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Research Article

# A Comparative Study of Patients Undergoing ReLEX® Smile with One Eye Interface Wash and the Contralateral Eye without Interface Wash

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## Abstract

**Purpose:** To compare the visual and refractive outcomes of ReLEx® SMILE with interface wash in one eye with no wash of interface in the other eye of the patient following removal of lenticule for myopic correction.

**Design:** Prospective, non-randomised, clinical study.

**Methods:** All patient included in the study (n = 40 eyes) undergoing ReLEx® SMILE were divided into 2 groups. Group 1 (n = 20 eyes) - patients who received interface wash with balanced salt solution and group 2 (n = 20 eyes) - patients who did not receive interface wash, following removal of lenticule, for myopic correction. Uncorrected Snellens visual acuity, Contrast sensitivity, higher order aberrations and Irregularity index was compared between both the eyes on day 1 and 2 weeks postoperatively.

**Results:** Uncorrected visual acuity in all eyes at day 1 was 20/25 or better. Right eye of 4 patients achieved 20/15 at day 1 itself, while 18 Left eyes achieved 20/20, no left eye attaining 20/15. There was a significant difference between the 2 eyes in contrast sensitivity, with contrast being better in RE at higher spatial frequencies: 12cycles/degree (p: 0.039) and 18 cycles/degree (p: 0.032) at 2 weeks. No statistically significant difference was observed in higher order aberrations or irregularity index. Corneal OCT showed no evidence of debris or edema in Left eye.

**Conclusion:** Interface wash following lenticule extraction in SMILE may lead to earlier visual recovery in terms of contrast and thus, in better patient satisfaction.

***Keywords:*** *ReLE; SMILE; Interface Wash; Myopic Correction*

## Introduction

We, as refractive surgeons have always strived to offer an effective and accurate, yet cost-effective surgical procedure to our patients, that will render them spectacle–free, providing a good quality of vision. Quality of vision depends on several factors, the most important of course being the refractive correction.

ReLEx® SMILE – all in one femtosecond laser represents a paradigm shift in the field of corneal refractive surgeries. Preformed exclusively with VisuMax®, SMILE offers innumerable advantages over the currently popular laser refractive surgeries (PRK and LASIK) for treatment of myopia and myopic astigmatism.

Refractive correction with ReLEx® SMILE is supposed to be of higher accuracy, as compared to LASIK. This is because any disruption of corneal stromal collagen during refractive surgeries changes corneal hydration thus creating variations in the amount of tissue removed/

ablated. In ReLEx® SMILE, as the complete refractive lenticule is created by Laser before the stromal tissue is exposed; there occur only minimal/no changes in stromal hydration. Hence refractive lenticule created is more accurate than the same amount of tissue ablated by excimer Laser post exposure of stroma [1-3].

However various other factors play an equally important role in determining the immediate recovery of vision and patient satisfaction, such as – higher order aberrations, status of dry eyes, and clarity at the interface.

Results of studies published on SMILE have already established the safety, efficacy and predictability of the procedure [4-7].

Whether to was the interface after removal of the lenticule, is a topic of controversy. Some surgeons don't like to wash the interface due to the fear of introduction of foreign bodies or infection, while others believe that interface washing may lead to better recovery of vision after SMILE. Hence, to address this controversial question, we conducted this prospective study to study the effect of interface washing on immediate visual recovery versus when it is not washed.

## Patients and Methods

40 eyes of 20 patients with myopia or myopic astigmatism upto -10.0D spherical equivalent were included in this prospective, non-randomized and comparative study. Inclusion criteria was age above 21 years and less than 40 years, stable refraction for atleast1 year, soft contact lens discontinued for minimum 1 week and rigid gas permeable contact lens discontinued for minimum 3 weeks, minimum corneal thickness 480µ, residual corneal thickness atleast 250µ/50% of original thickness (whichever is higher). Exclusion criteria was evidence of ocular diseases like meibomian gland diseases, herpetic keratitis, uveitis, glaucoma, visually significant cataract, retinal diseases like retinal dystrophies or diabetic retinopathy, progressive/unstable myopia and/or astigmatism, any pathologies of cornea like corneal dystrophies including keratoconus, any h/o corneal trauma or surgery within flap zone, dry eye status-schirmer's 2 test value less than 10 mm, taking any systemic medication likely to affect wound healing like corticosteroids or antimetabolites, h/o immunocompromised state or pregnancy or nursing mothers .

