Comparative Evaluation of the Visual and Refractive Outcomes Following SMILE, FS-LASIK, and T-PRK Surgery: A Retrospective, Non-Blinded Clinical Study

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Research article

Abstract

Background: To comparatively evaluate of the visual and refractive outcomes after small-incision lenticule extraction (SMILE), femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK), and transepithelial photorefractive keratectomy (T-PRK) surgery.

Methods: This was a retrospective, case-series, non-blinded clinical study. Consecutive eligible patients underwent SMILE, FS-LASIK, and T-PRK at the Department of Ophthalmology of Peking Union Medical Hospital, a tertiary referral center. All myopic patients were treated with corneal refractive surgery (SMILE, FS-LASIK, and T-PRK) using the VisuMax (Carl Zeiss Meditec AG, Jena, Germany) 500-kHz femtosecond laser system and the Amaris 750S excimer laser platform (SCHWIND eye-tech solutions, Kleinostheim, Germany). Visual and topographic astigmatism changes at 6 months were the main outcome measure. Secondary outcomes were the efficacy index at 1, 3, and 6 months postoperatively.

Results: We recruited 75 consecutive patients (mean age, 27.88 ± 5.76 years; 68% women; all Asian) with no significant differences between groups in terms of preoperative demographic data, except in preoperative spherical equivalent (SE) (-5.54 ± 1.86 D, -5.64 ± 1.66 D, and -3.78 ± 1.30 D, respectively; $P<0.001$), astigmatism (1.24 ± 1.62 D, 1.16 ± 0.75 D, and 0.72 ± 0.42 D, respectively; $P=0.008$), and residual bed thickness (313.08 ± 32.18 μm, 427.59 ± 30.69 μm, and 427.09 ± 41.07 μm, respectively; $P<0.001$). A superior efficacy index was shown in SMILE and FS-LASIK compared to T-PRK 1 month after surgery.

Conclusions: The results from this retrospective, non-blind, case-series clinical study suggest that all of the corneal refractive surgery options are safe and effective. However, while SMILE and FS-LASIK procedures have equal visual outcomes, they have superior efficacy index values in the early postsurgical period.

Background

Photorefractive keratectomy (PRK) was first introduced for the surgical correction of myopia [1]; laser ablation refractive surgery was widely applied for anterior segment operation. However, there are some complications after PRK, such as postoperative pain, discomfort, and high grade of corneal haze [2]. With advances in techniques used for epithelium removal, femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) has emerged as a new approache in the field of refractive surgery. For reduction of postoperative pain, corneal ectasia, and dry-eye symptoms [3–5], femtosecond lenticule extraction is a new one-step procedure to create a flap and a refractive lenticule. A modified procedure, small-incision lenticule extraction (SMILE), potentially offers biomechanical advantages over FS-LASIK surgery [6, 7].

The SCHWIND excimer laser (SCHWIND eye-tech-solutions, Kleinostheim, Germany) is a laser platform that uses a six-dimensional tracking system to compensate for eye movements to ablate corneal tissue during corneal refractive surgery [8]. Recently, SmartSurf[ACE] (Smart Pulse Technology, SCHWIND eye-tech-solutions) touch-free transepithelial PRK (T-PRK) has become a common surgical option, with a one-step

treatment system, rapid visual recovery, and functional binocular uncorrected distance visual acuity (UDVA) provided immediately after surgery [9–13]. However, the specific stromal ablation designed profiles were not mentioned [14, 15].

The refractive outcomes and visual quality differ between different surgical procedures, and straylight is an important assessment parameter related to visual quality. Xu et al. [16] found that surface ablation was significantly increased with forward light scattering after surgery, and stromal ablation was slightly increased in the early stage after surgery. However, a network meta-analysis showed that there were no statistically significant differences in either visual outcomes or visual quality between different procedures, and that FS-LASIK was more predictable than any other type of surgery [17].

