Post-operative outcomes of small-incision lenticule extraction in patients with moderate to high astigmatism

N V Arulmozhi Varman, Aadithreya Varman, Dinesh Balakumar

Purpose: To evaluate the visual outcomes of patients who underwent small-incision lenticule extraction (SMILE) for the treatment of myopic astigmatism with high cylinders (>2.5 diopters, D).

Methods: Forty-two eyes of myopic astigmatism with a spherical error of magnitude between −0.5 and −6.0 Ds, cylindrical error of −2.5 to −4.5 Dcyl were included in the retrospective study. All patients were tested preoperatively and on days 1, 10, and 30 for uncorrected distance visual acuity, manifest refraction, and corrected distance visual acuity. Additional preoperative assessments were done including measurement of corneal thickness, corneal topography, and examination for ocular surface disease. All procedures were performed by a single experienced surgeon. VisuMax laser system (Carl Zeiss Meditec AG, Jena, Germany) was utilized for all the corrective refractive procedures. Results: Forty-two eyes were included. The logarithm of the minimum angle of resolution Uncorrected distance visual acuity (UDVA) was 1 ± 0.25 preoperatively and 0.00 ± 0.00 on postoperative day 30. There was no loss of corrected distance visual acuity (CDVA) lines. Conclusion: SMILE is a successful procedure in the treatment of both myopic spherical and cylindrical refractive errors including high cylindrical errors >3 to >4.5 Dcyl.

Key words: Refractive surgery, SMILE, LASIK

Corneal refractive surgeries with lasers have been performed for decades, beginning with surface ablation procedures using the excimer laser in photorefractive keratectomy for the correction of myopia and myopic astigmatism. Surface ablation procedures have been associated with a long recovery period, corneal haze, discomfort, and regression of refractive correction. Laser in situ keratomileusis introduced a flap-based procedure where the excimer laser correction is performed on the corneal stroma under a flap created by a microkeratome. Compared to Photorefractive keratectomy (PRK), laser-assisted in situ keratomileusis (LASIK) had a faster recovery period and the ability to treat a higher amount of myopia and myopic astigmatism. The major downsides to LASIK being the occurrence of flap-related complications and the albeit rare occurrence of post-LASIK ectasia. The small-incision lenticule extraction (SMILE) uses high-frequency pulses of the femtosecond laser to ablate corneal tissue without the creation of a flap. The intrastromal lenticule created by the femtosecond laser can be extracted via a 2 mm incision.[3] This technique is employed in the flapless refractive surgical procedure, SMILE.[4] SMILE has an edge over the conventional refractive procedures owing to its advantages of small incision size, lesser damage to corneal nerves, faster recovery, improved strength of the cornea post-procedure, and no flap-related complications.[5,6] The lack of iris registration to compensate for the cyclotorsional movements of the eye cast doubts on the ability of SMILE to accurately correct myopic astigmatism. SMILE has proved to be reliable and accurate in correcting myopic astigmatism for up to 3D of the cylinder, with and without using a cyclotorsional compensation.[7,8] In October 2018, the US Food and drug Administration (FDA)-approved SMILE for the treatment of myopia up to 10 D and astigmatism up to 3 D. The objective of this study is to evaluate the visual outcomes of patients who have undergone SMILE for the correction of myopic astigmatism with high cylinder (>2.5 D).