All surgeries were performed by a single surgeon. Right eye of all patients received wash of interface with balanced salt solution, following removal of refractive lenticule through a 2mm side-cut incision, while in left eye of all patients no interface wash was given at the end of procedure.

### Follow-ups

Patients were called on day 1 and day15 following the surgery. UCVA was checked with Snellens test types and dry retinoscopy were done at day 1. Additional tests done on day 15 were aberrometry to measure RMS of higher order aberrations using Itrace, contrast sensitivity using F.A.C.T, corneal topography (orbscan and pentacam) and corneal OCT to look for any interface debris, and tissue edema. A subjective questionnaire was also given to the patients on day 1 postoperatively inquiring about any pain, pricking sensation, watering and redness and at day 15 inquiring about glare and its severity and overall patient satisfaction. Pain, glare and patient satisfaction is graded according to the following scale.

**Questionnaire given to the patients for subjective assessment on 1st day post-operative period**

| Parameter | RE | LE |
|---|---|---|
| Pain Score (Faces* pain scale) | | |
| Pricking Sensation (Y/N) | | |
| Watering (Y/N) | | |
| Redness (Y/N) | | |

***Table 1***

**Pain Scale [8]**


***Figure 1:*** *Wong-Baker Faces Pain Rating Scale.*

**Brief instructions:** Ask the patient to choose face that best describes own pain and record the appropriate number.

**Questionnaire given to the patients for subjective assessment at 15 Days of post-operative period**

| | RE | LE |
|---|---|---|
| Patient's Satisfaction in Terms of Quality of Vision | | |
| GLARE | | |

***Table 2***

**Grading According to Satisfaction of Patient**

| | |
|---|---|
| 1 | Excellent |
| 2 | Good |
| 3 | Fair |
| 4 | Poor |

***Table 3***

GLARE: Trouble seeing street signs due to bright light of oncoming headlights
Grading of Glare

| | |
|---|---|
| 0 | No Difficulty |
| 1 | Minimal Difficulty |
| 2 | Moderate Difficulty |
| 4 | Severe Difficulty |

***Table 4***

## Results

Right eye of 40 patients underwent ReLEx® SMILE with wash of interface with BSS, while left eye of the same 40 patients underwent the SMILE procedure but with no wash of interface. The information collected regarding all the selected cases was recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta.

Using this software, range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Paired 't' test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Pre-op spherical equivalent was -3.34 ± 1.76 for RE and -3.18 ± 1.25D in LE

Post-op at day 1, all 20 right eyes (100%) had achieved a vision of 20/20 or better, as compared to 18 (90%) left eyes (Figure 2).

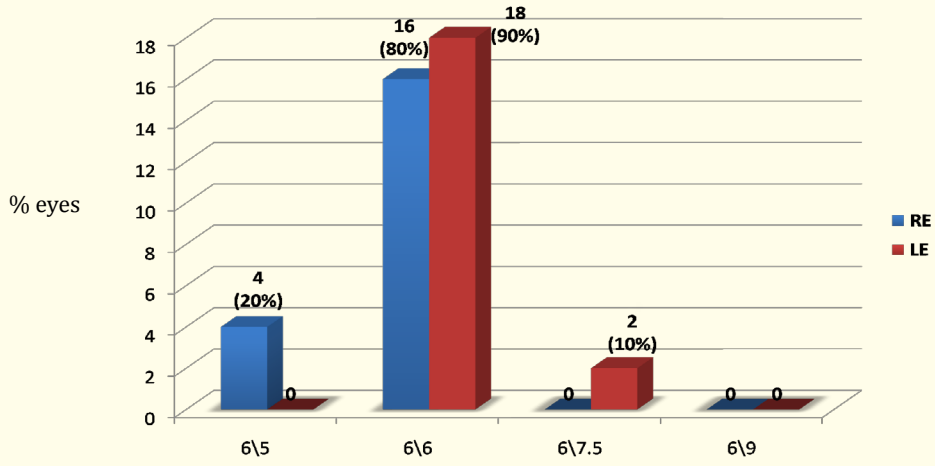


***Figure 2:*** *Shows 20 RE achieved 20/20 of which 4 eyes achieved 20/15. 18 LE achieved 20/20 while 2 eyes achieved 20/25 at day 1.*

Comparison between right eye and left eye at day 15 revealed that although all 20 left eyes had improved to 20/20 uncorrected vision, no eye achieved 20/15, as opposed to 4 right eyes which had UCVA of 20/15 at day 15 (Figure 3). Comparison between right eye and left eye at day 15.

