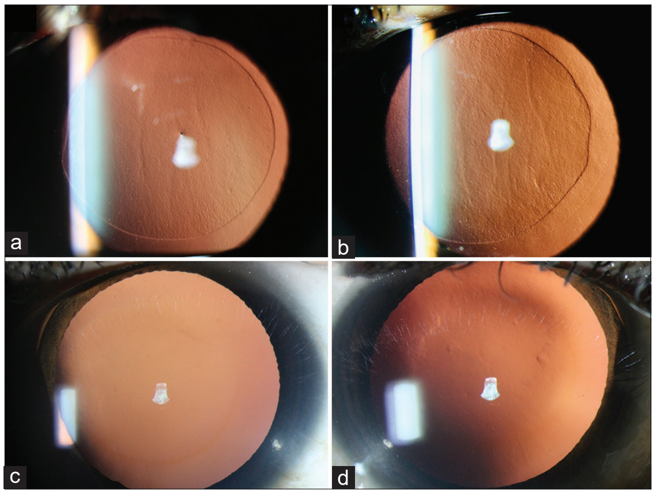

Figure 6: Clinical photographs of the same patient; (a and b) 2 weeks postoperative and (c and d) 5.8 years postoperative, for the right and left eyes, respectively

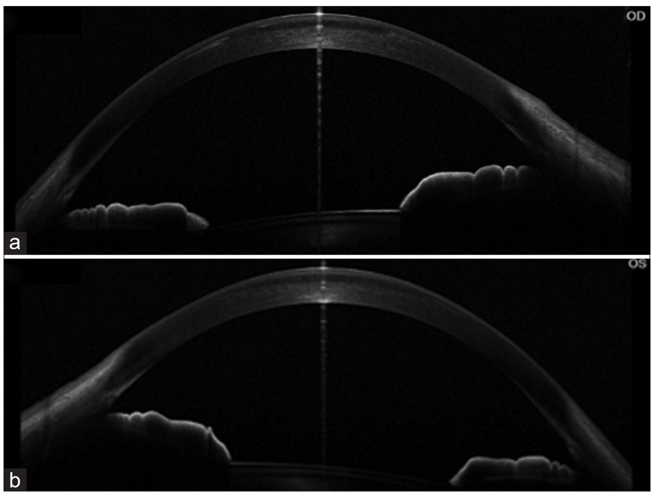

Figure 7: Anterior segment optical coherence tomography of both eyes, a (right eye) and b (Left eye), of the same patient at 5.8 years of follow up, with clear and well centred lenticules *in situ*

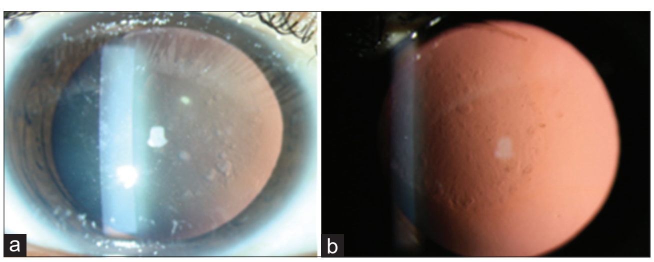

Figure 8: Dilated clinical pictures (a) oblique illumination, (b) (retro illumination), of left eye of a patient at 1.5 ± years postoperative, showing interface haze due diffuse lenticule scarring. The hazy lenticule was explanted and exchanged with a fresh lenticule 2 weeks later, which remained clear over a follow-up of 6 years

properties of the stromal collagen and keratocytes, making them susceptible to necrosis, possibly due to a relative lack of cell membrane protection by cryoprotectants used.[21] Pretreatment with gamma radiation has been suggested to deantigenize the donor tissue and prevent future rejection.[22,23]

Moshirfar *et al*. suggested the use of circle[24] software and the side cut only technique to convert the cap into a LASIK flap for the purpose of enhancement after sLIKE procedure for high hyperopia.[9] We achieved satisfactory outcomes using the BMR technique for treating residual refractive error after FILI, by potentially reversing the posterior corneal curvature changes.[19] Under topical anesthesia, the Hessburg-Barron trephine was applied and positioned, such that the center of the crosshairs was aligned on the first Purkinje image (microscope coaxial light reflex) of the cornea. Following this, vacuum was applied. The trephine was then rotated 90° (two spoke turns) to create an incision of approximately 120 µm to penetrate the Bowman's layer and superficial anterior stroma. Finally, the short end of a Seibel IntraLase flap lifter (Katena) and spatula was used to verify the incision into the Bowman's layer.

