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SMILE and ICL implantation on the ocular surface and meibomian glands in patients with postoperative myopia

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Abstract

Background Objectively compare the changes in ocular surface parameters in myopic patients who have undergone either SMILE or Implantable Collamer Lens (ICL V4c) surgery.

Methods This prospective cohort study enrolled 32 patients (32 eyes) undergoing SMILE surgery and 35 patients (35 eyes) receiving ICL V4c intraocular lenses. Examinations were performed at properative, 1-week, 1-month, and 3-month postoperative time points. The assessments included Schirmer's I Test (SIt), First Non-Invasive Break-Up Time (First-NIBUT), Average Non-Invasive Break-Up Time (Average-NIBUT), Tear Meniscus Height (TMH), Ocular Surface Disease Index (OSDI) score, conjunctival congestion score, meibomian gland loss score, lipid layer analysis score, lid margin opening detection score, and corneal fluorescein staining (CFS) score.

Results Repeated measures ANOVA revealed that SIT, TMH, and First-NIBUT initially decreased and then increased. At three months, SIT levels in the SMILE group were significantly lower than those in the ICL group. From the first month onward, TMH levels in the SMILE group remained significantly lower than those in the ICL group (P < 0.05). OSDI scores initially rose and then fell, with the SMILE group consistently showing higher OSDI levels than the ICL group. Conjunctival congestion scores in the SMILE group fluctuated less, while the ICL group exhibited a clear downward trend, with significant differences starting from the first week (P < 0.05). Over time, scores for meibomian gland loss, lipid layer analysis, and lid margin opening detection were all higher in the SMILE group compared to the ICL group.

Conclusions SMILE surgery has a more pronounced and prolonged impact on the ocular surface and meibomian gland function compared to ICL implantation. Objective dry eye parameters in the ICL group recover more quickly than those in the SMILE group one month post-surgery.

Keywords Small-incision Lenticule extraction, Implantable Collamer Lens, Dry eye disease, Ocular Surface disorders

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Background

Myopia, when left uncorrected, can lead to distant vision deterioration and is the major cause of vision problems globally [1]. Also, uncorrected refractive error is the second leading cause of vision malfunction or blindness, affecting over 108 million people as per 2010 statistics [2]. Importantly, the global prevalence of myopia is estimated to increase by at least 50%, whereas that for high myopia can reach up to 10% [3] by 2050. Since the first report of SMILE in 2011 [4], several studies have been conducted to test its effectiveness, safety, and predictability [5-7]. SMILE has gained widespread acclaim for its effectiveness in correcting myopia [8], offering a lower risk of dry eye post-surgery and improved corneal biomechanical stability after the procedure [9, 10]. However, being a "subtractive" procedure, SMILE has inherent limitations. For example, with higher degrees of myopia, deeper corneal ablation limits the range of treatment and increases aberrations; as a result, SMILE may elevate the risk of myopia regression [11], haze [12], and corneal ectasia [13]. Another notable procedure is Implantable Collamer Lens (ICL) surgery, an effective option for correcting moderate to high myopia [14]. As an "additive" procedure, it is particularly well-suited for patients who want to avoid glasses but are not ideal candidates for corneal surgery. ICL implantation has expanded the range of eligible patients, including those with thin corneas [15] and keratoconus [16]. It provides a high degree of vision correction, reversibility, minimal corneal damage, and reduced impact on the ocular surface. However, while there are limited reports on ocular surface changes post-ICL surgery, cases of postoperative dry eye do still occur [17].

Previous studies have mainly concentrated on the quality of visual recovery, often neglecting the condition of the ocular surface following myopia surgery. Dry eye is a common postoperative complication of refractive surgery, with patients frequently experiencing symptoms such as dryness, sensation of a foreign body in the eyes, redness, pain, and eye fatigue [18, 19]. At the same time, it may cause blurred vision and vision fluctuations, affecting the patient's postoperative quality of life [20]. However, the underlying patho-physiological mechanism of the dry eye remains unclear.Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles [21]. Several etiological factors are thought to contribute to this eye condition, such as damage to the sub-basal nerve plexus of the corneal epithelium, reduced corneal sensation [22], disruption of the limbal nerve trunks by the surgical incision orientation, and adverse reactions of pre- and postoperative eye drops to the corneal epithelium [23–25].

The Keratograph 5 M (OCULUS, Wetzlar, Germany) non-invasive ocular surface comprehensive analyzer is notable for its non-invasiveness, high accuracy, excellent repeatability, and strong patient acceptance [26]. It automatically and objectively measures a range of parameters, including First non-invasive break-up time(First-NIBUT), Average-NIBUT, TMH, corneal fluorescein staining (CFS), conjunctival redness, lipid layers, and meibomian glands. These features enable precise diagnosis and classification of dry eye syndrome. Consequently, this study uses the Keratograph 5 M to assess ocular surface parameters and meibomian glands, comparing and analyzing differences in these metrics after various myopia correction procedures.

