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ORIGINAL RESEARCH

Uncorrected visual acuity, postoperative astigmatism, and dry eye symptoms are major determinants of patient satisfaction: a comparative, real-life study of femtosecond laser in situ keratomileusis and small incision lenticule extraction for myopia

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Purpose: To compare factors affecting patient satisfaction after femtosecond laser in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE) for myopia in the real-life situation study.

Methods: The SMILE group included 100 eyes (51 patients) and the FS-LASIK group 200 eyes (102 patients). In addition to clinical examination, dry eye symptoms and patient satisfaction with far and near vision were reported and graded on the visual analog scale preoperatively and one month after the operation. Case–control pairs were selected for the SMILE patients from FS-LASIK-treated patients to ensure the homogeneity in spherical equivalent refraction, preoperative dry eye, and visual satisfaction.

Results: Eighty percent of SMILE eyes and 83% of FS-LASIK eyes achieved an uncorrected distance visual acuity of 20/20 or better. Predictability (±0.5 D of mean target spherical equivalent refraction) was 91% in SMILE and 93.5% in FS-LASIK. No eyes lost two or more Snellen lines of corrected distance visual acuity. Based on case–control pairs, dry eye symptoms remained the same after one month in the FS-LASIK-treated eyes (P=0.87) but decreased in the SMILE-treated eyes (P=0.01) compared with the preoperative situation. Patient satisfaction with far vision improved significantly in both groups ($P<0.001$), but satisfaction with near vision improved significantly only in FS-LASIK ($P<0.001$) and not in SMILE (P=0.58). There was more postoperative astigmatism in SMILE in comparison with FS-LASIK (P=0.002).

Conclusions: In a real-life situation, patients with preoperative dry eye experience were often directed to the SMILE operation, which resulted in beneficial decrease in their dry eye symptoms. Patient satisfaction with far vision decreased with increasing dry eye symptoms and postoperative astigmatism in both SMILE- and FS-LASIK-treated emmetropic patients. Safety, efficacy, and predictability were comparable in both treatments.

Keywords: femtosecond laser in situ keratomileusis, FS-LASIK, small incision lenticule extraction, SMILE, dry eye, patient satisfaction, myopia, astigmatism

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Plain language summary

Dr Pietilä's team in Finland investigated patient satisfaction and dry eye symptoms in two different types of refractive eye surgery. The most widely used refractive surgery to improve

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vision and to replace the use of spectacles or contact lenses is laser in situ keratomileusis (LASIK), in which a hinged flap is created in the cornea of the eye either with a mechanical microkeratome or with a femtosecond laser (FS-LASIK). The exposed part of the cornea is reshaped with the excimer laser and the flap is repositioned. Small incision lenticule extraction (SMILE) is a more recent refractive surgery in which the cornea of the eye is reshaped by creating a removable small lenticule inside the cornea with the femtosecond laser. In addition to the clinical examination of the eyes before the operation and one month after the surgery, the patients rated their dry eye experience as well as far and near vision satisfaction by using visual analog scale grading. FS-LASIK and SMILE seemed comparable based on clinical evaluations. In the real-life situation, patients with preoperative dry eye experience were directed to the SMILE operation, which resulted in beneficial decrease in their dry eye symptoms. Patient satisfaction with far vision improved significantly in both FS-LASIK and SMILE: FS-LASIK-treated patients were more satisfied with the improvement of their near vision than SMILE-treated patients. FS-LASIK-treated patients had also less astigmatism vision than SMILE-treated patients.

Introduction

Small incision lenticule extraction (SMILE) is a novel technique used to correct refractive errors using only one type of laser, the femtosecond laser, for the complete operation. Contrary to femtosecond laser in situ keratomileusis (FS-LASIK), no corneal flap is created; instead, an intrastromal lenticule is removed through a small incision.[1,2] Theoretically, SMILE is a less invasive procedure because of the absence of flap cutting and thus affecting less subbasal corneal nerves and ocular surface parameters, such as tear volume, corneal sensitivity, and subjective symptoms after refractive surgery.

Corneal refractive surgeons report dry eyes as the most common complication of LASIK.[3] According to the definition of the Dry Eye Workshop, dry eye disease is a multifunctional pathology at the ocular surface, which includes tear film changes with or without corneal damage, ocular symptoms, visual degradation, and increased tear osmolarity, together leading to the degradation of the quality of life.[4] Immediately after LASIK, up to 95% of patients report some dry eye symptoms; however, these are usually transient in nature.[5] LASIK-associated dry eye symptoms are also the main reason for patient dissatisfaction.[6] It has been estimated that SMILE may reduce not only complications associated with flap cutting and epithelial ingrowth but also dry eye symptoms and thus increase patient satisfaction.[7] Recent meta-analyses have indicated that FS-LASIK-treated myopic eyes suffer more severely from dry eye symptoms than SMILE-treated eyes.[8–11] According to one recent meta-analysis, SMILE does not show superiority over FS-LASIK with similar and acceptable objective parameters, but SMILE may have milder subjective symptoms.[12] In this study, we investigated the factors affecting patient satisfaction in subjects who underwent FS-LASIK or SMILE for myopic eyes. Dry eye symptoms and patient satisfaction were reported in this real-life situation study in the self-questionnaire based on the visual analog scale (VAS) grading. To ensure the homogeneity of the samples, a case–control subgroup from the FS-LASIK-treated eyes was created based on preoperative patient satisfaction and dry eye symptoms in order to find a match for SMILE-treated eyes.

Patients and methods

This retrospective, nonrandomized comparative study involved 153 patients (87 females and 66 males, 300 eyes) who were scheduled for refractive correction at two Silmäasema Eye Hospitals in Tampere and Helsinki (Finland) from May to October 2016. We have used the patient database, refractive surgery technical data, and quality control data of patient satisfaction of these two Silmäasema Eye Hospitals for the study. According to the EU legislation, retrospective analyses of existing data do not need the approval of an ethics committee. The data used were deidentified. The study included 100 eyes (51 patients) in the SMILE group and 200 eyes (102 patients) in the FS-LASIK group. The selection of the procedure type was based on the patient's own preference for the treatment and the discussion with the operating surgeon (JP) corresponding to a real-life setting at the time of the study.

Preoperative examinations

All patients had a complete preoperative ophthalmologic examination before the FS-LASIK or SMILE surgery to exclude any contraindication for the surgery, such as corneal ectasia or retinal or lenticular pathology. The examination included biomicroscopy, the measurement of corneal thickness and three-dimensional corneal topography (Allegro Oculyzer, WaveLight AG, Erlangen, Germany), the determination of refraction, the measurements of uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively), the measurement of intraocular pressure (iCare TA01i, iCare Finland Oy, Vantaa, Finland), and wavefront analysis (Allegro Analyzer, WaveLight AG). Patients had to discontinue wearing soft contact lenses for at least one week before the treatment.

Surgical techniques

All surgical procedures were performed by a single surgeon (JP). The following drops were instilled into the eyes prior

to the surgery: antibiotic eye drops, levofloxacin 5 mg/mL (Oftaquix, Santen Oy, Tampere, Finland); for pain and inflammation, diclofenac 1 mg/mL (Voltaren Ophtha, THEA, Clermont-Ferrand, France); to constrict conjunctival vessels, brimonidine tartrate 2 mg/mL (Alphagan, Allergan, Westport, Ireland); and topical anesthetic, oxybuprocaine hydrochloride 4 mg/mL (Oftan Obucain, Santen Oy). An aspirating speculum (no 15961, Geuder, Heidelberg, Germany) was used to open the eyelid.

