Removing Soft Contact Lenses 1 day vs. 1 month before Microkeratome Laser In Situ Keratomileusis Procedure: Functional Outcomes And Results

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Abstract

Purpose

To compare the outcomes, safety, efficacy, and predictability of microkeratome laser in situ keratomileusis (LASIK) 24 hours and one month or more after removing soft contact lenses.

Setting: ULTRALASIK Eye Center, Dubai, United Arab Emirates.

Methods

The patients were divided based on the time of discontinuation of the soft contact lenses before LASIK (Group 1 at 24 hours and Group 2 at one month or longer), and the two groups were well matched. Schirmer's testing, corrected distance visual acuity, uncorrected distance visual acuity, manifest refraction spherical equivalent, and infection rate were evaluated preoperatively and at one week, one month, and six months after treatment.

Results

Group 1 (G1) comprised 1025 eyes, and group 2 (G2) had 1052 eyes. The groups were comparable preoperatively. The overall-mentioned outcomes were comparable between groups with uncorrected distance visual acuity of -0.084+/-0.12 logMAR in G1 and -0.078+/-0.17 logMAR in the G2 at 6 months (P=0.322). Schirmer's testing results were also comparable with no evidence of increased risk of dry eyes or non-inflammatory complications in any of the groups on follow-up visits at 1 week (P=0.421), 1 month (P=0.101), and 6 months (P=0.399) postoperatively. Finally, no infectious complications were recorded in either of the groups.

Conclusion

With the absence of corneal warpage, no statistical or clinical difference in microkeratome LASIK outcomes and safety was spotted between the groups despite the difference in SCL discontinuation time before the procedure.

Introduction

Soft contact lenses (SCL) have been used for refractive problems by more than 150 million people worldwide[1]. SCL use requires compliance and good hygiene; it is well known to cause many infectious and non-infectious complications[2]. Furthermore, SCL are not a definitive treatment for refractive errors.

Actually, for people seeking to reduce the need for spectacles or SCL and even seeking a nearly definitive treatment for their refractive problems, Laser In-Situ Keratomileusis (LASIK) has been one of the best options[3, 4]. In addition, many previous SCL users seek to do Laser vision correction[5, 6]. However, SCL use might affect the procedure's outcome due to inducing corneal changes. Moreover, it can cause

modifications in corneal astigmatism, shape, thickness, curvature, and aberrations. These effects could vary according to the material used as well as the duration of SCL use and may last for weeks.[7–9]

Therefore, different recommendations have been suggested on the SCL removal duration before the preoperative evaluation. They vary from 1 day, according to the Royal College of Ophthalmology, to 2 weeks according to the Food and Drugs Administration[10, 11]. Thus, no specific guidelines describe the precise time for contact lenses removal before refractive surgery. Most ophthalmologists consider a period of at least 3 to 7 days as sufficient[12, 13]. The variation in waiting periods may cause stress for patients, especially those accustomed to a spectacles-free lifestyle and planning for LASIK.

This study compared LASIK's outcomes, safety, efficacy, and predictability after removing the SCL 24 hours and one month or more before the procedure in a large, diverse sample of patients.

Patients And Method

In this retrospective cohort study, 2077 myopic eyes (right eye) of 2077 patients were compared between May 2019 and June 2020. The study took place at Ultralasik Eye Center, Dubai, after the Institutional Review Board approval, and it was conducted in accordance with the ethical principle of the Declaration of Helsinki. All patients signed informed consent prior to treatment, and all surgical procedures were performed by one surgeon (A.F).

Selection Criteria

Patients in this study were 18 years or older with stable refraction for at least one year. They did not have any contraindication for LASIK and had a central corneal thickness of more than 500 µm. Ocular hypertension was ruled out with IOP less than 21 mmHg. Exclusion criteria were: a history of herpetic eye disease or corneal dystrophy, any topographic evidence of warpage or keratoconus from contact lenses, glaucoma, corneal scarring, and severe dry eye (Schirmer's with anesthesia less than 5mm), systemic and collagen vascular diseases. Hard contact lens wearers were also excluded.

Groups

The patients were divided based on the time of discontinuation of the SCL before LASIK (Group 1 at 24 hours and Group 2 at one month or longer). Patients included in the first group were primarily SCL-dependent patients who did not use spectacles. Both groups were comparable according to age, sex, and manifest refraction spherical equivalent (MRSE). The preoperative and postoperative screening consisted of a complete ophthalmic examination. It included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, anterior and posterior segments evaluation with a dilated fundus examination, and keratometric evaluation. Schirmer's test was also done at each visit. Follow-up examinations were scheduled at the baseline, at 1 week, 1 month, 3 months, and 6 months. The patients included were those who presented to all follow-up visits.