In recene years, the incidence of dry eye has been increasing year by year due to the popularity of refractive errors surgery. As the maim type of dry eye, hyperevaporative dry eye is mostly caused by meibomian gland dysfuncion (MGD) resulted from abnormal quality or quantity of lipid layer [27]. Researchers have found that MGD also plays an important role in postoperative dry eye [28].

Previous studies on postoperative dry eye have predominantly focused on comparisons among similar surgical types, with few investigations examining the effects of ICL surgery or comparing the impact of ICL surgery with laser-based procedures on postoperative ocular surface health. Therefore, we conducted a prospective cohort study to objectively evaluate short-term changes in ocular surface and meibomian gland function following two types of myopia correction surgeries: SMILE and ICL implantation.

Methods

Study population

A total of 67 eligible myopic patients (67 eyes), who were treated at Taiyuan Central Hospital from January 2023 to January 2024 were randomly enrolled in this study and divided into two groups, namely the SMILE group with 32 cases (32 eyes) and the ICL group with 35 cases (35 eyes). The SMILE group included 16 male and 16 female patients, with an average age of 27.5 ± 6.90 years. Likewise, the ICL group had 11 male and 24 female patients, with an average age of 28.6 ± 5.6 years.

Inclusion criteria [19]: (1) provide consent to undergo myopia laser correction surgery with no surgical contraindications; (2) absence of any pre-surgery dry eye symptoms such as foreign body sensation, eye dryness, burning sensation, or vision fluctuation; (3) having normal eyelid structure and morphology with normal appearance and function of the lacrimal puncta, and unobstructed tear ducts; (4) provide consent for the surgical method, postoperative medication plans, and necessary examinations; (5) must be able to attend follow-up appointments at the hospital as scheduled, and (6) should not use of any eye drops within 4 h before the examination.

Exclusion criteria [29]: (1) history of systemic diseases such as cardiovascular and cerebrovascular diseases, diabetes, rheumatoid arthritis, gout, and neuromuscular diseases affecting blinking, like Bell's palsy and Parkinson's disease; (2) involvement in long-term outdoor work or prolonged stay in air-conditioned environments; (3) long-term night driving; (4) extensive computer usage; (5) existing moderate to severe dry eye symptoms, and (6) patients who could not maintain the scheduled follow-up visits.

In addition, patients who developed keratoconjunctivitis during the surgery, or those who developed postoperative complications such as inappropriate rotation of the intraocular lens requiring a secondary surgery; and patients who used random medications on their own without following the postoperative medical instructions are also excluded from this study.

This prospective cohort study was approved by the Taiyuan Central Hospital's Institutional Review Board, strictly conforming to the tenets of the Helsinki Declaration.

Ocular examinations

Examination sequence

All candidates meeting the inclusion criteria were required to fill out an additional Ocular Surface Disease Index (OSDI) questionnaire form before undergoing ophthalmic examinations to record the pre-treatment conditions as a reference. The patient's demographics, including age, gender, occupation, and history of contact lens wear, were also collected. All participants underwent a comprehensive eye examination for uncorrected visual acuity, best-corrected visual acuity (BCVA), slit-lamp examination, intraocular pressure, indirect ophthalmoscopy, fundus photography, macular OCT examination, corneal topography, and the Oculus Keratograph 5 M assessment. The non-anesthetic Schirmer's I test (SIT) was the last step in the whole process of clinical examinations. The same procedures were repeated at one week, one month, and three months postoperatively to evaluate the impact of the two surgical methods on dry eye at each time point.

OSDI

OSDI score [30] was developed by the International Dry Eye workgroup and consists of three sections - ocular discomfort, visual function, and environmental triggers. The OSDI score was calculated as follows: (Sum of the scores for each question \times 25) / (Number of questions Page 3 of 10

answered). A higher score suggests a more severe impact of dry eye symptoms.

Oculus keratograph 5 M

The Oculus Keratograph 5 M was used for comprehensive analyses of NIBUT, TMH, conjunctival redness, CFS score, lipid layer analysis score, lid margin opening scores, and meibomian gland loss scores. All examinations were conducted independently by the same operator in a dark room. Each subject's affected eye was examined three times with a ten-minute interval between each examination.

NIBUT

In this process, the subject was instructed to naturally open the eyes and blink twice. Then, the device automatically started to detect the tear film break-up location and time for the concerned eye. The device recorded the patient's initial tear film break-up time, the average tear film break-up time, and the classification of tear film stability and plotted a distribution map for all selected parameters identifiable by specific colors [31].

ТМН

The device's built-in measurement tool, equipped with a scale feature, was used to measure the tear meniscus height just below the center of the pupil in the affected eye. The same ophthalmologist conducted this measurement three times, and the results were organized from lowest to highest value.

Hyperemic index

Focusing on the corneal surface and covering it with a diffuser plate marker, the subject was instructed to keep their eyes wide open (scanning area \geq 4 mm²) during the photo session. After capturing the image, the device automatically assessed the degree of conjunctival congestion. This assessment was standardized and quantified, with a scale of 0 indicating minimal congestion, 1 and 2 indicating normal levels, and values above 2 indicating abnormal congestion. Conjunctival congestion, as a clinical indicator of ocular surface inflammation, provides insight into the extent of postoperative ocular surface inflammation and dry eye.