FS-LASIK technique

For flap creation in the FS-LASIK, the FEMTO LDV Z6 I femtosecond laser (Ziemer Ophthalmic Systems, Port, Switzerland) was used in Tampere (79 patients, 156 eyes) and the VisuMax® femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) in Helsinki (23 patients, 44 eyes). The FEMTO LDV Z6 I delivered 100 nJ pulse energy and 10 MHz repetition rate. The target flap thickness ranged from 90 to 100 µm. All flaps were roundly shaped and set from 60° to 90° angled edge. A plastic single-use suction ring with the 9.5 mm diameter was used with the target flap diameter of 9.3 mm. The target hinge length was 4.0 mm. The vacuum pressure was 700 mbar and the cutting time 28 seconds. In the VisuMax, the target flap thickness was also ranging from 90 to 100 µm, the flap diameter was 8.9 mm, and the S glass was used. The flaps were set at 60° angled edge, and the target hinge length was 3.8 mm. The cutting time was 18 seconds. In both cases, the excimer laser treatment was done on the exposed stroma using the WaveLight EX500 excimer laser (WaveLight AG).

SMILE technique

In the flap-free SMILE surgery, the VisuMax femtosecond laser was used to create an intrastromal lenticule. The VisuMax had a repetition rate of 500 kHz and a pulse energy of 130 nJ. The cap thickness was 120 µm and the cap diameter 7.9 mm. The optical zone varied from 6.5 to 7.0 mm. The laser created a peripheral corneal incision from 2.8 to 3.0 mm. The incision site was at 11–12 o'clock. Special SMILE forceps were used to go through the incision and remove the lenticule.

Postoperative treatment

In both FS-LASIK and SMILE, chloramphenicol and dexamethasone containing drops (Oftan Dexa-Chlora, Santen Oy) were used for the first week with the tapered dose. On the day of the surgery, drops were used every two hours, on the following day every three hours five times daily. On the third and fourth day, drops were used four times daily, and on the fifth and sixth day, three times daily, and on the seventh day two times daily. Artificial tear drops were used as needed after the surgery for the following month. Gel-like moisturizing eye drops were used for the night day and every morning. The frequency of using artificial tears was not monitored in this study.

Follow-up examinations

On the one-month follow-up visit, UDVA, CDVA, and refraction were tested; clinical examination was performed; and a patient questionnaire was filled in.

Patient questionnaire

Patients were given a subjective questionnaire preoperatively and one month after the operation to rate their dry eye symptoms and satisfaction with far vision and near vision separately. Dry eye symptoms were graded on the VAS from 0 (no dryness) to 10 (extremely dry eyes). The patients were also asked to rate their satisfaction with both far vision and near vision on the VAS from 0% (poor) to 100% (excellent). The patients were asked to mark their response on the vertical line, at the point of their choice, and the length of the line segment was measured and recorded for analysis.

In the cases when both eyes were treated with either FS-LASIK or SMILE, in emmetropia both eyes had 0 as a target sphere. In monovision, one eye had 0 as a target sphere while the other eye had a myopic target sphere (max −1.50 D). All complications during FS-LASIK and SMILE procedures and at one-month follow-up time were recorded.

Statistical methods

All measured data were collected and entered into standardized study spreadsheets of Excel 2016 (Microsoft Corporation, Redmond, WA, USA). Values were given as mean ± standard deviation. The independent Student's *t*-tests were used to compare data between the SMILE and FS-LASIK groups, and the paired Student's *t*-tests were used for statistical analysis to compare data before and after the treatment for a given group. The chi-squared test, the Fisher's exact test, or the mixed-effect model was used to compare the study group frequencies or repeated measures.

The FS-LASIK–SMILE (case–control) pairs were created by matching each individual SMILE patient with an FS-LASIK patient with the most similar attempted correction, preoperative dry eye sensation, and preoperative patient satisfaction with near and far vision. The similarity

of a given SMILE patient and available FS-LASIK patients was evaluated by generating a Euclidean distance matrix. Then by locating the smallest distance measure from the matrix, the FS-LASIK–SMILE pair with the most similar attempted correction, preoperative dry eye sensation, and preoperative patient satisfaction with near and far vision could be obtained.

Linear regression was used to analyze the relationship between different parameters. We made correlations with dry eye symptoms and patient satisfaction with the case–control pair data using the following factors: preoperative and postoperative spherical equivalent (SEQ) refraction, postoperative UDVA, postoperative cylinder, and patient age. For each patient, the eye with a better postoperative UDVA was chosen.

Statistical tests were performed with the GraphPad Prism software (La Jolla, CA, USA). A P-value <0.05 was considered statistically significant. The R software version 3.3.1 (R Core Team, R Foundation for Statistical Computing, Vienna, Austria) was used to match the case–control pairs. Figures were created with the SigmaPlot software (Systat Software, San Jose, CA, USA).

Results

Altogether 153 patients underwent refractive surgery for myopia resulting in 300 operated eyes. The age of the patients ranged from 18 to 54 years (mean age: 34.1±7.7 years). There were 100 eyes (51 patients) in the SMILE group and 200 eyes (102 patients) in the FS-LASIK group (Table 1). All patients completed the one-month follow-up examination (Table 2).

Refraction

The preoperative mean SEQ refraction was −4.08±1.65 D (range: −1.38 to −8.25 D) in the SMILE group and −4.37±2.28 D (range: −0.63 to −11.63 D) in the FS-LASIK group (Figures 1 and 2). The postoperative mean SEQ refraction was −0.07±0.45 D (range: −1.75 to +0.75 D) and −0.06±0.52 D (range: −1.75 to +1.25 D) in the SMILE and FS-LASIK groups, respectively.

Efficacy, predictability, and safety

Postoperatively, 80 (80%) of all eyes in the SMILE group achieved a UDVA of 20/20 or better. The corresponding value for the FS-LASIK group was 166 (83%). Figures 1A and 2A show the preoperative cumulative Snellen CDVA in comparison with one-month postoperative UDVA in SMILE- and FS-LASIK-treated eyes with the plano target. When only the plano target was taken into consideration, in SMILE-treated eyes the efficacy was 85% and in FS-LASIK-treated eyes 94%. With the plano target, UDVA was within one line of CDVA in 96.3% of SMILE-treated eyes and in 98.7% of FS-LASIK-treated eyes (Figures 1B and 2B). One month postoperatively, no eyes in the FS-LASIK group had lost any Snellen lines CDVA and two eyes (2%) in the SMILE group lost one line of CDVA (P=0.11; Figures 1C and 2C). One of these eyes had a slower recovery achieving the 20/20 of UDVA at 3 months postoperatively. The other, however, had not recovered after six months. The slower recovery of CDVA or the loss of it was not related to any recorded complications. At one month, the refraction was within ±0.5 D of mean target SEQ refraction in