LASIK Procedure

All included patients underwent primary LASIK procedure in both eyes by the same refractive surgeon (A.F.) using the VISX STAR S4 IR® excimer laser system and guided by the iDesign system (Abbott Medical Optics, Inc.). Inclusion criteria were myopia between -1.00D and -10.00 D, and 5.00 D or less for corneal astigmatism. LASIK procedures were performed in a standardized manner.

As a local anesthetic, one drop of Tetracaine 1% was instilled in each eye 5 minutes and immediately before the procedure. Afterward, a povidone-iodine 3% (Betadine) preparation of the eyelids was performed. A drape isolated eyelashes and a speculum with suction was placed into the operative eye. The cornea was marked with a corneal marker using gentian violet staining. The microkeratome settings (suction ring, flap stop) were chosen according to the Flat K (manufacturer's nomogram), aiming for the maximum flap diameter. The Moria SBK 90-µm single-use head was used for the desired cut depth of 90µm and a nasal hinge. In all cases, the standard speed of pass ("speed 2": 15,000 rpm, 2 seconds of cutting time) was used. For both eyes, one single-use head was utilized and discarded upon completion of the procedure (the right eye was always done first). After the microkeratome passed, the flap was lifted. The flap was floated back into position following the laser ablation, and a balanced salt solution was used to irrigate the stromal bed. Flap alignment was checked using gentian violet premarkings on the cornea, and a striae test was performed to ensure proper flap adherence. Twenty minutes after the procedure, all patients were examined to check flap adherence.

Postoperatively, patients were given moxifloxacin 0.5% drops (Vigamox) 4 times a day for 1 week, tobramycin 0.3% and dexamethasone 0.1% drops (Tobradex) 4 times a day for 2 weeks, and sodium hyaluronate 0.2% drops 4 times a day for 3 months. Patients were advised to wear protective eye shields at night and return the following day.

Outcome Measures

In this study, the outcomes compared between both groups were Schirmer's test, uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA). In addition, MRSE within 0.5 Diopters of attempted correction was assessed for the predictability. The outcomes mentioned above were measured on the first day of the procedure, after 1 week, 1 month than 6 months.

The efficacy index, the ratio of the mean postoperative decimal UDVA at 6 months to the mean preoperative decimal CDVA, and the safety index, the ratio of the mean postoperative decimal CDVA at 6 months to the mean preoperative decimal CDVA, were used for a more precise assessment of the outcomes.

The safety, in general, was assessed by evaluating intra-operative (epithelial defect, bleeding, incomplete or free flap) and postoperative complications (Infectious and non-infectious keratitis, epithelial ingrowths, and interface inflammation).

Statistical Analysis

One eye was chosen in each patient, the right one, to facilitate the analysis and avoid complicated statistical tests that might induce a high risk of bias. Statistical software (SPSS version 17.0; SPSS, Chicago, IL, USA) was used to perform all statistical analyses. Independent T-Test (for continuous variables) and Chi-square test (for categorical variables) were used to determine any significant difference between the 2 groups at each point of time. A *P*-value <0.05 was defined as statistically significant.

Results

Pre-LASIK

Two thousand seventy-seven (2077) eyes were included in this study, with a mean age of 27.2+/-4.1 years in the 1st group (48.6% males) and 26.9+/-4.3 years in the 2nd group (47.6% males). The age range of the patients varied between 18 and 57. The refraction range was between -0.50 D to -9.75 D for spherical error and from 0 to -5.00 D for astigmatism.

The mean preoperative MRSE value was -5.1 +/-2.1 D in the 1st group and -5.4 +/-2.7 D in the second (P=0.155). The same goes for the Schirmer's test: no significant difference was noted between both groups (P=0.121). There was no statistically significant difference in any baseline characteristics of patients in both study groups. (Table 1)

Post-LASIK

Briefly, at the 1-week follow-up, there was no significant difference between both groups regarding the mean UDVA (P=0.455), CDVA (P=0.222), and MRSE within 0.5 D (P=0.355). At 1 month also, no statistically significant difference was detected in both groups regarding the mean UDVA (P= 0.220), CDVA (P=0.207), and MRSE (P=0.505). Similar results were found at 6 months follow-up.

Moreover, concerning the Schirmer's test, the results were comparable with no significant statistical difference between the groups at every follow-up visit at 1 week (P=0.421), 1 month (P=0.101), and 6 months (P=0.399) (Table 2).

The efficacy index was 1.023 and 1.022 for groups 1 and 2, respectively (P=0.877). The safety index was 1 and 1.021 for groups 1 and 2, respectively (P=0.762).

Complications

Finally, intraoperative complications were comparable between both groups. 2 free flaps in group 1 and 1 free flap in group 2 (P=0.428) were reported. Epithelial defects were present in 18 eyes in group 1 and 17 eyes in group 2 (P=0.340). No other intra-operative complication was noted. No postoperative epithelial growth was seen in both groups.