CFS score

The subjects' conjunctival sacs were instilled with a 1% sodium fluorescein solution (Tianjin Jingming, China) and were instructed to blink several times. The examination interface for corneal fluorescein staining was then accessed, where the image was automatically focused and captured using cobalt blue light. The system's built-in image processing software counted the number of fluorescein-stained spots on the cornea and assigned a

score. The cornea was divided into five regions (superior, inferior, central, nasal, and temporal), with a maximum total score of 12 points [32]. The scoring scale was as follows: 0 points for no staining; 1 point for 5 spots; 2 points for 6–15 spots; 3 points for 16–30 spots. An additional 2 points were given for the presence of corneal filaments, and 1 point for one patch of staining in any region, or 2 points for two or more patches of staining in any region.

Meibomian gland imaging and assessment

Meibomian Gland Loss Scoring: The ocular surface analyzer was first set to infrared photography mode, and then the upper and lower eyelids were flipped to expose the conjunctival surface and adjust the focal length as needed. The images were automatically analyzed and processed by the system. Meibomian gland loss is graded and scored based on its extent: 0 points for no loss; 1 point for loss covering less than 1/3 of the total area; 2 points for loss covering between 1/3 and 2/3 of the total area; and 3 points for loss covering 2/3 or more of the total area [33].

Lipid Layer Analysis: The instrument was focused on the tear film lipid layer while the patient blinked naturally. The lipid layer [34]was then assessed for its color, structure, and granularity, and classified into three grades: Grade 1 for a thin, blurred, and dull-colored lipid layer; Grade 2 for a normal, clear lipid layer with a rich color palette; and Grade 3 for a thick, highly clear lipid layer with very vibrant color. An excessively thin lipid layer indicated an abnormality in meibomian gland function.

Lid Margin Opening Detection Scoring: The patient was instructed to look upward and press the middle third area of the lower eyelid, where there are 8 meibomian glands, using the thumb. The consistency of the secretion from each gland was scored on a 0-24 point scale to semi-quantitatively evaluate the properties of the meibum following this gradation system [35]: 0 points for clear meibum; 1 point for turbid meibum; 2 points for turbid meibum with cloudy particles or debris; and 3 points for thick meibum resembling toothpaste.

Shirmer I test (SIT)

Without surface anesthesia, a tear fluid detection filter strip (5×40 mm, Tianjin Jingming, China) was placed in the conjunctival sac of the lower eyelid between the outer and middle thirds. The subjects were then instructed to gently close their eyes for 5 min when the device measured and recorded the length of the tear film area.

Surgical procedures and postoperative treatment SMILE procedure for refractive lenticule extraction

The SMILE procedure was performed as described previously [4, 36]. Briefly, the 500 kHz femtosecond laser system (Visumax; Carl Zeiss, Germany) was set to 110–120 μ m as the intended cap thickness and 7.8 mm as the intended cap diameter. A small tunnel incision (2 mm) was created at a 90° angle, and the refractive lenticule was extracted through the incision hole using a spatula. For all myopic corrections, the optical zone size was 6.8 mm. After the surgery, all patients were administered 0.5% gatifloxacin eye drops 4 times/d for 10 days, and 0.1% fluorometholone eye drops tapered every 3 days from 8 times/d to once a day within 3 weeks.

ICL surgical procedure

A 3.0 mm clear corneal incision [37] was made in the upper cornea, and an appropriate amount of sodium hyaluronate (Bausch & Lomb, USA) was injected into the anterior chamber. Using an injector (STAAR Surgical), the ICL V4C intraocular lens was pushed through the 3.0-mm corneal incision. After placing the ICL in the posterior chamber, the surgeon completely removed the viscoelastic agent from the eye using a balanced salt solution, sealed the incision, and covered the eye with a dressing. Surgeries were uneventful and no intraoperative complications were observed afterward. Following surgery, 0.1% Tobramycin dexamethasone (a combination of antibacterial and steroidal medication) was prescribed four times daily for 3 days followed by fluorometholone eyedrops tapered gradually over 2 weeks. Antibiotic eyedrops (0.5% Ofloxacin; Japan) were then prescribed four times daily for 1 week, along with non-steroidal antiinflammatory eyedrop Pranoprofen four times daily for 2 weeks, and artificial tears four times daily for one month.

Statistical analysis

The Shapiro-Wilk test was used for normality analyses. The mean (standard deviation, SD) and median (quartiles, IQR) were used to describe age, scores, and other measured data. T-test and Mann-Whitney U test were used for intergroup comparisons. The gender was described using the number of cases (percentage; %) and compared between the groups using the chi-square ($\chi 2$) test. Repeated measure analysis of variance was used to describe the measured parameters and scores of patients at different time points across the groups. For indicators that did not conform to the sphericity test, Greenhouse-Geisser correction was applied. Indicators without the time-group interaction were described using main effects to show their intergroup differences, while indicators with positive interactions were described using separate effects. Paired t-tests were used to compare differences between the overall population and different groups at different time points. In this study, the significance level α was set at 0.05. All statistical analyses and graph plotting were performed using SPSS 27.0 and R 4.4.1 software packages.