Table 1 Preoperative patient data

Variable	SMILE N=100 eyes	FS-LASIK N=200 eyes	*P*-value
Number of patients (female/male)	51 (26/25)	102 (61/41)	0.30[a]
Age (year)	33.4±7.2 (range: 20 to 52)	34.4±7.9 (range: 18 to 54)	0.45
Sphere (D)	−3.81±1.63 (range: −1.25 to −8.00)	−3.98±2.27 (range: −11.50 to 0.0)	0.61[b]
Cylinder (D)	−0.55±0.45 (range: 0.0 to −1.75)	−0.79±0.70 (range: 0.0 to −3.25)	**0.04**[b]
Spherical equivalent (D)	−4.08±1.65 (range: −1.38 to −8.25)	−4.37±2.28 (range: −0.63 to −11.63)	0.40[b]
Keratometric power K_1 (D)	43.30±1.20	43.31±1.39	0.93[b]
Keratometric power K_2 (D)	44.20±1.33	44.29±1.43	0.76[b]
Central corneal thickness (μm)	556.7±32.8	548.7±32.7	0.20[b]
Dry eye sensation	3.78±2.46 (range: 0.5 to 9.5) (N=51 all patients)	2.75±1.92 (range: 0 to 9.0) (N=102 patients)	**0.01**
Patient satisfaction, far vision (%)	80.29±13.85 (range: 30 to 98) (N=51 patients)	73.10±21.28 (range: 10 to 99) (N=102 patients)	**0.01**
	79.72±13.27 (N=32 emmetropia)	71.75±21.84 (N=56 emmetropia)	**0.04**
	81.26±15.09 (N=19 monovision)	74.74±20.69 (N=46 monovision)	0.16
Patient satisfaction, near vision (%)	88.04±13.77 (range: 28 to 100) (N=51 patients)	82.36±20.44 (range: 11 to 100) (N=102 patients)	**0.04**
	90.03±11.08 (N=32 emmetropia)	88.05±16.40 (N=56 emmetropia)	0.50
	84.68±17.22 (N=19 monovision)	75.43±22.80 (N=46 monovision)	0.08

Notes: Values are presented as mean ± SD. Values shown in bold are statistically significant. *P*-values calculated with the Student's unpaired *t*-test, except for the following: [a]chi-squared test; [b]mixed-effects model.

Abbreviations: FS-LASIK, femtosecond laser in situ keratomileusis; SMILE, small incision lenticule extraction.

Table 2 Postoperative 1-month variables

Variable	SMILE N=100 eyes	FS-LASIK N=200 eyes	*P*-value
Sphere (D)	0.04±0.48 (range: −1.75 to +1.00)	−0.03±0.52 (range: −1.75 to +1.75)	0.33[a]
Cylinder (D)	−0.22±0.29 (range: −1.25 to 0.0)	−0.07±0.17 (range: −1.00 to 0.0)	**0.0012**[a]
Spherical equivalent refraction (D)	−0.07±0.45 (range: −1.75 to +0.75)	−0.06±0.52 (range: −1.75 to +1.25)	0.91[a]
Efficacy (%)	80.00 (80/100)	83.00 (166/200)	0.52[b]
Efficacy, plano target (%)	85.19 (69/81)	93.51 (144/154)	0.64[b]
Predictability (%)	91.00 (91/100)	93.50 (187/200)	0.43[b]
Safety, loss of one or more Snellen lines of CDVA (%)	2.00 (2/100)	0 (0/200)	0.11[c]
Dry eye sensation	2.80±1.76 (range: 0.2 to 8.0) (N=51 all patients)	3.35±2.20 (range: 0 to 9.8) (N=102 patients)	0.10
Patient satisfaction, far vision (%)	89.84±12.42 (range: 44 to 100) (N=51 all patients)	90.18±13.59 (range: 22 to 100) (N=102 all patients)	0.88
	89.03±14.47 (N=32 emmetropia)	90.27±15.82 (N=56 emmetropia)	0.71
	91.21±8.06 (N=19 monovision)	90.07±10.41 (N=46 monovision)	0.64
Patient satisfaction, near vision (%)	89.31±11.37 (range: 47 to 100) (N=51 all patients)	91.20±12.09 (range: 15 to 100) (N=102 all patients)	0.35
	90.66±12.06 (N=32 emmetropia)	94.44±7.94 (N=56 emmetropia)	0.12
	87.05±10.01 (N=19 monovision)	87.24±14.89 (N=46 monovision)	0.95

Notes: Values are presented as mean ± standard deviation. Values shown in bold are statistically significant. *P*-values calculated with the Student's unpaired *t*-test, except for the following: [a]mixed-effects model; [b]chi-squared test; [c]Fisher's exact test.
Abbreviations: CDVA, corrected distance visual acuity; FS-LASIK, femtosecond laser in situ keratomileusis; SMILE, small incision lenticule extraction.

91 (91%) eyes in the SMILE group and 187 (93.5%) in the FS-LASIK group (Figures 1E and 2E). The postoperative astigmatism is presented in Figures 1F and 2F for SMILE- and FS-LASIK-treated eyes, respectively. Postoperative astigmatism in SMILE-treated patients was −0.22±0.29 D and in FS-LASIK-treated patients −0.07±0.17 (P=0.0012). The target-induced astigmatism vs surgically induced astigmatism is presented in Figures 1G and 2G for SMILE and FS-LASIK, respectively. The refractive astigmatism angle of error for SMILE and FS-LASIK is presented in Figures 1H and 2H, respectively.

Patient questionnaire results for all patients

The preoperative mean score of the subjective questionnaire for dry eye sensation was 2.75±1.92 in the FS-LASIK group. The dry eye sensation increased significantly (P=0.009) post-operatively in the FS-LASIK group (3.35±2.20; Figure 3A). In the SMILE group, the preoperative dry eye sensation (3.78±2.46) decreased significantly (P=0.01) compared with the postoperative dry eye sensation (2.80±1.76).

Patient satisfaction with far vision improved significantly in both groups; FS-LASIK-treated eyes improved from 73.10±21.28 to 90.18±13.59 (P<0.001) and SMILE-treated from 80.29±13.85 to 89.84±12.42 (P<0.001; Figure 3B). The mean score for patient satisfaction with near vision improved significantly in the FS-LASIK-treated eyes (from 82.36±20.44 to 91.20±12.09, P<0.001; Figure 3C). In the SMILE-treated patients, there was no significant change in patient satisfaction with near vision (from 88.04±13.77 to 89.31±11.37, P=0.57).

Patient questionnaire results for case–control pairs

The patients undergoing a SMILE or LASIK surgery had differences in their preoperative dry eye experiences. Patients with stronger preoperative dry eye symptoms preferred SMILE (P=0.011). Therefore, to ensure the homogeneity of our study, 51 case–control pairs were chosen from the FS-LASIK group to match with the SMILE group based on attempted correction, preoperative dry eye symptoms, and