Discussion

The main focus of this study was to compare the outcomes of a specific refractive surgical modality, LASIK, after discontinuation of SCL in a large sample of patients. However, only two other studies have focused on SCL removal and refractive surgery in general[14, 15].

In recent years, many recommendations and guidelines have proposed the removal of SCL at least 3 to 14 days before LASIK, but still, there are no consensus[16, 17]. Shehadeh-Mashor et al.[14], in their case-control study concerning the duration of SCL removal before myopic refractive surgery, have found a significant difference between the patients who removed their SCL in less than 1 day and those who removed them in more than 1 day before the PRK procedure. However, they found no significant difference between those who discontinued the SCL between 1 to 3 days and those who discontinued them for more than 3 days before PRK.

As for LASIK, literature has shown little evidence on the effect of late discontinuation of SCL before the procedure. Shehadeh-Mashor et al.[14] found no statistical difference between the SCL discontinuation in less than 1 day, 1 to 3 days, and more than 3 days before LASIK. These results were concordant with the actual study's results, mainly that they also used a microkeratome LASIK.

Nevertheless, Fragkopoulou et al.,[18] evaluated the effect of SCL discontinuation for 7 days on LASIK outcomes in 113 patients and found a significant difference between the postoperative and target spherical and cylindrical refraction. The previously mentioned study had many limitations due to the small sample size and the lack of a control group; therefore, it was concluded that the period needed to discontinue SCL remains to be determined by further investigations.

Consequently, this actual study brings additional evidence on the safety of performing LASIK 24 hours after discontinuing SCL use, especially with the large sample of patients included compared to the previous studies and the presence of a control group.

Furthermore, it has been well documented that SCL usage, regardless of the type, causes many corneal modifications: topographic and biomechanical[19, 20]. The hypoxia caused by SCL is thought to be the primary factor in corneal layer modification, leading to corneal injury caused by keratocyte apoptosis and other complex mechanisms[21]. Even though less severe with silicone hydrogel (siHy) SCL use, these mentioned changes could take around 2 weeks or even more to stabilize after the discontinuation of the SCL[7, 15, 19]. Thus, statistically significant, those changes did not affect LASIK safety, efficacy, and predictability in most studies where the SCL was removed between 3 to 7 days before the procedure. However, in this study, the control group was comparable to that of non-SCL wearers due to their SCL removal 1 month before the LASIK procedure, ensuring that most corneal changes and distortions, whether topographic or not keratometric, were stabilized[9, 22].

As mentioned in the results, the discontinuation of the SCL 24 hours before the procedure did not affect the visual outcomes in analogy to the outcomes of LASIK reported by other authors[23, 24]. Surprisingly, SCL wearing was even positively correlated with better LASIK and PRK results regardless of the discontinuation time (at least 24 hours) in comparison to non-SCL wearers, according to Lloyd-McKernan

et al.,[25]. Their results could be explained by the age discrepancy between both groups in the study[26]. Moreover, SCL users who already had increased corneal surface irregularities adapted better to the induced spherical aberrations, and residual refractive error after LASIK could also be an explanation[27]. On a side note, those results are not entirely valid in the case of this actual study because Lloyd and colleagues used femtosecond LASIK.

In this study, two antibiotics were used postoperatively: an aminoglycoside (Tobramycin) and a fourth-generation fluoroquinolone (Moxifloxacin). Thus, no signs of infectious keratitis were documented using both antibiotics despite the increased risk of keratitis caused by SCL themselves and by the corneal changes that they induce, especially in group 1.[28]

Moreover, both SCL and LASIK are known to increase the risk of dry eyes[29, 30]. It might be convenient to predict that the SCL removal 24 hours before the surgery might predispose to an increased risk of dry eyes after LASIK, especially in long-term users. However, Schirmer's test results reported were comparable in this study. Previous similar studies did not report the incidence of post-LASIK dry eyes 24 hours after the discontinuation of SCL. The literature showed an incidence range of 20 to 50% of dry eyes after LASIK, significantly earlier, but this may also be affected by patients' education and compliance with the postoperative eye drops treatment[31]. Long-term SCL use can be assumed as a risk factor for dry eyes post LASIK[32]. However, the risk of developing dry eye post-LASIK may not be influenced by the SCL use with the absence of predisposing dry eye disease and lack of corneal warpage[33].

Consequently, screening patients for dry eyes preoperatively could help predict the risk of dry eyes postoperatively. Eventually, this study may confirm that the variation in the duration of discontinuation of SCL before LASIK will not predispose patients to develop dry eyes, which can be explained by the different pathophysiology of SCL-induced dry eyes and post LASIK dry eyes[34–36].