Results

Comparison of baseline characteristics of patient populations

As detailed in Table 1, there were no significant differences in age and gender distributions between the SMILE and the ICL groups (P>0.05). There were no significant changes in terms of OSDI (score), logMAR UDVA, SE(D) level, SIT (mm/5 minutes), first-NIBUT (S), average-NIBUT (S), TMH (mm), conjunctival congestion score, CFS, meibomian gland loss score, lipid layer analysis score, and meibomian gland orifice detection score between the two groups at baseline(P>0.05).

Comparisons of indicators across the groups

SIT and TMH met the assumptions of the sphericity test (The specific detailed data description is presented in Supplementary Table 2), while first-NIBUT and average-NIBUT were corrected using the Greenhouse-Geisser method (The specific detailed data description is presented in Supplementary Table 3) and the corrected results were reported. The results of the repeated measures ANOVA showed that, among the four indicators, only average-NIBUT did not exhibit a time effect $(F_{SIT-time} = 14.754 \ P < 0.001; \ F_{first-NIBHUT-time} = 11.601 \ P < 0.001; \ F_{average-NIBHUT-time} = 2.744, \ P = 0.052 \ F_{TMH-time}$ = 66.620, P < 0.001). As shown in Fig. 1 and, all three indicators displayed a decreasing trend initially before increasing further. Paired t-tests revealed significant differences in SIT between the baseline and one-week or one-month time points. Moreover, SIT scores at oneweek and one-month time points were significantly different compared to the three-month scores. In the

Table 1 Preoperative demographic data and clinical characteristics of the SMILE group and ICL group

variable	Smile group	ICL group	<i>P</i> value
	n=32		
Gender(male/female)	16/16	11/24	0.122
Age	27.5 ± 6.9	28.6 ± 5.6	0.410
log MAR UDVA	1(0.7,1)	1(1,1)	0.102
SE(D)	-6.29 ± 1.42	-6.64 ± 0.92	0236
OSDI	6.12 ± 2.11	7.17 ± 2.95	0.134
SIT(mm/5min)	16.28 ± 2.20	15.86 ± 5.43	0.682
First NIBUT(S)	13.10+4.52	11.44 ± 4.81	0.15
Average NIBUT(S)	16.17 ± 2.17	14.92 ± 3.12	0.064
TMH(mm)	0.35 ± 0.05	0.36 ± 0.05	0.602
conjunctival congestion score	1.19 ± 0.55	1.03 ± 0.33	0.155
CFS score	0	0	1.000
Meibomian Gland Loss Score	1(1,2)	1(1,2)	0.139
Lipid Layer Analysis Score	1(0,1)	1(0,1)	0.945
Lid Margin Opening scores	0(0,1)	0(0,1)	0.889

SMILE, Small-incision lenticule extraction; ICL, implantable collamer lens; N number of eyes; OSDI, ocular surface disease index; SIT, Schirmer I test; CFS, corneal fluorescein staining; NIBUT, non-invasive breakup time; TMH, tear meniscus height

SMILE group, there was a significant difference in SIT scores between baseline and one-week, one-month, or three-month. Whereas, in the ICL group, differences in scores across all time points were consistent with the overall group (P < 0.05); In the overall population, first-NIBUT differed significantly across all time points except for the baseline and three-month. In the SMILE group, differences between different time points were consistent with the overall population, while in the ICL group, the level of first NIBUT at one week was significantly lower than that at the other three time points (P < 0.05). Among the overall population, TMH values varied significantly across all time points. In the SMILE group, TMH values were significantly different for all time points except for baseline and three-month groups. In the ICL group, a significant difference in TMH values was observed for any two-time points, except for the baseline and onemonth time points (P < 0.05).

Comparison of time and group differences for scoring indicators

According to the results of the sphericity test (The specific detailed data description is presented in Supplementary Table 2), the scores for conjunctival congestion and lipid layer analysis met the criteria of the sphericity test. While OSDI, CFS, meibomian gland loss score, and meibomian gland orifice detection scores were corrected using the Greenhouse-Geisser method (The specific detailed data description is presented in Supplementary Table 3). The results of the repeated measures ANOVA revealed that, among the six indicators shown in Fig. 2, except for CFS, all other indicators had a time effect ($F_{OSDI-time} = 29.370, P < 0.001$; $F_{conjunctival congestion score-time} = 13.320, P < 0.001$; $F_{Lipid Layer Analysis Score-time} = 27.019, P < 0.001$; $F_{Lid Margin Opening scores-time} = 34.176, P < 0.001$).