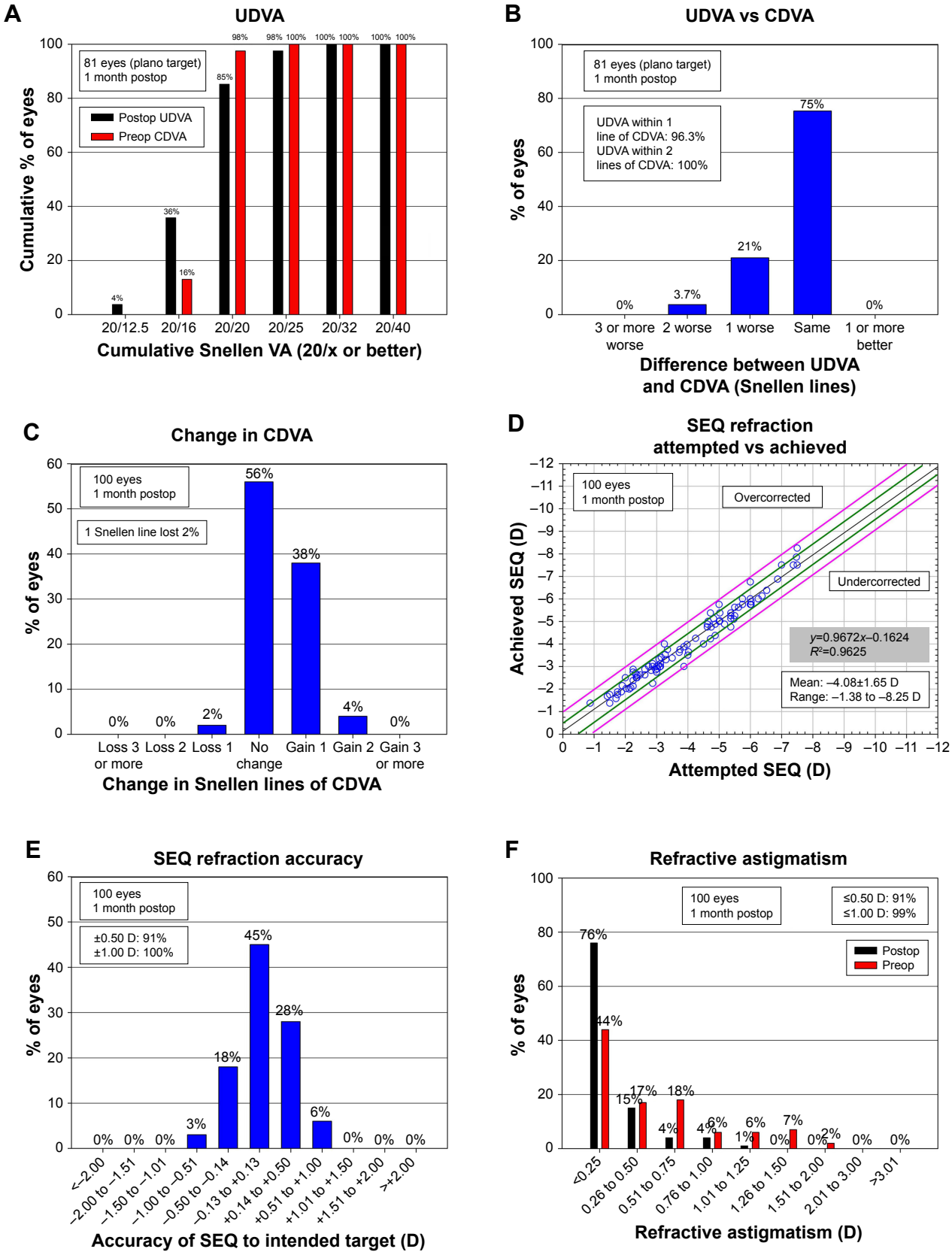


Figure 1 (*Continued*)

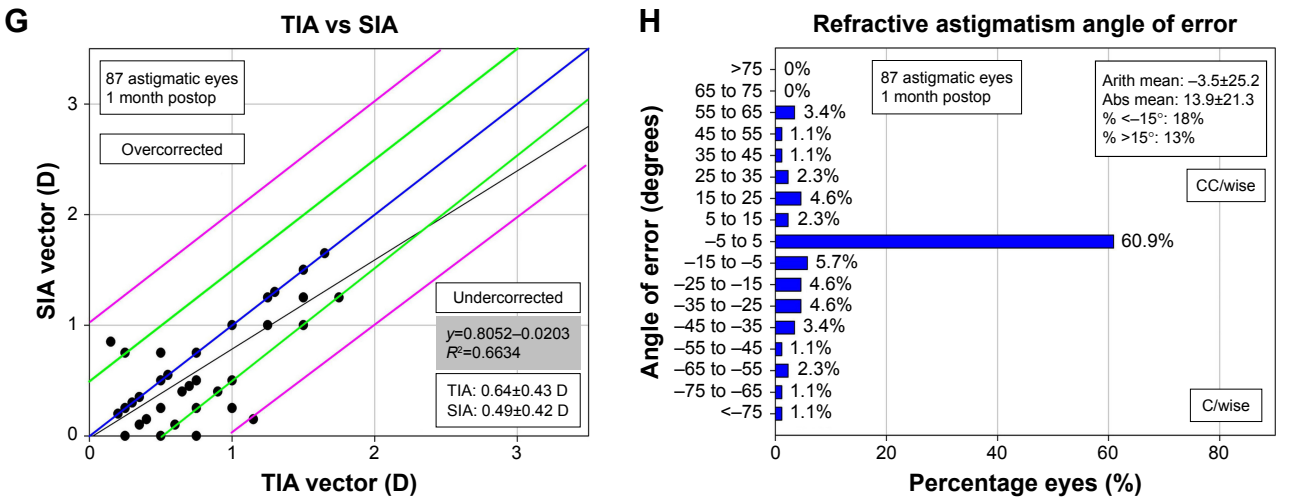
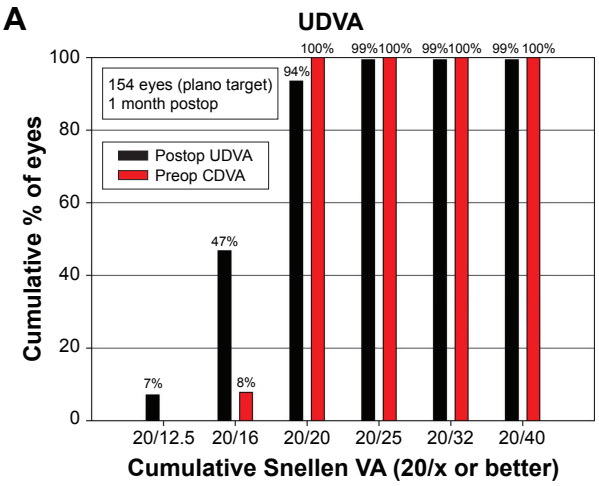


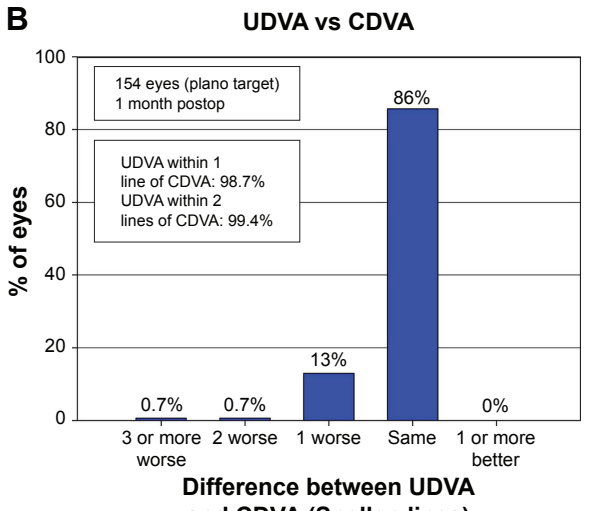
Figure 1 Standard graphs for reporting refractive surgery outcomes in SMILE-treated eyes.
Notes: (**A**) UDVA; (**B**) UDVA vs CDVA; (**C**) change in CDVA; (**D**) SEQ refraction attempted vs achieved; (**E**) SEQ refraction accuracy; (**F**) refractive astigmatism; (**G**) TIA vs SIA; and (**H**) refractive astigmatism angle of error. In **D** and **G**, the values were according to the green line within 0.5 D and the pink line within 1.0 D.
Abbreviations: CC/wise, counterclockwise; C/wise, clockwise; CDVA, corrected distance visual acuity; postop, postoperative; preop, preoperative; SEQ, spherical equivalent refraction; SIA, surgically induced astigmatism; SMILE, small incision lenticule extraction; TIA, target-induced astigmatism; UDVA, uncorrected distance visual acuity.

