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Research Article

Visual Outcome with Irrigation of the Interface in Small-Incision Lenticule Extraction

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Abstract

Purpose: To compare the refractive and visual outcomes after Small-Incision Lenticule Extraction (SMILE) in patients receiving irrigation of the stromal interface versus no irrigation in the United States based on FDA-approved parameters.

Methods: In this US-based, single-center, consecutive, retrospective case series, patients undergoing SMILE received irrigation in one eye versus no irrigation in the other eye. Primary outcome measures included uncorrected visual acuity (UCVA) post-op day 1, post-op week 1, and post-op month 1, mean manifest refraction spherical equivalent (MRSE), and the number of patients within ±0.5 D and ±1.0 D of refractive target. Same-day post-op pachymetry and anterior-segment OCT were also obtained. Safety was assessed by noting the incidence of complications and need for additional surgery.

Results: 32 patients were included in the study, with 32 eyes in both the irrigated and non-irrigated groups. All patients were targeted for plano refraction. UCVA on POM1 was 0.0038 ± 0.164 D for irrigated eyes and -0.0154 ± 0.141 D for non-irrigated eyes (P = 0.40). The MRSE on POM1 was -0.232 ± 0.483 D for irrigated eyes and -0.274 ± 0.539 D for non-irrigated eyes. In the irrigated eyes group on POM1, 21 of 21 patients were within ±1.0 D of refractive target compared to 18 of 21 in the non-irrigated group. Adjusting for expected pachymetry, irrigated eyes had an average of 15.406 ± 0.347 microns thicker post-operative pachymetry readings compared to the non-irrigated eyes (P = 0.006).

Conclusion: Irrigated eyes had better UCVA, lower MRSE, and deviated less from their refractive target compared to non-irrigated eyes. Irrigated eyes had a significant increase in corneal pachymetry measured immediately postoperatively compared to non-irrigated eyes, however its effect on visual outcome was not significant.

Keywords: SMILE; Refractive Surgery; Ophthalmic Surgery

Introduction

Small-incision lenticule extraction (SMILE) is a relatively new type of laser refractive surgery that utilizes a femtosecond laser to treat patients with myopia and myopic astigmatism. Approved by the Food and Drug Administration (FDA) in 2016, it is proposed to be a safer alternative to other types of laser refractive surgery due to a variation in the mechanics of the surgery and in how the laser manipulates the corneal tissue [1]. The SMILE procedure is an evolution from the femtosecond lenticule extraction procedure (FLEx), which was first introduced in 2007 and uses the laser to create a corneal flap from which a lenticule is then removed. Unlike FLEx and laser-assisted in situ keratomileusis (LASIK) however, the SMILE procedure does not include the creation of a corneal flap. Rather, both a lower and upper interface of the lenticule are created

by the laser, followed by a small 2 - 4 mm incision. The lenticule is then removed from this incision [2]. The creation of a small incision versus large corneal flap is a main benefit of utilizing SMILE for patients undergoing refractive surgery. SMILE is therefore safer for patients who engage in activities that carry risk of traumatic flap rupture. Additionally, there is a decreased risk of post-operative dry eye, making SMILE a great choice for patients with pre-existing dry eye [3]. Lastly, SMILE may be more efficacious than LASIK as it has been found to result in fewer higher-order aberrations (HOA's), such as glare or shadows. However, a drawback of performing SMILE is that it is a more technical and difficult surgery for refractive surgeons to perform compared to LASIK, noticed especially in the early stages of a surgeon performing it. Therefore, patient selection and surgical skill are crucial. For example, the dissection and extraction of the lenticule is particularly difficult. In patients with lower myopia, a thinner lenticule will be created, making for a more difficult extraction. If suction loss occurs during the procedure, lenticule dissection and extraction is made even more difficult. Surgeons may find that some patients are unsuitable for SMILE for these reasons or others, including high astigmatism, difficult anatomy of the orbit, or an uncooperative patient [4,5].

There is a large amount of literature that examines the efficacy of SMILE on parameters including but not limited to visual acuity, myopia and myopic astigmatism, and post-operative patient visual satisfaction. However, there is a lack of research that examines the effect of stromal irrigation during SMILE on human eyes and its effects on patient VA's, mean manifest refraction spherical equivalent (MRSE), and post-operative pachymetry. There are various reasons to irrigate the stroma, but also associated risks. By irrigating the stroma, surgeons can wash out inflammatory cytokines, minimize the risk of infection by flushing out contaminants, and decrease epithelial ingrowth. However, stromal irrigation can lead to early post-operative stromal edema and reduced postoperative uncorrected visual acuity (UCVA) [6,7]. If stromal irrigation is found to be efficacious for patients undergoing SMILE by this proposed study, it can be adopted by refractive surgeons for improved refractive and visual outcomes.

Methods

This consecutive retrospective case series took place at a center in Cleveland, Ohio, USA. The patients included underwent the SMILE procedure and received irrigation in one eye, with the other eye left non-irrigated and used as a comparison. The primary outcome measures of the study included uncorrected visual acuity (UCVA) on post-op day 1 (POD1), post-op week 1 (POW1), and post-op month 1 (POM1), mean manifest refraction spherical equivalent (MRSE), and the number of patients within ±0.5 D and ±1.0 D of refractive target. Immediately postoperatively, each patient underwent corneal pachymetry and anterior-segment OCT readings. The safety of the procedure was assessed by noting the incidence of complications and any need for additional surgery. Data and statistical analysis were performed post-operatively using the patient's medical records.