Lamellar surgery with SMILE lenticules for keratoconus and SMILE-ectasia

The technique of using SMILE tissue has shown promising results when used for potential management of keratoconus[6] and post-SMILE ectasia.[25]

After extraction from the donor eye, the SMILE lenticule was thoroughly rinsed 3 times in a balanced salt solution and stained with 0.23% riboflavin solution. A 3.0 mm trephine was used to punch the center of the lenticule to create a doughnut-shaped lenticule tissue.

For keratoconus,[6] a stromal pocket was created at 100 microns depth using the VisuMax FS laser and interface was injected with 0.23% riboflavin dye.

For SMILE ectasia,[25] the old SMILE incision was opened and dissected using the Reinstein dissector. 0.23% riboflavin dye was then injected into the interface for 60 s and then washed followed by insertion of doughnut-shaped lenticule tissue.

After the insertion of the tissue, the eye was finally exposed to ultraviolet, a radiation using a power of 18 mW/cm^2 for 5.8 min, delivering a total energy of 6.3 J.

Results in keratoconus

Six eyes from six patients were included in the study. Clinical improvement was noted in uncorrected distance visual acuity (1.06 ± 0.48 logMAR vs. 0.38 ± 0.27 logMAR), corrected distance visual acuity (0.51 ± 0.20 logMAR vs. 0.20 ± 0.24 logMAR), and manifest SE (−3.47 ± 1.15 D vs. −1.77 ± 1.7 D). There was flattening of mean keratometry in 3-mm and 5-mm zones by 3.42 ± 2.09 D and 1.70 ± 1.31 D, respectively. The mean pachymetry in the central and midperipheral zones increased by 18.3 ± 7.3 µm and 33.0 ± 8.8 µm, respectively.

Table 4: Visual and refractive results of *n*=4 eyes, enhanced with Bowman membrane relaxation in the series

Parameter	Pre-FILI, mean (range)	Preenhancement, mean (range)	Postenhancement, mean (range)
UDVA (LogMAR)	0.80 (0.50–1.00)	0.55 (0.5–0.6)	0.33 (0.3–0.4)
Sphere (diopter)	+6.88 (+6.50–+7.00)	+1.50 (+1.00–+2.50)	+0.25 (0.00–+0.50)
Cylinder (diopter)	+0.69 (+0.50–+1.00)	+1.50 (+0.50–+3.00)	+0.12 (−1.50–+1.25)
SE (diopter)	+7.22 (+6.75–+7.50)	+2.25 (+1.75–+2.50)	+0.31 (−0.50–+1.125)
CDVA (LogMAR)	0.30 (0.2–0.4)	0.35 (0.3–0.4)	0.30 (0.2–0.4)

FILI=Femtosecond intrastromal lenticule implantation, UDVA=Uncorrected distant visual acuity, CDVA=Corrected distant visual acuity, SE=Spherical equivalent, LogMAR=Logarithm of the minimum angle of resolution

Results in SMILE Ectasia

Four eyes of 3 patients developed features of Keratectasia at a mean period of 3 years after myopic SMILE correction. All cases were managed with insertion of heterologous SMILE lenticules in the previously created pocket, followed by simultaneous accelerated CXL. At a mean follow-up of 7.67 months, there was an improvement in corrected distance visual acuity and reduction in keratometry and higher-order aberrations in all eyes. The visual, refractive, and topographic parameters remained stable at the last visit compared with the 2-week follow-up visit.

Other Uses of SMILE-derived Lenticules

Jacob *et al*., recently, described a new technique called PrEsbyopic Allogenic Refractive Lenticule (PEARL) that uses an inlay obtained from a small incision lenticule extraction (SMILE) lenticule.[7] The PEARL inlay acts as a shape-changing inlay by increasing the central radius of curvature and resulting in a hyperprolate corneal shape. Recently, the initial clinical outcomes of the small incision lenticule extraction (SMILE)-derived glued lenticule patch graft for the management of microperforations and complicated corneal tears were reported.[8,26] In our single-center case series, 7 eyes that presented with microperforations, partial-thickness corneal defect, and traumatic complicated corneal tear were repaired with a lenticule patch graft obtained from the SMILE procedure. The patch was secured to the recipient eye using fibrin glue.

Conclusion

Lamellar corneal surgeries using SMILE lenticules appears to be a feasible and exciting concept with encouraging results for the management of various corneal conditions. Future research is also suggested in the areas of nomogram refinement, evaluating biomechanical changes, epithelial and stromal remodeling, tissue treatments, and preservation to prevent rejection following this procedure.

Data availability statement

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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Nil.

Conflicts of interest

The authors declare that there are no conflicts of interests of this paper.

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