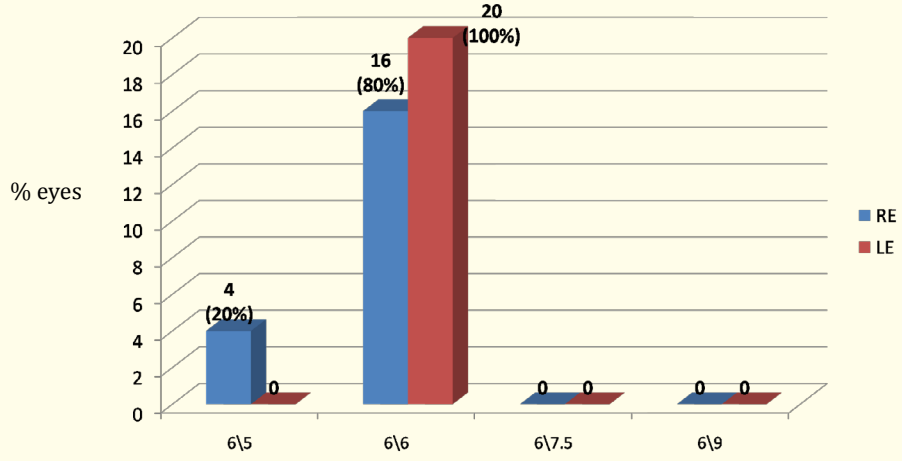


***Figure 3:*** *By day 15, all 20 LE achieved 20/20. 16 RE maintained UCVA of 20/20 and 4 RE 20/15.*

Mean spherical equivalent postoperatively in RE was -0.25 ± 0.23D and in LE was -0.32±0.22D at day 1 (p = 0.63).

Higher order aberrations at 3months post-op in RE and LE were 0.28 ± 0.08 and 0.31 ± 0.13μ (p = 0.3851) respectively (Figure 4).

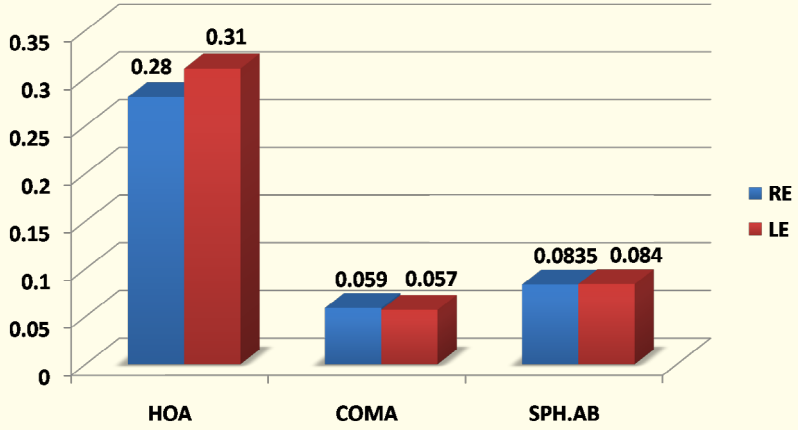


***Figure 4:*** *Shows postoperative higher order aberrations total, coma and spherical aberrations were similar in both eyes.*

RMS coma was 0.0595 ± 0.0372μ and 0.0575 ± 0.0396 μ in RE and LE respectively (p = 0.87), while RMS of spherical aberrations was 0.0835 ± 0.0291μ and 0.084 ± 0.0356μ in RE and LE respectively (p= 0.961) (Figure 4).