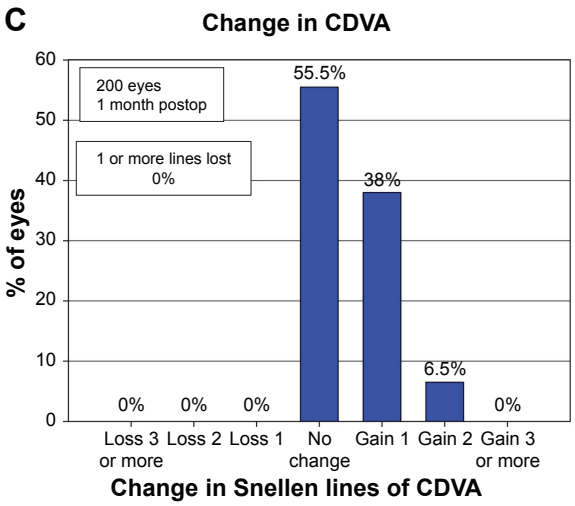
preoperative patient satisfaction with far and near vision. For each patient, the eye with a better postoperative UDVA was chosen. The SMILE data had 26 females and 25 males, and the FS-LASIK data resulted with 36 females and 15 males. Of the 51 patients in both groups, 32 eyes had emmetropic correction and 19 eyes had a specific monovision correction. The age was 33.41±7.16 years in the SMILE group and 33.6±8.47 years in the FS-LASIK group (P=0.9). The amount of attempted correction was −4.06±1.66 D in the SMILE group and −4.42±2.11 in the FS-LASIK group (P=0.33). We noted that postoperative cylinder was larger in SMILE-treated patients (−0.17±0.20 D) than in FS-LASIK-treated patients (−0.06±0.13 D; P=0.002).

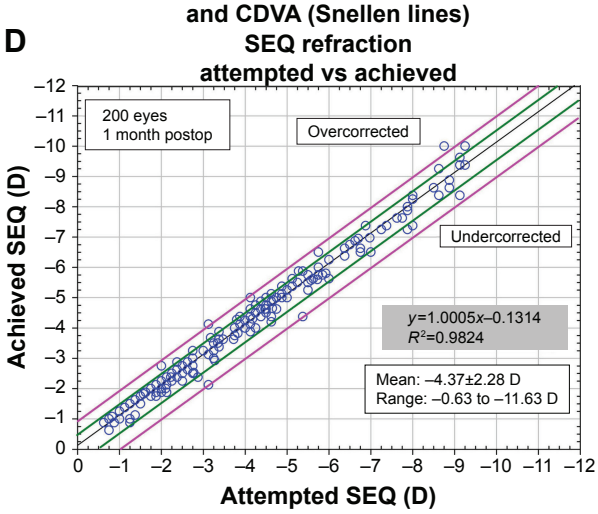
After adjusting the case–control pairs, the preoperative dry eye experience was very similar; 3.78±2.46 in the SMILE group and 3.41±2.23 in the FS-LASIK group (P=0.43). This relatively high level of dry eye experience was decreased significantly in the SMILE group (−0.98±2.77; P=0.01) but not in the FS-LASIK group (−0.05±2.12; P=0.87) after the operation (Figure 3A). Patient satisfaction with far vision improved significantly in FS-LASIK-treated eyes from 79.82±15.01 to 93.0±9.29 (P<0.001) and in SMILE-treated from 80.29±13.85 to 89.84±12.42 (P<0.001; Figure 3B). The mean score for patient satisfaction with near vision improved significantly in the FS-LASIK-treated eyes (from 88.2±12.44 to 93.22±8.81; P<0.001) but not in SMILE-treated eyes (from 88.04±13.77 to 89.31±11.37, P=0.58; Figure 3C).

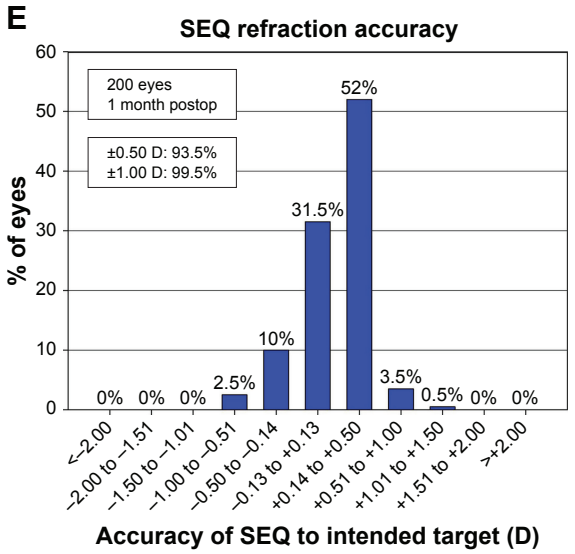
Correlation figures of case–control patients for postoperative dry eye symptoms and patient satisfaction with far and near vision are presented in Figure S1. Patient satisfaction with far vision was negatively correlated with postoperative dry eye experience (r=–0.36, P=0.046; Figure S1A) and postoperative astigmatism (r=–0.51, P=0.003; Figure S1B) in FS-LASIK-treated emmetropic patients. The same correlation was found in SMILE-treated emmetropic patients: dry eye experience (r=–0.46, P=0.01; Figure S1C) and postoperative astigmatism (r=–0.47, P=0.01; Figure S1D). In addition, we found a positive correlation in far vision satisfaction with postoperative SEQ refraction (r=0.42, P=0.02; Figure S1E) and postoperative UDVA (r=0.49, P=0.004; Figure S1F) in SMILE-treated emmetropic eyes. In SMILE-treated monovision patients, patient satisfaction with far vision also positively correlated with postoperative UDVA (r=0.49, P=0.03; Figure S1G) and in FS-LASIK-treated monovision patients with postoperative SEQ refraction (r=0.58, P=0.01; Figure S1H). In SMILE-treated emmetropic patients, patient satisfaction with near vision correlated negatively with postoperative astigmatism (r=–0.55, P<0.001; Figure S1I) and positively with postoperative UDVA (r=0.39, P=0.03; Figure S1J). In FS-LASIK-treated monovision patients, patient satisfaction with near vision correlated negatively with age (r=–0.81, P<0.0001; Figure S1K) and positively with postoperative UDVA (r=0.47, P=0.04; Figure S1L). In FS-LASIK-treated emmetropic patients, postoperative dry eye experience correlated negatively with postoperative UDVA (r=–0.39, P=0.03; Figure S1M).