Importantly, the OSDI scores initially increased before decreasing, showing significant differences across all time points in the overall population. In the SMILE group, significant differences were observed among all time points except between one week and one month and between the one-month and three-month time points. In the ICL group, significant differences were found between any two time points except between baseline and three-month (P<0.05). (The specific detailed data description is presented in Supplementary Tables 1 and 4).

At baseline, the conjunctival congestion score was significantly higher compared to one week, one month, and three months in the overall population (P<0.05). In the SMILE group, the fluctuation was less pronounced, with no significant differences between time points (P>0.05). In the ICL group, there was a clear downward trend, with significant differences among all time points except between one-week and one-month time points (P<0.05).



Fig. 1 Differences in objective measurement indicators at different times and between different groups

(The specific detailed data description is presented in Supplementary Tables 1 and 4).

The score for meibomian gland loss showed a slow increase until January. From January to March, the SMILE group exhibited an upward trend, while the ICL group showed a downward trend, with significant differences observed in both groups (P<0.05). (The specific detailed data description is presented in Supplementary Tables 1 and 4).

The lipid layer analysis score showed an overall trend of increasing followed by decreasing, with significant differences among all time points except between one week and one month. In the SMILE group, significant differences were found among all time points except between one week and one month and between one week and three months. In the ICL group, significant differences were observed among all time points (P<0.05). (The specific detailed data description is presented in Supplementary Tables 1 and 4).

The score for meibomian gland orifice detection showed an overall trend of increasing followed by decreasing, with significant differences among all time points except between one week and one month. In the SMILE group, significant differences were noted between



Fig. 2 Differences in scoring indicators at different times and between different groups

baseline and all subsequent time points. In the ICL group, significant differences were found among all time points except between baseline and three-month (P<0.05). (The specific detailed data description is presented in Supplementary Tables 1 and 4).

Discussion

In this study, SIT, First-NIBUT, and TMH displayed an initial decrease followed by an increase over time. In the SMILE group, First-NIBUT significantly decreased one week postoperatively but returned to normal levels by three months. In the ICL group, First-NIBUT also decreased at one week but normalized by one month. The trend for Average-NIBUT generally mirrored that of First-NIBUT.

For TMH, the SMILE group showed a significant decrease at one week postoperatively, gradually recovering to preoperative levels by three months. Conversely, in the ICL group, TMH experienced a transient decrease at one week but returned to preoperative levels by one month. One week postoperatively, the SMILE group's TMH decline was attributed to lipid layer thinning (as detailed in the lipid layer scores section), leading to excessive tear film evaporation compared to preoperative levels. There was a correlation among TMH, NIBUT, and the lipid layer. The decrease in tear film stability after SMILE surgery can be attributed to:

Corneal ablation alters the corneal curvature, affecting the stability and distribution of the tear film, which increases tear evaporation and shortens NIBUT.

The inevitable cutting of corneal nerves during surgery weakens their neurotrophic effect on epithelial cells, reduces blink rate, and diminishes both normal and reflexive tear production, ultimately leading to decreased TMH and NIBUT.

In the ICL group, while TMH and NIBUT decreased at one week and one month postoperatively, they generally returned to preoperative levels by three months, aligning with findings from other studies [38]. ICL implantation, which involves placing an artificial lens, generally has a smaller impact on tear film stability. However, the clear corneal incision on the temporal side might cause more significant disruption to trigeminal nerve fibers and related neurotransmitters, leading to inflammation in the conjunctival epithelial cells, reduced local corneal sensation, and shortened NIBUT, thus causing tear film instability. Conversely, the incision on the upper side tends to be less disruptive to corneal nerves and provides better protection. Therefore, opting for an upper incision, rather than a nasal or temporal one, is recommended to minimize damage to corneal sensory nerves and enhance patient comfort [23, 39].

The OSDI questionnaire is commonly used to assess the subjective experience of dry eye symptoms. Its reliability has been confirmed by several studies [40, 41]. In this study, the OSDI score in the SMILE group significantly increased at one week postoperatively, which was consistent with Li's study [42], and then decreased but could not return to the preoperative level by three months, which was inconsistent with Li's study. The change from a low OSDI score preoperatively to a high score postoperatively may be due to changes in objective dry eye parameters such as NIBUT, SIT, and TMH, as well as the need for patients to adapt to changes in refractive status and visual habits before and after surgery.

Patients in the ICL group also experienced noticeable dry eye symptoms early postoperatively, with a significant increase in OSDI scores at one week postoperatively, but recovery to preoperative levels by three months. This may be due to the relatively less invasive nature of ICL implantation, which involves fewer procedures and shorter surgical times, resulting in less damage to the ocular surface [43]and quicker symptom resolution. However, further research is needed to confirm this.