All corneal refractive surgeries can be broadly divided into 3 categories: corneal surface ablation surgery, corneal stromal ablation surgery (involving the creation of corneal flap), and refractive corneal lenticule extraction (a form of stromal ablation that does not require a flap). This retrospective study aimed to comparatively evaluate the visual and refractive outcomes after SMILE, FS-LASIK, and T-PRK.

Methods

Patients

A total of 150 eyes (75 patients) that underwent SMILE, FS-LASIK, and T-PRK between May 2014 and December 2018 at the Department of Ophthalmology of Peking Union Medical College Hospital (Beijing, China) were included in this retrospective study. The study protocol followed the guidelines of the Declaration of Helsinki and the Institutional Review Board for Human Studies and was approved by the Peking Union Medical College Hospital Institutional Ethics Committee. Written informed consent was obtained from all patients prior to the commencement of the study.

Patients included in the study received corneal refractive surgery to correct myopia and myopic compound astigmatism. All patients demonstrated at least 1 year of stable refraction before undergoing refractive surgery, and the patients were followed up for at least 6 months. Exclusion criteria included amblyopia, ocular pathology, retinal disorders, previous ocular surgery, or insufficient follow-up.

Preoperative examination

All patients underwent a standard ophthalmologic examination preoperatively. The investigation included manifest refraction, cycloplegic refraction, slit-lamp examination, ultrasound pachymetry, dilated funduscopy, and intraocular pressure (IOP) measurement using a Goldmann applanation tonometer. UDVA and corrected distance visual acuity (CDVA) were assessed using Snellen charts. The CDVA was always assessed using trial frames and not contact lenses. Central corneal thickness was measured by ultrasonic pachymetry (TOMEY, Aichi, Japan), in which each single measurement is the average of five consecutive measurements. Corneal topography was measured by TMS-4N (TOMEY, Erlangen, Germany). The value of residual bed thickness (RBT) was defined as shown in Table 1.

Table 1
Preoperative and demographic data of patients.

Parameters	Group			P value
	SMILE	FS-LASIK	T-PRK	
No. of eyes (n)	50	50	50	-
Age (y)	27.32 ± 5.66	28.12 ± 5.20	29.76 ± 6.62	0.109
Sex (F/M) (n)	34/16	40/10	32/18	-
Preoperative SE (D)	-5.54 ± 1.86	-5.64 ± 1.66	-3.78 ± 1.30	< 0.001
Preoperative Ast. (D)	1.24 ± 1.62	1.16 ± 0.75	0.72 ± 0.42	0.008
K_s (D)	43.48 ± 1.34	43.78 ± 1.44	43.66 ± 2.04	0.375
K_f (D)	42.25 ± 1.85	42.62 ± 1.18	42.94 ± 1.97	0.132
IOP (mmHg)	15.47 ± 2.91	14.95 ± 2.02	14.76 ± 3.13	0.410
CCT (μm)	541.04 ± 30.66	528.40 ± 28.23	541.08 ± 39.48	0.078
*RBT (μm)	313.08 ± 32.13	427.59 ± 30.69	427.09 ± 41.07	< 0.001
Optical Zone (mm)	6.44 ± 0.16	6.42 ± 0.16	6.44 ± 0.19	0.562

SMILE = small-incision lenticule extraction, FS-LASIK = femtosecond laser-assisted *in situ* keratomileusis, T-PRK = transepithelial photorefractive keratectomy, y = years, F = female, M = male, SE = spherical equivalent, D = diopters, Ast. = astigmatism, K_s = steepest keratometry, K_f = flattest keratometry, IOP = intraocular pressure, CCT = central corneal thickness, RBT = residual bed thickness.

*LASIK: RBT = CCT − Ablation depth − Flap thickness; T-PRK = CCT − Ablation depth.