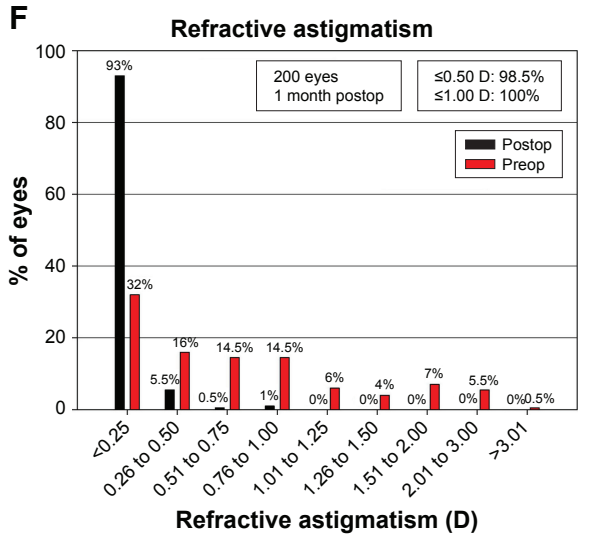












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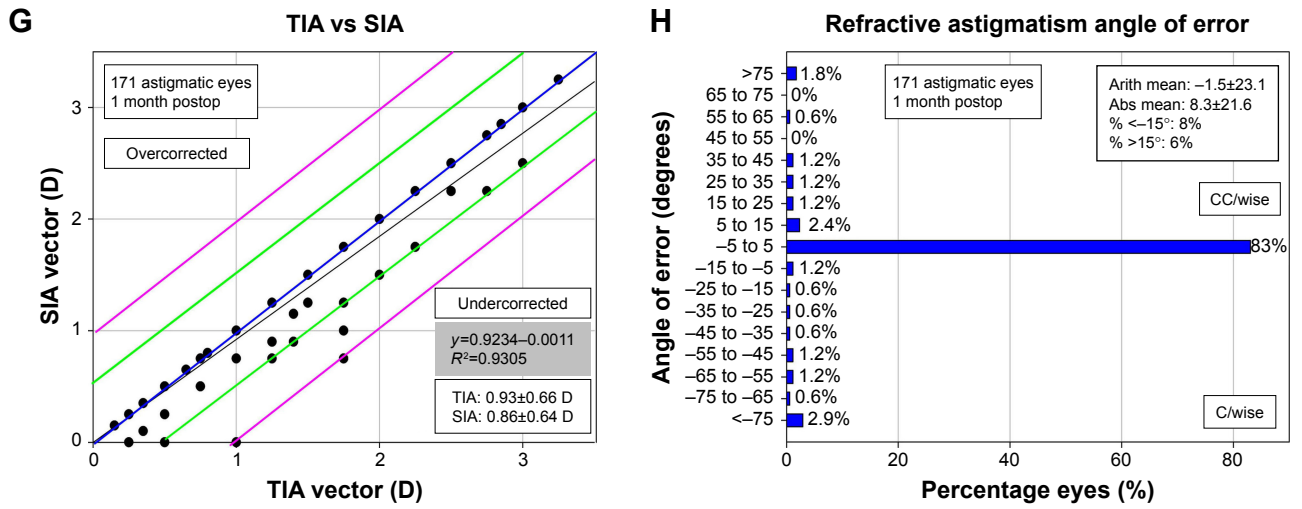

Figure 2 Standard graphs for reporting refractive surgery outcomes in FS-LASIK-treated eyes.
Notes: (**A**) UDVA; (**B**) UDVA vs CDVA; (**C**) change in CDVA; (**D**) SEQ refraction attempted vs achieved; (**E**) SEQ refraction accuracy; (**F**) refractive astigmatism; (**G**) TIA vs SIA; and (**H**) refractive astigmatism angle of error. In **D** and **G**, the values were according to the green line within 0.5 D and the pink line within 1.0 D.
Abbreviations: CC/wise, counterclockwise; C/wise, clockwise; CDVA, corrected distance visual acuity; FS-LASIK, femtosecond laser in situ keratomileusis; postop, postoperative; preop, preoperative; SEQ, spherical equivalent refraction; SIA, surgically induced astigmatism; TIA, target-induced astigmatism; UDVA, uncorrected distance visual acuity.

Complications

In the SMILE group, one eye had a suction loss. The eye was redocked, and the procedure was completed. Furthermore, in the SMILE-treated eyes, wrinkles appeared in two caps. In the FS-LASIK group, the Barraquer eye speculum was used in four eyes, canthotomy was done in one eye, and a decentered flap was observed in one eye. None of the complications appeared to affect visual acuity.

Discussion

In the present study, FS-LASIK- and SMILE-treated eyes were comparable in terms of efficacy, predictability, and safety. This is in good accordance with the previously published literature.[8–12] Since 2016, five meta-analyses[8–12] have been conducted to assess possible differences in clinical outcomes when FS-LASIK and SMILE were used to correct myopia and myopic astigmatism, showing that FS-LASIK and SMILE were comparable in terms of efficacy, predictability, and safety.[8,9] However, it is noteworthy that there are only few studies, which have been conducted on patient satisfaction and dry eye symptoms with a self-reporting questionnaire.[13–19] Therefore, we investigated patients' dry eye experience and patient satisfaction with far and near vision using a self-questionnaire based on the VAS grading in the real-life situation. To ensure the homogeneity of the data, we formed case–control pairs with respect to attempted correction, preoperative dry eye sensation, and preoperative patient satisfaction to further evaluate the differences in FS-LASIK and SMILE. To the best of our knowledge, the current study is the first to investigate the clinical factors affecting patient satisfaction after SMILE and FS-LASIK.

There were no significant differences in the change of patient satisfaction with far vision between SMILE and FS-LASIK. However, patient satisfaction with near vision was better in FS-LASIK-treated eyes than in SMILE-treated patients. In FS-LASIK-treated presbyopic monovision patients, satisfaction with near vision decreased with age. SMILE-treated eyes had more postoperative astigmatism than FS-LASIK-treated eyes.

The self-reported dry eye sensation and postoperative astigmatism appeared to be major determinants of patient satisfaction with far vision. Both in SMILE- and FS-LASIK-treated emmetropic patients, satisfaction with far vision decreased with increasing dry eye symptoms and postoperative astigmatism. In SMILE-treated emmetropic patients, satisfaction with far vision also increased with increasing postoperative SEQ refraction and UDVA. In SMILE-treated emmetropic patients, patient satisfaction with near vision increased with increasing postoperative UDVA and decreased with increasing postoperative astigmatism. Chan et al[20] found in the low to moderate myopic astigmatism corrections the postoperative cylinder to be higher in the SMILE group than in the FS-LASIK group, which supports our results. However, Zhang et al[21] found