Results

A total of 32 patients were included in this study, with 32 eyes in both the irrigated group and the non-irrigated group. 17 patients were male, and 15 patients were female. The average age of patients was 33.7 ± 8.96 years. All patients included had a refractive target aimed for plano refraction.

The UCVA results were reported through LogMar. On POD1, the average UCVA for irrigated eyes was 0.0478 ± 0.123, and 0.0616 ± 0.137 for non-irrigated eyes (p = 0.92). On POW1, the average UCVA for irrigated eyes was 00.005 ± 0.133, and 0.0148 ± 0.158 for non-irrigated eyes (p = 0.77). On POM1, the average UCVA was 0.0038 ± 0.164 D for irrigated eyes and -0.0154 ± 0.141 D for non-irrigated eyes (p = 0.40).

The average MRSE on POD1 for irrigated eyes was -0.239 ± 0.533, and -0.264 ± 0.463 for non-irrigated eyes. The average MRSE on POW1 for irrigated eyes was -0.313 ± 0.398, and -0.347 ± 0.406 for non-irrigated eyes. The average MRSE on POM1 for irrigated eyes was -0.232 ± 0.483, and -0.274 ± 0.539 for non-irrigated eyes.

For refractive target measured at POM1 in irrigated eyes, 16 of 21 patients (76.1%) were within ±0.5 D of refractive target, and 21 of 21 (100%) were within ±1.0 D of refractive target. For non-irrigated eyes, 17 of 21 patients (81.0%) were within ±0.5 D of refractive target, and 18 of 21 (85.7%) were within ±1.0 D of refractive target.

Average preoperative pachymetry in the irrigated group was 547 microns, and 557.593 microns in the non-irrigated group. The average post-operative pachymetry was 517.718 microns in the irrigated group and 502.312 microns in the non-irrigated group.

Adjusting for expected pachymetry, irrigated eyes had an average of 15.406 ± 0.347 microns thicker post-operative pachymetry readings compared to the non-irrigated eyes (p= 0.006).

Discussion and Conclusion

By performing stromal irrigation during the SMILE procedure, this study found that irrigated eyes had better UCVA at all post-operative visits. However, this difference was not statistically significant between the two treatment groups. UCVA is key for patients, as it is a marker for how well they will see without the use of spectacles or contacts. Therefore, it is possible that irrigating the eyes of patients during the SMILE procedure may be beneficial in terms of achieving a better UCVA, with regards to the concern that it can reduce patients' post-operative UCVA due to stromal edema [6,7].

Additionally, patients' irrigated eyes had a lower MRSE and deviated less from their plano refractive target compared to the non-irrigated group, although these findings were also not statistically significant.

Finally, the irrigated eyes had a statistically significant increase in corneal pachymetry, measured immediately post-operatively, as compared to non-irrigated eyes. However, the effect of this increased pachymetry on visual outcome was found to not be statistically significant.

This study on the effects of stromal irrigation during the SMILE procedure has limitations, with its biggest being the sample size of the study. A larger sample size would be beneficial to better understand the effects of stromal irrigation on patient outcomes. In conclusion, this study provides valuable insight into the refractive and visual effects of stromal irrigation during the small lenticule extraction (SMILE) procedure and showed that stromal irrigation did not lead to significant difference in UCVA and MRSE between treatment groups but did significantly increase postoperative corneal pachymetry.

Key Points

Does stromal irrigation during the SMILE procedure lead to better refractive and visual outcomes for patients?

Findings Support

This study found that irrigated eyes during the SMILE procedure had non-significant increases in UCVA, MRSE, and decreased deviation from refractive target, as well as a significant increase in corneal pachymetry postoperatively.

Meaning

This study shows that stromal irrigation during the SMILE procedure did not have any benefit with regards to differences in MRSE and UCVA between the two treatment groups, but did significantly impact corneal pachymetry.

Summary Statement

Stromal irrigation during the SMILE procedure leads to a significant increase in patients' corneal pachymetry, but did not significantly affect postoperative UCVA, MRSE, and deviation from preoperative refractive target. The need for stromal irrigation should be determined on a case by case basis and by surgeon preference.

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Conflict of Interest

No conflicting relationship exists for any author.

Bibliography

1. Moshirfar M., *et al*. "Hyperopic small-incision lenticule extraction". *Current Opinion in Ophthalmology* 30.4 (2019): 229-235.

2. Ganesh S., *et al*. "Refractive lenticule extraction small incision lenticule extraction". *Indian Journal of Ophthalmology* 66.1 (2018): 10-19.

3. Shah R. "History and Results; Indications and Contraindications of SMILE Compared With LASIK". *The Asia-Pacific Journal of Ophthalmology* 8.5 (2019): 371-376.

4. Titiyal JS., *et al*. "Learning Curve of Small Incision Lenticule Extraction: Challenges and Complications". *Cornea* 36.11 (2017): 1377-1382.

5. Titiyal JS., *et al*. "Small incision lenticule extraction (SMILE) techniques: patient selection and perspectives". *Clinical Ophthalmology* 12 (2018): 1685-1699.

6. Wang H., *et al*. "Effect of corneal stromal pocket irrigation in small-incision lenticule extraction". *Eye* 34 (2020): 2328-2335.

7. Liu YC., *et al*. "Effect of Intraoperative Corneal Stromal Pocket Irrigation in Small Incision Lenticule Extraction". *BioMed Research International* (2015): 928608.

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