Ocular surface inflammation is crucial in the pathophysiology of dry eye [44]. Conjunctival congestion, an indicator of early conjunctival inflammation after refractive surgery, is closely related to the severity of ocular inflammation [45]. In this study, no significant difference was observed in conjunctival congestion scores in the SMILE group before and after surgery. In contrast, the ICL group showed a clear downward trend with significant differences. Possible reasons include: (1) Damage to corneal nerves from refractive surgery can trigger ocular surface inflammatory responses, leading to conjunctival congestion and other inflammatory manifestations. (2) Although ICL implantation is an intraocular procedure, it causes less nerve damage compared to the temporal clear corneal incision. The superior clear corneal incision results in less nerve damage compared to the temporal incision. The recovery of conjunctival congestion scores to preoperative levels by three months postoperatively suggests that the ocular surface inflammatory response is temporary and recovers relatively quickly.

The preoperative and postoperative CFS scores did not show significant differences between the two groups, indicating that different surgical techniques have minimal impact on keratofluorescein staining scores.

Changes in the ocular surface after corneal refractive surgery can affect the meibomian glands [46]. This study observed a gradual increase in the meibomian gland loss score, which was significantly higher in the SMILE group than in the ICL group by the third month. The quality and quantity of meibum secreted by the meibomian glands influence the tear film lipid layer. Obstructions or changes in meibum properties directly affect the lipid layer quality, leading to decreased tear film stability [47]. Different meibum types impact tear film stability differently, with pasty secretions often indicating lipid deficiency in dry eye patients [48]. The scores of lid margin opening detection and lipid layer analysis show a trend of first increasing and then decreasing, indicating that these two deficiencies occur earlier than the loss of meibomian glands. For the lipid layer scores, during the period from one month to three months, the recovery in the SMILE group was later than that in the ICL group. Similarly, the scores for lid margin opening detection also followed this pattern of change. By the end of the third month, the lipid layer scores and lid margin opening detection in both groups had generally returned to the preoperative levels.

It is well known that the tear film stability is closely related to the MG function [49]. In this study, the MGrelated parameters also presented a consistent trend with BUT and TMH values. Lid margin abnormalities and the quantity and quality of MG secretion changed obviously after surgeries. Meanwhile, the destruction of the ocular surface lipid layer was relatively severe in the short term, which was more likely to be the cause of postoperative dry eye. Our results are consistent with the reports of Han et al. [50]. which analyzed preoperative and postoperative parameters of DE and MGD and found that the MGD changes significantly influenced the stability of tear film and caused the postoperative dry eye. The possible reason for the significantly higher meibomian gland loss in the SMILE group compared to the ICL group is that the ocular surface structure becomes irregular after corneal ablation, leading to uneven distribution and reduced adhesion of the tear film's lipid layer. It could also be due to a decrease in the amount of lipid secreted by the meibomian glands caused by reduced blinking and diminished corneal sensation. The ICL implantation procedure involves changing the refractive state by implanting an artificial lens without altering the ocular surface structure, hence having a smaller impact on the stability of the tear film, resulting in less meibomian gland loss and a lower incidence of dry eye postoperatively.

The major goal of this study was to enhance personalized preoperative planning and surgical method selection, providing a diagnostic and treatment strategy to effectively reduce the incidence of refractive surgeryassociated postoperative dry eye.

Conclusions

In summary, SMILE surgery appears to have a more severe and prolonged impact on the ocular surface and meibomian gland function compared to ICL implantation. At one week post-surgery, both groups exhibited decreases in TMH, NIBUT, and SIT, as well as increases in lipid layer scores, lid margin opening scores, and OSDI scores, indicating altered dry eye parameters. The ICL group's dry eye parameters recovered faster than those in the SMILE group at one month. Short-term structural changes in the meibomian glands were minimal, but by the third month, meibomian gland loss scores increased, with the SMILE group showing significantly higher scores than the ICL group. This study offers valuable insights into ocular surface changes in myopic patients following different refractive surgeries and provides a foundation for further research into the relationship between these changes and dry eye syndrome. Future research should involve a larger sample size, extended follow-up periods, and correlation analyses to explore the temporal relationships among various indicators.

Abbreviations

SMILE ICL	Small-incision lenticule extraction Implantable collamer lens
Ν	Number of eyes
OSDI	Ocular surface disease index
SIT	Schirmer I test
CFS	Corneal fluorescein staining
NIBUT	Non-Invasive Break-Up Time
BUT	Break-Up Time
ТМН	Tear meniscus height
DE	Dry eye
BCVA	Best-corrected visual acuity
UDVA	Uncorrected Distance Visual Acuity
SD	Standard deviation

Supplementary Information

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Supplementary Material 1

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Author contributions

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Data availability

Data is provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Qelsinki, and approved by the Ethics Committee of Taiyuan Central Hospital.Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

Clinical trial number

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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References