Contrast sensitivity was measured using F.A.C.T (functional acuity contrast test). Measurements were carried out monocularly before surgery with spectacle correction. Absolute values of log contrast sensitivity were obtained for each patient for each spatial frequency, and means and standard deviations were then calculated. Contrast in RE was better postoperatively at day 15 than LE (Figure 5) and the difference between the 2 eyes was significant (Table 5) for higher spatial frequencies of 12 cycles/degree (p = 0.038) and 18 cycles / degree (p = 0.032).

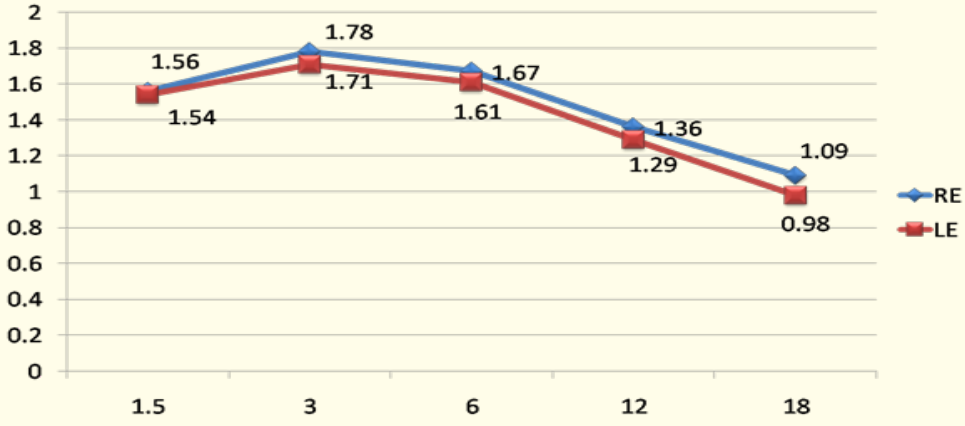


***Figure 5:*** *Shows contrast was better at day 15 in RE than LE.*

| Contrast Sensitivity | Value in | | | | Paired 't' test |
|---|---|---|---|---|---|
| | Right eye | | Left eye | | |
| | Mean | S.D. | Mean | S.D. | |
| A | 31.05 | 5.61 | 28.5 | 5.85 | 0.1678 |
| B | 51.35 | 10.77 | 46.25 | 9.32 | 0.1176 |
| C | 49.75 | 8.44 | 44.5 | 8.25 | 0.0539 |
| D | 28.4 | 3.28 | 25.65 | 4.72 | 0.0388 |
| E | 15.0 | 2.51 | 13.1 | 2.88 | 0.0323 |

***Table 5:*** *Contrast Sensitivity in RE and LE at 15 days postop. Contrast was better in RE at all spatial frequencies, significantly better at higher spatial frequencies.*

Irregularity index at 3mm and 5mm zone showed no significant difference between the right and left eyes (Table 6).

| Index | Value in | | | | Paired 't' test |
|---|---|---|---|---|---|
| | Right eye | | Left eye | | |
| | Mean | S.D. | Mean | S.D. | |
| Pre operative | | | | | |
| 3 mm | 1.18 | 0.4 | 1.25 | 0.41 | 0.6121 |
| 5 mm | 1.52 | 0.48 | 1.55 | 0.39 | 0.8025 |
| Post operative | | | | | |
| 3 mm | 1.65 | 0.4 | 1.78 | 0.57 | 0.4098 |
| 5 mm | 2.38 | 0.54 | 2.5 | 0.93 | 0.622 |

***Table 6:*** *Shows irregularity index at 3mm and 5mm zone pre-op and post-op at 15 days. No difference in irregularity index between RE and LE seen*

Subjective questionnaire on presence of pain, redness, pricking sensation and haziness given to patients was given a score of 1for every yes answer and 0 for no answer. Final score (Table 7) was 0.7 ± 1.03 in RE and 1.5 ± 1.1 in LE (p = 0.022). 8 patients complained of haziness in LE while 1 patient complained of haziness in RE.

| Eye | Patient Complaint Score | |
|---|---|---|
| | Mean | S.D |
| Right eye | 0.7 | 1.03 |
| Left eye | 1.5 | 1.1 |

***Table 7:*** *Patient complaint score- higher in LE than RE.*

## Discussion

ReLEx® SMILE the latest development in laser corneal refractive surgeries is performed using VisuMax® femtosecond laser which is a solid-state laser source. Tissue interaction is virtually independent of ambient humidity, ventilation, and corneal hydration. All these parameters affect treatment results in Excimer (gas)-based treatment modalities, including LASIK [1]. Femtosecond laser applies ultra short, and high-intensity focused laser pulses into the cornea stroma, at a depth preselected (we use 100μ), creating plasma bubbles which fuse and provide a plane for dissection of the lenticule. The surgeon manually dissects the remaining tissue bridges and separates the refractive lenticule, for easy extraction via the side cut incision (we used 2 mm incision).