Surgical procedure

All surgeries targeted individuals with emmetropia and were performed by an experienced surgeon (Y.L.). Topical anesthetic eye drops containing 0.5% proparacaine (Alcaine; Alcon-Couvreur, Puur, Belgium) were administered. For FS-LASIK and T-PRK, the treatment plan followed the Custom Ablation Manager protocol. FS-LASIK flaps were cut using the VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, Jena, Germany; Standard, Version 2.1) with superior hinges, flap thickness of 90−100 μm, and 7.90-mm flap diameters. Ablations were performed using the AMARIS 750S excimer laser (SCHWIND eye-tech solutions, Kleinostheim, Germany). All corneal ablations were performed with Aberration-Free mode [8] and corneal topography was obtained by videokeratoscopy (Keratron Scout topographer, Optikon 2000 SpA, Rome, Italy) under photopic conditions (270 lux), similar to the conditions under the operating microscope [18]. Ablation was performed on a 6.0-mm to 6.8-mm optical zone. After surgery, a bandage contact lens (PureVision™ Bausch & Lomb, Rochester, NY, USA) was placed over the surgical site.

The VisuMax Femtosecond Laser System (Carl Zeiss Meditec AG, 500-kHz repetition rate) was used to perform SMILE. A small curved interface cone was used during each surgery. The anterior surface of the lenticule (spiral-out pattern) and the posterior surface of the lenticule (spiral-in pattern) were followed by a side-cut of the cap. The options value of power and spot distances for lenticule creation were 140 nJ and 4.5 μm, respectively. Parameters for the femtosecond laser were 6.0-mm to 6.5-mm lenticule diameter, 110-μm cap thickness, a 4-mm hinge width at 120 degrees position for lenticule extraction, and a 7.5-mm to 7.6-mm cap diameter with a 90 degree side-cut angle. A spatula was inserted through the side-cut over the roof of the refractive lenticule to dissect this plane to reach the bottom of the lenticule. The lenticule was subsequently grasped with modified McPherson forceps (Geuder GmbH, Heidelberg, Germany) and removed.

After surgery, topical tobramycin-dexamethasone (Tobradex; Alcon, Fort Worth, TX, USA) were administered to the eyes 4 times daily for 1 week. Flumetholon (0.1% fluorometholone; Santen, Osaka, Japan) was used 4 times daily for the second week, after which the frequency decreased by 1 administration per day each week for 1 month. Finally, an antibiotic (0.5% levofloxacin; Santen, Japan) was administered topically 4 times daily for 2 weeks.

Postoperative evaluation

Patients were followed at 1 week and 1, 3, and 6 months postoperatively. All postoperative follow-up visits included the assessment of UDVA, IOP, and corneal topography (TMS-4N; TOMEY, Erlangen, Germany).

Analysis of surgically induced astigmatism

Astigmatic polar value of net astigmatism (AKP) analysis methods [19] were used to analyze astigmatism changes after surgery. All keratometric values were converted to a plus power (@) net cylinder format with the magnitude of keratometric astigmatism in diopters, and the direction in degrees following the steepest keratometric meridian axis. To calculate the postoperative astigmatic polar values, the preoperative steepest keratometric meridian axis was consistently used as a reference, and the changes in polar values from preoperative to postoperative conditions were calculated and compared. The preoperative and postoperative AKP have been defined by Naeser et al. [20]; for the preoperative net cylinder A@a and the postoperative net cylinder B@b, the calculation formulae are as follows:

$AKP(+ 0)_{preop} = A$

$AKP(+ 45)_{preop} = 0$

$AKP(+ 0)_{postop} = B \times \{\sin^2 [(b + 90) - a] - \cos^2 [(b + 90) - a]\}$

$AKP(+ 45)_{postop} = B \times \{\sin^2 [(b + 45) - a] - \cos^2 [(b + 45) - a]\}$

$\triangle AKP(+ 0) = AKP(+ 0)_{postop} - AKP(+ 0)_{preop}$

$$\triangle AKP(+45) = AKP(+45)_{postop} - AKP(+45)_{preop}$$

Statistical analysis

Data were entered into an Excel spreadsheet (Microsoft; Redmond, WA, USA) and statistical analyses were performed using SPSS for MAC, version 25.0 (IBM SPSS; Armonk, NY, USA). Normality was tested using the Shapiro-Wilk test. The Wilcoxon rank-sum test and Mann-Whitney U test were used for non-parametric analysis. Comparative evaluation of AKP changes was done during a 6-month follow-up. Friedman's analysis of variance (ANOVA) with Bonferroni correction was applied if the case the data were not normally distributed. P values of < 0.05 were considered significant.