- 1. Holden BA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. Ophthalmology. 2016;123:1036–42.
- Bourne RRA, et al. Causes of vision loss worldwide, 1990–2010: a systematic analysis. Lancet Global Health. 2013;1:e339–49.
- Si Yao Wang, Yu Li, Jing Zhang, et al. Domestic and international research status and trend of adolescent myopia: bibliometrics based analysis. Int Eye Sci. Sep. 2023;23:9.
- Sekundo W, Kunert KS, Blum M. Small incision corneal refractive surgery using the small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism: results of a 6 month prospective study. Br J Ophthalmol. 2011;95:335–9.
- Wang Y, Ma J. Future developments in SMILE: higher degree of myopia and hyperopia. Asia Pac J Ophthalmol (Phila). 2019;8:412–6.
- Jorge. Verónica, Olena. Small incision lenticule extraction (SMILE) in the correction of myopic astigmatism: outcomes and limitations - an update. Eye Vis 2017 Nov 15:426.
- Randleman JB. Small incision Lenticule extraction (SMILE): what now? What Next? Ophthalmol. 2020;127:1035–6.
- Dishler JG, Slade S, Seifert S, Schallhorn SC. Small-incision Lenticule extraction (SMILE) for the correction of myopia with astigmatism: outcomes of the United States Food and Drug Administration Premarket approval clinical trial. Ophthalmology. 2020;127:1020–34.
- Liu Y-C, et al. Comparison of tear proteomic and neuromediator profiles changes between small incision lenticule extraction (SMILE) and femtosecond laser-assisted in-situ keratomileusis (LASIK). J Adv Res. 2021;29:67–81.
- Shetty R, et al. Corneal biomechanical changes and tissue remodeling after SMILE and LASIK. Invest Ophthalmol Vis Sci. 2017;58:5703–12.
- 11. Wang S, Dai J, Chu R, Zhou X. Long-term outcome of epi-LASIK for high myopia. Eur J Ophthalmol. 2012;22(Suppl 7):S98–105.
- Rosman M, Ali óJL, Ortiz D, Perez -Santonja, Juan J. Comparison of LASIK and Photorefractive Keratectomy for Myopia from – 10.00 to – 18.00 diopters 10 years after surgery. J Refract Surg. 2010;26:168–76.
- Randleman JB, Russell B, Ward MA, Thompson KP, Stulting RD. Risk factors and prognosis for corneal ectasia after LASIK. Ophthalmology. 2003;110:267–75.
- Sanders DR, et al. Implantable contact lens for moderate to high myopia: phase 1 FDA clinical study with 6 month follow-up. J Cataract Refract Surg. 1998;24:607–11.
- Bhikoo R, Rayner S, Gray T. Toric implantable collamer lens for patients with moderate to severe myopic astigmatism: 12-month follow-up. Clin Exp Ophthalmol. 2010;38:467–74.

- Abdelmassih Y, et al. Toric ICL Implantation after Sequential Intracorneal Ring segments implantation and corneal cross-linking in Keratoconus: 2-Year follow-up. J Refract Surg. 2017;33:610–6.
- 17. Chen H, Feng X, Niu G, Fan Y. Evaluation of Dry Eye after Implantable Collamer Lens surgery. Ophthalmic Res. 2021;64:356–62.
- AmbrósioR, TervoT, WilsonSE. LASIK-associated dry eye and neurotrophic epitheliopathy: pathophysiology and strategies for prevention and treatment. J Refract Surg. 2008;24(4):396–407.
- Zhang C, Ding H, Chen LL, et al. Comparison of short-term changes in Dry Eye indexes between Femtosecond Lenticule extraction and small incision Lenticule Extraction[J]. Chin J Optometry Ophthalmol Visual Sci. 2018;20(12):725–30. https://doi.org/10.3760/cmaj.issn.1674-845X
- Fakih D, et al. Chronic dry eye induced corneal hypersensitivity, neuroinflammatory responses, and synaptic plasticity in the mouse trigeminal brainstem. J Neuroinflammation. 2019;16:268.
- Craig JP, Nichols KK, Akpek EK, Caffery B, Dua HS, Joo CK, Liu Z, Nelson JD, Nichols JJ, Tsubota K, et al. TFOS DEWS II definition and classification report. Ocul Surf. 2017;15:276–83.
- 22. Liu Y, et al. Corneal subbasal nerve analysis using in Vivo Confocal Microscopy in patients with Dry Eye: analysis and clinical correlations. Cornea. 2019;38:1253–8.
- Mao Zu Hong, Wang Le, Shao Yi.et al. Effects of different incision in phacoemulsification on corneal nerve injury and tearfilm function. Rec Adv Ophthalmol. December 2013;33(12).
- 24. Liu Z. Luo Lihui, Zhang Zhenping.Tear film changes after phacoemulsification. Chin J Ophthalmol May 2002;138(5).
- Bo Lu, Jin Song Zhang. The effect of artificial tears on tear film changes after phacoemulsification and intraocular lens implantation. Int J Ophthalmol Aug 2007;7(4).
- Tian L, Qu J-H, Zhang X-Y, Sun X-G. Repeatability and Reproducibility of Noninvasive Keratograph 5 M Measurements in Patients with Dry Eye Disease. J Ophthalmol. 2016;8013621(2016).
- Sabeti S, Kheirkhah A, Yin J, et al. Management of meibomian gland dysfunction:a review[J]. Surv Ophthalmol. 2020;65(2):205–17. https://doi.org /10.1016/j.survoPhthal.2019.
- Song P, Sun Z, Ren S, Yang K, Deng G, Zeng Q, et al. Preoperative management of MGD alleviates the aggravation of MGD and dry eye induced by cataract surgery: a prospective, randomized clinical trial. BioMed Res Inter. 2019;2019:1–10.
- Huang WJ, Yan J, Yu Q. Comparison of postoperative ocular surface indicators between small incision Lenticule extraction and Photorefractive Keratectomy in myopic Patients[J]. J Chin Physician. 2021;7(237). https://doi.org/10.3760/c ma.cn431274-20200529-00693
- Ozcura F, Aydin S, Helvaci MR. Ocular surface disease index for the diagnosis of dry eye syndrome. Ocul Immunol Inflamm. 2007;15:389–93.
- Anji W. et al. Assessment of Lower Tear Meniscus. Optometry and vision science: official publication of the American Academy of Optometry. 2016;93.
- Hara, S. et al. The impact of tear functions on visual outcome following keratoplasty in eyes with keratoconus. Graefes Arch Clin Exp Ophthalmol. 2013;251:1763–1770.
- Koh YW, Celik T, Lee HK, Petznick A, Tong L. Detection of meibomian glands and classification of meibography images. J Biomed Opt. 2012;17:086008.
- 34. Cui G, et al. Changes of dry eye parameters after small incision lenticule extraction surgery in patients with different ocular surface disease index scores. Sci Rep. 2024;14:863.