Methods

A retrospective analysis was conducted on 42 eyes that underwent SMILE between October 2019 and February 2021. The inclusion criteria were patients with preoperative myopia of −0.5 to −6 D with myopic astigmatism of −2.5 to −4.5 D. All the patients who were above the age of 18 −32 years. The preoperative workup included manual cycloplegic refraction. The refraction was correlated with the iTrace aberrometer. Manual cycloplegic refraction was repeated with confirmative subjective refraction which included the use of Jackson’s cross-cylinder and duochrome. All the patients had a stable refractive error for at least 1 year. The central corneal thickness was measured. All the patients included in the study had a Central Corneal thickness (CCT) within normal limits. Corneal topography was performed using the Costruzione Strumenti Oftalmici (CSO) Sirius Topographer Model-13071866. All the patients...
included in the study had a normal topography. Fundoscopy was performed for all the patients via binocular indirect ophthalmoscopy. The patients were assessed for dry eye and ocular surface disease and treated for the same if present. All the patients had a corrected distance visual acuity (CDVA) of 6/6 or better. The tenets of the Declaration of Helsinki were followed and ethical approval was obtained from the ethics committee. All procedures were performed by a single experienced surgeon. The VisuMax laser system (Carl Zeiss Meditec AG, Jena, Germany) was utilized for all the corrective refractive procedures. The repetition rate of the laser was 500 kHz and the pulse energy was 132 nJ. The diameter of the lenticule was 6.0 mm, the diameter of the cap was 6.5 mm, and the cap thickness intended was 110–130 microns. The spot size was 5 microns. The anterior surface cut was spiral out and the posterior surface cut was spiral. The length of the side cuts was 2 mm. The intended refractive lenticule was then gently dissected with a spatula through the side cuts. This was later gently peeled away with forceps. The potential intraoperative complications of SMILE include retention of refractive lenticular fragments, tears of the incision, and improper dissection. None of these were noted in all the subjects. After surgery, all the patients received a topical antibiotic-steroid eye drop combination for 1 week followed by a steroid eye drop alone for 4 weeks along with topical lubricants to use throughout the day on a need basis. All patients were evaluated immediately postoperatively, postoperative day 1, postoperative day 8, and postoperative day 30. In all visits, the patients were evaluated for postoperative refractive outcome, uncorrected visual acuity, aberrometry, and topography estimated with the iTrace aberrometer.

Results

A total of 42 eyes were included in the study. Table 1 elaborates the patient population under study. The average age of the patients was 24.88 ± 4.07. The mean spherical error was -3.75 ± 1.96. The mean cylindrical error was -2.92 ± 0.50. The mean spherical equivalent of refraction was 5.36 ± 1.92. The logarithm of the minimum angle of resolution UDVA was 1 ± 0.25 preoperatively and 0.00 ± 0.00 on postoperative day 30. Fig. 1 demonstrates the efficacy of the treatment. The mean spherical equivalent (SE) at the end of 1 month was -0.28 ± 0.89. The mean cylinder was -0.40 ± 0.18. Fig. 2 demonstrates the safety of the treatment. No loss of Snellen’s lines was noted for any of the patients. Table 2 elaborates the efficacy of treatment.

Out of the 42 eyes. On postop day 0: 8 eyes achieved visual acuity of 6/18, 28 eyes had visual acuity of 6/12, and 6 eyes had visual acuity of 6/9. On postop day 1: 2 eyes had visual acuity of 6/9 and 40 eyes had achieved 6/6. On postop day 10: 42 eyes had achieved 6/6.

Fig. 3 shows the Mean Spherical Equivalent (MSE) scatterplot and Fig. 4 shows the accuracy of MSE to target, 100% being within ± 0.50 D of the intended correction. Fig. 5 shows the accuracy of astigmatism.

All the eyes maintained CDVA of 6/6 preoperatively and UDVA of 6/6 on postop day 30.

Discussion

SMILE is the newer alternative to conventional laser vision correction procedures. Although it is known that SMILE has a longer recovery period and delayed recovery to good quality of vision, studies have shown that the visual outcomes of SMILE are comparable to Femto-second (FS)-LASIK.\cite{13-16} Shah et al.\cite{11} concluded that early visual recovery and refractive outcomes after femtosecond lenticule extraction were affected by the scanning trajectory of the laser. In our case scenario, we have noticed a good recovery of visual acuity as early as postop day 1 in all the patients. This is probably due to the lesser energy used and also meticulous surgical handling of the tissues and flap. The use of low-energy settings for SMILE has proven to provide visual outcomes similar to FS-LASIK.\cite{9,12} Many studies have reiterated the efficacy, predictability, and index of the safety of SMILE in the correction of myopia and myopic astigmatism.\cite{15-16} Moreover, studies have demonstrated that SMILE offers greater biomechanical stability of the corneal tissue compared to the FS-LASIK minimizing the chances of post-LASIK ectasia.\cite{18} Better wound healing and lesser response to inflammation were noted in SMILE as compared to FS-LASIK which settles in the first week after the procedure. Lesser apoptosis of keratocytes, proliferation, and inflammation are the keys behind why SMILE has an edge over FS-LASIK.