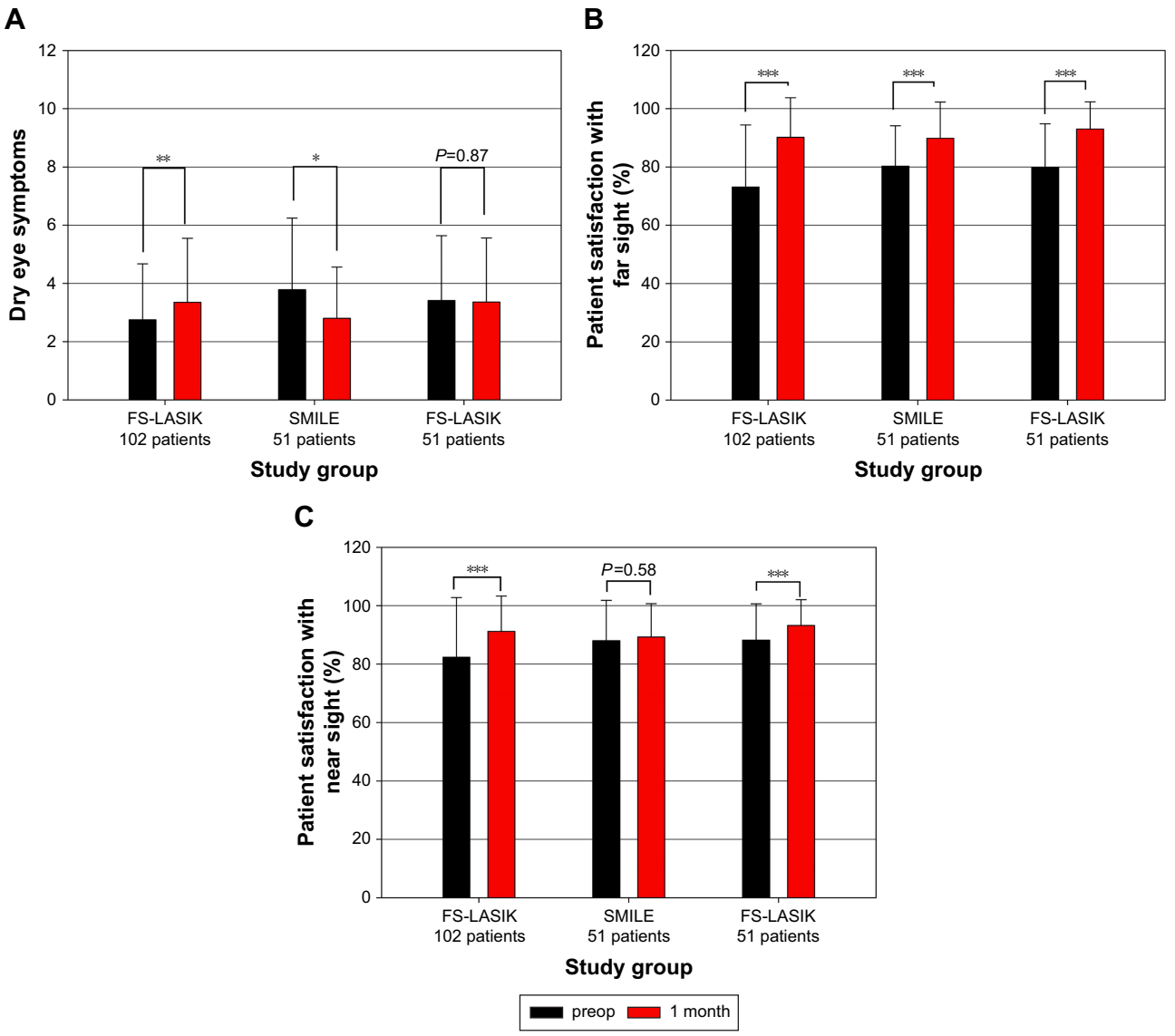

Figure 3 Changes in dry eye symptoms, patient satisfaction with near and far vision one month after SMILE or FS-LASIK operation (before and after case–control filtering).

Notes: (**A**) Preoperative and one-month patient dry eye experience in SMILE and FS-LASIK on a scale of 0 (no dryness) to 10 (extremely dry eyes). (**B**) Preoperative and one-month patient satisfaction with far vision in SMILE and FS-LASIK on a scale of 0% (poor) to 100% (excellent). (**C**) Preoperative and one-month patient satisfaction with near vision experience in SMILE and FS-LASIK on a scale of 0% (poor) to 100% (excellent). *$P<0.05$, **$P<0.01$, ***$P<0.001$.

Abbreviations: FS-LASIK, femtosecond laser in situ keratomileusis; preop, preoperative; SMILE, small incision lenticule extraction.

no differences in the surgically induced astigmatism in moderate- to high-astigmatism corrections in SMILE and FS-LASIK. In our studies, we discovered that when the nomogram of the VisuMax was used, more astigmatism was detected; therefore, a customized nomogram should be used to reduce residual astigmatism. The correlation of the self-reported far vision satisfaction with the severity of dry eye symptoms could be explained, at least partly, by optical factors. Dry eye symptoms reflect the condition of the quality of the tear film, and thus, the optical quality of the anterior surface of the cornea. To improve patient satisfaction, an intensive use of artificial tears after the operation may thus be beneficial, especially for the FS-LASIK patients.

In the real-life situation, SMILE-treated patients benefitted from the treatment by a decrease in dry eye symptoms. The decrease in dry eye symptoms may be related to the commonness of dry eye symptoms and the cessation of contact lens wear after the refractive surgery as contact lenses are known to induce discomfort and dry eye symptoms.[22] The use of eye drops may have also helped to reduce the dry eye sensation after the refractive surgery. Previously published data on the comparison of SMILE and FS-LASIK have

shown that SMILE-treated eyes have less dry eye symptoms than FS-LASIK-treated eyes.[13–18,23]

Patients who have more preoperative dry eye symptoms often prefer the SMILE treatment rather than the FS-LASIK procedure. This is probably due to the information that they are given by health care providers and their friends, getting from the written media, and increasingly from the Internet and the social media. It was also evident in our study that the patients with more dry eye symptoms chose more often SMILE than FS-LASIK. To overcome this, we used a case–control pair strategy. Interestingly, among these case-controlled patients, the self-reported dry eye sensation after FS-LASIK remained the same while it increased in the original FS-LASIK group of all patients compared with the preoperative situation. This might be explained by the fact that when selecting case–control pairs for the SMILE patients we also selected the FS-LASIK patients having more and more severe dry eye symptoms (Figure 3A). One could speculate that there might have been some kind of a ceiling effect of dry eye symptoms after FS-LASIK that could have influenced the results. Patients having more severe preoperative dry eye symptoms did not report any more worsening symptoms after the operation. The constant, postoperative use of artificial tears has probably been one reason to this ceiling effect.

This study investigated patient satisfaction in the real-life setting using a simplified and quick self-questionnaire based on the VAS grading. Furthermore, we were able to make case–control pairs from our study groups to reduce the differences in the patient groups. VASs are practical, efficient, and easy-to-use methods. There are, however, limitations, eg, responders often avoid the ends of the scale. Therefore, the linearity of the symptom scale at both ends of VAS scale might be a problem in this respect and in these regions may not be a valid reflection of the severity of the health state that is being estimated. There are also other limitations in the present study. We did not measure uncorrected near visual acuity. We also did not include any physiological measurements in the study, and the questionnaire could have been more well-established such as the Ocular Surface Disease Index. An elevated patient number could have strengthened the study. Finally, a longer follow-up time, for at least three to six months, would be advisable for more stable refractive outcomes.

Conclusions

FS-LASIK and SMILE were comparable in terms of efficacy, predictability, and safety for the treatment of myopia. Subjective dry eye symptoms remained the same after one month compared with the preoperative situation, in the FS-LASIK-treated eyes, but decreased in the SMILE-treated eyes. Patient satisfaction with far vision improved significantly in both study groups. Patient satisfaction with near vision improved significantly only in the FS-LASIK-treated eyes. SMILE-treated eyes had more postoperative astigmatism than FS-LASIK-treated eyes. The self-reported dry eye sensation and postoperative astigmatism and UDVA appeared to be major determinants of patient satisfaction with far vision. In both techniques, the single major determinant of patient satisfaction seemed to be the accuracy of refractive correction.

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Disclosure

JP has financial interest in the Ziemer Ophthalmic Systems; the other authors have no proprietary interest in the materials presented. The authors report no other conflicts of interest in this work.