- Tomlinson A, Bron AJ, Korb DR et al. The international workshop on meibomian gland dysfunction: report of the diagnosis sbucommittee[J]. Invest ophthalmol Vis Sci. 2011;52(4):2006–2049.
- Ang M, Tan D, Mehta JS. Small incision lenticule extraction (SMILE) versus laser in-situ keratomileusis (LASIK): study protocol for a randomized, noninferiority trial. Trials. 2012;13:75.
- Chen Xun MH, Wang, Xiaoying, et al. Comparison of early changes in and factors affecting vault following posterior chamber phakic Implantable Collamer Lens implantation without and with a central hole (ICL V4 and ICL V4c)[J].
 BMC Ophthalmol. 2016;16(1):161. https://doi.org/10.1186/s12886-016-0336-8
- Xu J. Guo Haike.Analysis of the effects of implantable contact lens and femtosecond laser small incision lenticule extraction for high myopia on ocular surface. J OTOLARYNGOL OPHTHAL Shandong UNIV. Aug 2017;31(4).
- Botelho SY, Hisada M, Fuenmayor N. Functional innervation of the lacrimal gland in the cat. Origin of secretomotor fibers in the lacrimal nerve. Arch Ophthalmol. 1966;76:581–8.
- 40. Dougherty BE, Nichols JJ, Nichols KK. Rasch analysis of the ocular surface Disease Index (OSDI). Invest Ophthalmol Vis Sci. 2011;52:8630–5.
- Fydanaki O, Chalkiadaki E, Tsiogka A, Gartaganis PS, Karmiris E. Preoperative dry eyes disease in cataract patients with deficient tear break up time: evaluation of OSDI questionnaire, its subcategories and Keratograph 5 M device results. Int Ophthalmol. 2022;42:3017–25.
- Li M, et al. Comparison of dry eye and corneal sensitivity between small incision lenticule extraction and femtosecond LASIK for myopia. PLoS ONE. 2013;8:e77797.
- Igarashi A, Shimizu K, Kamiya K. Eight-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. Am J Ophthalmol. 2014;157:532–e5391.
- Knop E, Knop N. [Inflammation in Dry Eye Disease Information on Diagnostic Testing and Therapy using the scientific online information platform OSCB-Berlin.org]. Klin Monbl Augenheilkd. 2020;237:627–36.
- 45. Ganesalingam K, Ismail S, Sherwin T, Craig JP. Molecular evidence for the role of inflammation in dry eye disease. Clin Exp Optom. 2019;102:446–54.
- Jung JW, Kim Jung Yong. Assessment of meibomian glands and tear film in post-refractive surgery patients[J]. https://doi.org/10.1111/ceo.12993
- 47. Bron AJ, Tiffany JM, Gouveia SM, Yokoi N. Voon, L. W. Functional aspects of the tear film lipid layer. Exp Eye Res. 2004;78:347–60.
- Chhadva P, Goldhardt R, Galor A. Meibomian Gland Disease: the role of Gland Dysfunction in Dry Eye Disease. Ophthalmology. 2017;124:S20–6.
- Chen H,Xueyan, Feng G, Niu et al. Evaluation of Dry Eye after Implantable Collamer Lens Surgery.Ophthalmic Res 2021;64:356–362. https://doi.org/10.1 159/000511197
- Han KE, Yoon SC, Ahn JM, Nam SM, Stulting RD, Kim EK, et al. Evaluation of dry eye and meibomian gland dysfunction after cataract surgery. Am J Ophthalmol. 2014;157(6):1144–e501.

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