Our study demonstrates the potential benefits of SMILE as a modality of correction of refractive errors with high cylinders.
All the outcomes were repeatable and compared accurately as the surgery was performed by a single surgeon with no alteration in the parameters of the lasers. As far as the efficacy of the procedure was concerned, uncorrected visual acuity was restored to 6/6 and was stable when estimated at the end of 1 month. The postoperative refraction ranged from ±0.25 to ±0.50 D of the sphere to ±0.25 to ±0.75 D of the cylinder.

There were no noticeable complications in all cases like corneal haze, suction loss, tears at the incision edge, cap perforation, difficult lenticule extraction, or residue of part of the intrastromal lenticule and epithelial ingrowth or interface haze.

A comparative study done by Ganesh et al. also concluded that with high refractive accuracy and fast postoperative recovery, SMILE provides all of the advantages of LASIK while avoiding the limitations (reduced corneal biomechanical strength, increased postoperative Higher order aberration (HOAs), low-contrast sensitivity under mesopic conditions, and dry eyes) commonly associated with it. No complications like corneal haze, epithelial ingrowth, or keratitis were seen in any of the cases.

That being said, there seems to be a tendency toward under correction of myopic astigmatism with SMILE, especially when dealing with higher magnitudes of cylindrical error. This has been attributed toward the lack of cyclotorsional compensation in SMILE which could lead to under correction of myopic astigmatism. Ganesh et al. described a technique of compensating for the cyclotorsion by making limbal markings at 0° and 180° which could serve as reference marks for identifying cyclotorsion when the patient was placed in a supine position. This technique was successfully able to correct a mean preoperative cylinder for -2.48 D to a postoperative cylinder of -0.31 D. Jun et al. described a triple centration technique of marking two points at the horizontal meridian 7 mm apart and one mark bisecting the first purkinje image. Our study was comparable with the studies performed with respect to the overall safety and efficacy of the procedure for correction of refractive errors including myopic astigmatism >3D. No compensatory mechanism for the cyclotorsional movement of the eye was employed for our patients and yet we were able to achieve satisfactory postoperative visual outcomes. This is probably due to the meticulous preoperative planning and refraction to accurately measure the magnitude and vector of astigmatism in our population under study.

| Gender Females/Males | 11/10 |
|----------------------|-------|
| Age                  | 24.88±4.07 |
| Mean sphere          | -3.75±1.96 |
| Mean cylinder        | -2.92±0.50 |
| Mean spherical equivalent | 5.36±1.92 |
| Pachymetry           | 542±30.52 |

### Table 2: Efficacy of the treatment

| Total Number of eyes=42 | 6/18 | 6/12 | 6/9 | 6/6 |
|-------------------------|------|------|-----|-----|
| POD 0                   | 8    | 30 (71.4%) | 4 (9.6%) | 0 |
| POD 1                   | 0    | 0    | 0   | 42 (100%) |
| POD 10-30               | 0    | 0    | 0   | 42 (100%) |
| After 1 month           | 0    | 0    | 0   | 42 (100%) |

Figure 3: Attempted spherical equivalent of refraction

Figure 4: Attempted spherical equivalent of refraction to target

Figure 5: Pre- and postop refractive astigmatism
Conclusion

SMILE is a successful procedure in the treatment of both myopic spherical and cylindrical refractive errors. The faster healing and flapless advantage along with the lesser incidence of dry eyes have an edge over the conventional laser vision correction procedures. To conclude, SMILE is a safe and effective procedure for the correction of myopic refractive errors including myopic astigmatism with a high cylindrical component.

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Conflicts of interest

There are no conflicts of interest.

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