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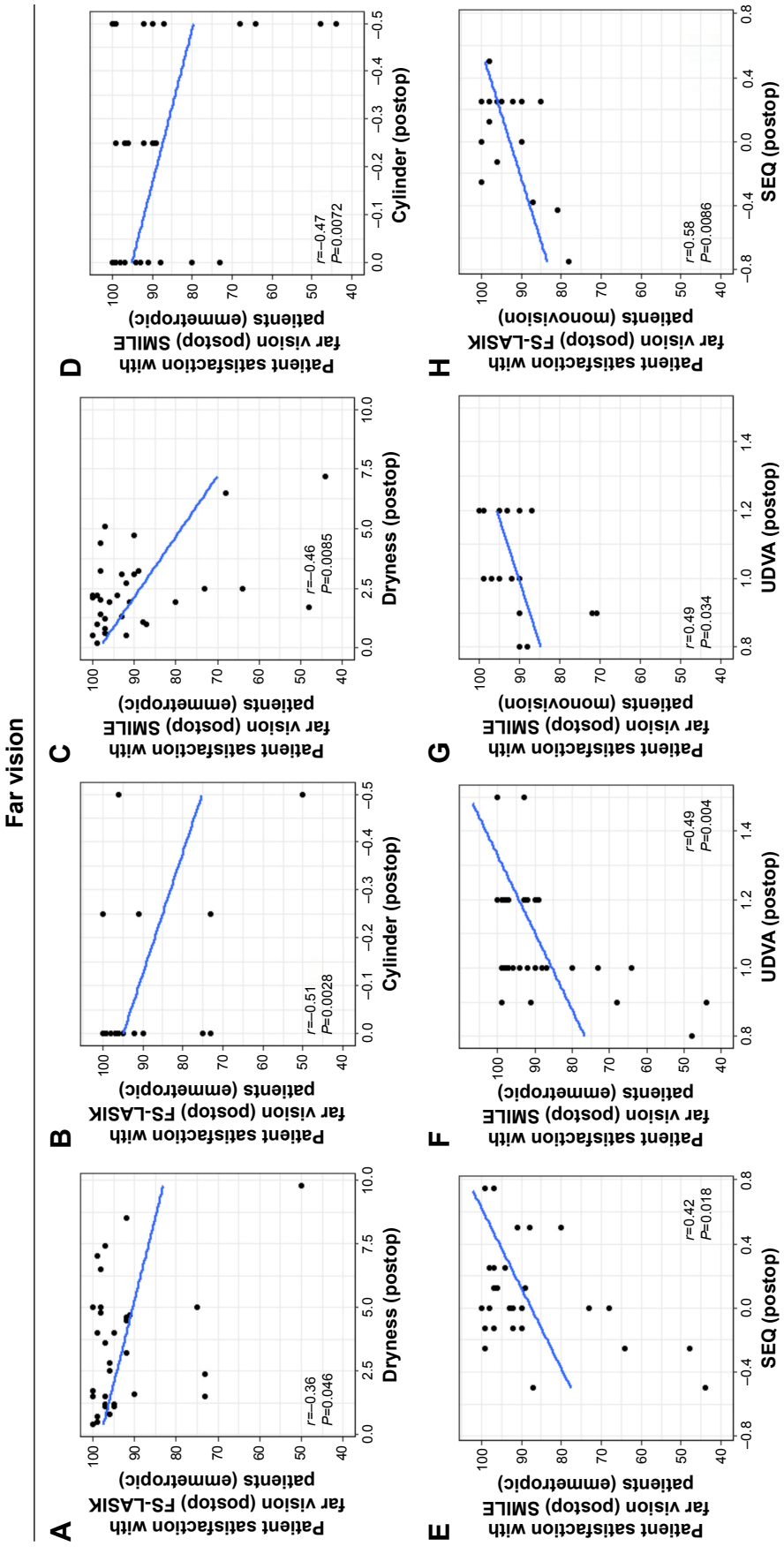
Supplementary material



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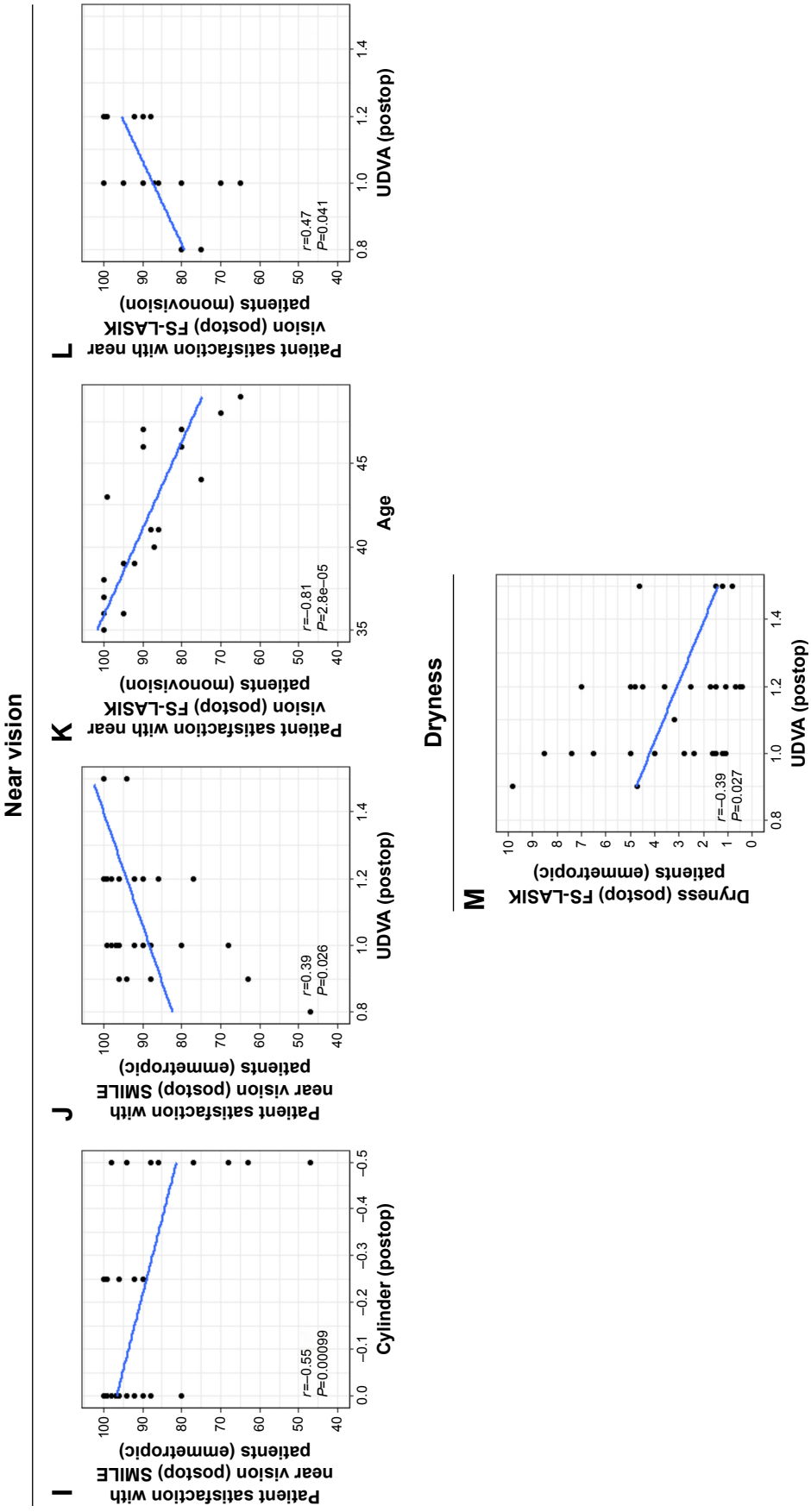

Figure S1 Significant correlations of case–control patients with respect to postoperative patient satisfaction with far vision (**A–H**), near vision (**I–L**), and postoperative dry eye sensation (**M**).
Abbreviations: FS-LASIK, femtosecond laser in situ keratomileusis; postop; postoperative; SEQ, spherical equivalent refraction; SMILE, small incision lenticule extraction; UDVA, uncorrected distance visual acuity.