As for intra-operative epithelial defect and corneal flap incidence, there was no statistical difference between both groups; therefore, it is safe to presume that the duration of SCL removal before LASIK did not increase the risk of these complications. However, controversial evidence exists on the effect of the duration of SCL-use wear (years) and epithelial defect requiring further investigations[37, 38]. Last but not least, no further complications like limbal bleeding, non-infectious keratitis, or central toxic keratopathy were reported.

Like other studies, this one had its limitations. Since it is a retrospective and non-randomized study; a double-blinded, randomized clinical trial with a large enough sample size should be done, or even a prospective study would also be a good start; it would give more evidence on the specific duration needed for discontinuation of SCL before LASIK. Additionally, another previously-mentioned confounding factor that was not controlled in this study is the duration of SCL use (long-term or short-term users); it could also affect LASIK outcomes due to the induction of a different spectrum of morphologic corneal changes[39].

Furthermore, topographic follow-up and reporting with cut-off limits and values would have added another dimension to this study and would have given more information for future patient selection recommendations. Moreover, higher-order aberrations (HOA) assessment after LASIK were not reported in this study or any other study to assess the effect of late SCL discontinuation. Thus, the groups may differ regarding HOA measurements despite having the same refractive outcomes.

The LASIK flap creation in this study was done using a microkeratome. Another study using femtosecond LASIK and even the new SMILE procedure would also be of use for future recommendations on SCL removal.

Finally, the removal of SCL 24 hours before the LASIK procedure is considered an unusual practice in refractive surgery. However, it did not negatively affect the outcomes and safety of the procedure. It remains to be seen if these results could be duplicated in prospective studies.

While it looks safe and efficient, also it has better patient satisfaction; this particular practice is not recommended or included in the guidelines. Therefore, a case-by-case selection process is recommended to be done by an expert refractive surgeon. Moreover, it is advised that refractive surgeons select their patients carefully, ensuring that Schirmer's test, break-up time test, and other routine tests are within usual international standards before performing LASIK within 24 hours of SCL discontinuation.

Declarations

Declarations of interest (None) and Funding Disclosure

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Informed Consent

Written informed consent was obtained from all individual participants included in the study.

Ethics Approval

The study took place at Ultralasik Eye Center, Dubai, after the Ethics Committee approval at UltraLasik Eye Center. It was conducted in accordance with the ethical principles of the 1964 Declaration of Helsinki.

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Tables

Table 1

Demographics and Preoperative measurements comparison between the two study groups (Right eye was chosen for all patients)

Parameters	G1 (1025)	G2 (1052)	P value
	Mean +/- SD	Mean +/- SD	
Age (years)	27.2+/-4.1	26.9+/-4.3	0.210
Sex (Male/Female)	1025 (499/526)	1052 (501/551)	0.629
UDVA (LogMAR)	0.667+/-0.32	0.682+/-0.30	0.671
CDVA (LogMAR)	-0.074+/-0.20	-0.068+/-0.19	0.401
MRSE (D)	-5.1 +/-2.1	-5.4 +/-2.7	0.155
Schirmer's test (mm)	14.7 +/- 2.1	15.4 +/-2.5	0.121

CDVA=Corrected distance visual acuity; D: Diopters; LogMAR: Logarithm of the Minimum Angle of Resolution; MRSE=Manifest refraction spherical equivalence; UDVA=Uncorrected distance visual acuity.

Table 2

Postoperative outcomes comparison of the two study groups after 1 week, 1 month, and 6 months (Right eye was chosen for all patients)

Post-op Period	Parameters	Group 1 (1025)	Group 2 (1052)	P value
		Mean +/- SD	Mean +/- SD	
1 week	UDVA (LogMAR)	-0.080+/-0.12	-0.079+/-0.11	0.455
	CDVA (LogMAR)	-0.075+/-0.15	-0.074+/-0.16	0.222
	MRSE (D)	-0.65+/-0.23	-0.62+/-0.20	0.355
	Schirmer's test (mm)	9.4 +/- 1.8	9.8+/-2.3	0.421
1 month	UDVA (LogMAR)	-0.082+/-0.12	-0.085+/-0.15	0.220
	CDVA (LogMAR)	-0.072+/-0.15	-0.071+/-0.12	0.207
	MRSE (D)	-0.50+/-0.25	-0.55+/-0.27	0.505
	Schirmer's test (mm)	12.4 +/- 1.8	12.9+/-2.3	0.101
6 months	UDVA (LogMAR)	-0.084+/-0.12	-0.078+/-0.17	0.204
	CDVA (LogMAR)	-0.079+/-0.12	-0.081+/-0.17	0.198
	MRSE (D)	-0.62+/-0.21	-0.58+/-0.25	0.322
	Schirmer's test (mm)	14.5 +/- 1.6	14.9+/-1.7	0.399

CDVA: Corrected distance visual acuity; D: Diopters; MRSE: Manifest refraction spherical equivalence; UDVA: Uncorrected distance visual acuity.