Use of a concave patient interface allows a well defined corneal and a minimal increase in intraocular pressure.

Various energy parameters have been described with various authors [5,7]. We prefer use of high energy (500KHz) with spot separation of 2μ. We found reduced occurrence of opaque bubble layer with these settings, which in turn increases the ease of dissection of lenticule reducing manipulations in the stromal interface.

Besides an accurate retinoscopy, refraction correction, and energy settings of LASER, surgical procedure and any variations in its steps may also influence the immediate and final visual outcomes.

In this study we have tried to study the effect of wash of stromal interface, following lenticule removal on postoperative refraction and contrast sensitivity of the patients.

40 eyes of patients undergoing ReLEx® SMILE were included in this study. RE of all patients received interface wash while LE received no interface wash.

Postoperatively refractive outcomes were excellent in our study with all eyes irrespective of wash or no-wash achieving UCVA of 20/25 or better. However vision in RE was better than LE, with 20%of RE (4 eyes) achieving UCVA of 20/15 on day 1. 100% of RE had UCVA 20/20 or better, while in 2 left eyes, UCVA was 20/25. Rest of the Left eyes had UCVA of 20/20.

The difference between spherical equivalent of the 2 eyes was not statistically significant (p: 0.293)

This shows that refractive outcomes depends primarily the degree refractive correction and laser energy settings. Effect of interface wash though minimal, maybe critical in refining visual outcomes and achieving better UCVA in our patients.

By post-op day 15 all eyes had UCVA of 20/20 or better. However, none of the left eyes attained 20/15. This further proves the importance of wash of interface in attaining better UCVA.

We found no significant difference between RMS higher order aberration, coma and spherical aberrations of the 2 eyes. This could be due to the fact that postop induction of coma depends on centration, while post-op spherical aberrations depend on pre-op variables such as magnitude of sphere/spherical equivalent, optical zone and ablation zone, keratometry and asphericity [9].

In SMILE, lower rise in IOP during suction allows good centration thus reducing the risk of decentred treatments and hence lower RMS coma in BE post-op. Again, as spherical aberrations depends on pre-op variables, post-op RMS spherical aberrations showed no significant difference between the 2 eyes.

Thus irrespective of the wash given or not higher order aberrations were low and similar in BE.

Evaluation of contrast sensitivity was done using F.A.C.T. We found significant differences between contrast of the 2 eyes, with RE contrast being better postoperatively. This was the most significant difference we found between the 2 eyes of a patient in this study.

We also evaluated irregularity index at the 3mm and 5mm zone and found no statistical difference between RE and LE.

AS-OCT to evaluate corneal interface revealed no debris or edema in any eye.

BE of the patient showed smooth interface with no difference in the corneal OCT picture between RE and LE.

Subjective evaluation revealed complaints of haziness in LE by patients. No significant difference was noted between the 2 eyes as far as pain, pricking sensation or redness was concerned.

We concluded that wash of interface probably aids in removal of debris. We hypothesize that the cold BSS may help reduce inflammatory mediators, the presence of which in LE being the reason for slight differences in UCVA, haziness complained by the patient and lower

contrast. Wash of interface with BSS may cause hydration of corneal stroma with smoothening out of the Bowmans membane microdistortions, tissue interface, and reduction of gap from where the lenticule was extracted, resulting in a potentially better quality of vision.

## Conclusion

Following the removal of lenticule in ReLEx® SMILE, wash of interface with balanced salt solution may lead to earlier visual recovery in terms of contrast and thus, in patient satisfaction. Interface if left without wash results postoperatively in lower contrast, lower UCVA and complaints of haziness.

## Financial Disclosure

No author has a financial or proprietary interest in any material or method mentioned.

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