Results

We recruited 75 consecutive patients (mean age, 27.88 ± 5.76 years; 68% women; all Asian) and found that there were statistically significant differences in the preoperative spherical equivalent (-5.54 ± 1.86 D, -5.64 ± 1.66 D, and -3.78 ± 1.30 D, respectively; $P < 0.001$), astigmatism (1.24 ± 1.62 D, 1.16 ± 0.75 D, and 0.72 ± 0.42 D, respectively; $P = 0.008$), and RBT (313.08 ± 32.18 µm, 427.59 ± 30.69 µm, and 427.09 ± 41.07 µm, respectively; $P < 0.001$) between groups (more details are shown in Table 1). There were no major intraoperative complications in any participants during the study.

All standard visual and refractive outcomes in terms of efficacy, safety, and topographic astigmatism changes during a 6-month follow-up (Figs. 1 and 2, and Tables 2 and 3). There were no statistically significant differences between groups in AKP(+ 0) and AKP(+ 45) during the 6 months following surgery (Table 2).

Table 2
Polar value analysis of astigmatism changes after corneal refractive surgery.

Parameter	SMILE	FS-LASIK	T-PRK	P value
Group				
Pre-op				
AKP(+ 0)	1.24 ± 1.62	1.16 ± 0.75	0.72 ± 0.42	0.008
AKP(+ 45)	0	0	0	1.00
Post-op 1 month				
AKP(+ 0)	0.04 ± 0.53	0.11 ± 0.56	-0.08 ± 0.65	0.280
AKP(+ 45)	-0.02 ± 0.35	0.00 ± 0.48	0.01 ± 0.52	0.969
Post-op 3 months				
AKP(+ 0)	0.11 ± 0.43	0.00 ± 0.45	0.12 ± 0.60	0.657
AKP(+ 45)	0.01 ± 0.45	0.01 ± 0.43	-0.10 ± 0.58	0.726
Post-op 6 months				
AKP(+ 0)	0.02 ± 0.43	0.05 ± 0.45	-0.09 ± 0.43	0.231
AKP(+ 45)	-0.05 ± 0.37	-0.04 ± 0.52	-0.02 ± 0.58	0.965
Change				
△AKP(+ 0)	-1.22 ± 1.63	-1.11 ± 0.81	-0.81 ± 0.61	0.106
△AKP(+ 45)	-0.05 ± 0.37	-0.04 ± 0.52	-0.02 ± 0.58	0.965

SMILE = small-incision lenticule extraction, FS-LASIK = femtosecond laser-assisted *in situ* keratomileusis, T-PRK = transepithelial photorefractive keratectomy, Pre-op = preoperative, Post-op = postoperative, AKP = astigmatic polar value of net astigmatism, Change = the difference between 6 months postoperative and preoperative values of AKP, △ = change.

Table 3
Efficacy indices for 6 months after corneal refractive surgery.

Follow-up period	SMILE	FS-LASIK	T-PRK	P value
1 month	1.00	1.04	0.93	0.049
3 months	1.01	1.02	1.08	0.273
6 months	1.02	1.02	1.03	0.862

SMILE = small-incision lenticule extraction, FS-LASIK = femtosecond laser-assisted *in situ* keratomileusis, T-PRK = transepithelial photorefractive keratectomy.

*Efficacy index = postoperative UDVA / preoperative CDVA.

In the current study, all procedures achieved superior refractive efficacy at 6 months, and SMILE and FS-LASIK achieved better efficacy outcomes in the early stage. As observed in terms of the efficacy index in 1.00 ± 0.16, 1.04 ± 0.26, and 0.93 ± 0.18 ($P = 0.049$), 1 month after surgery (SMILE, FS-LASIK, and T-PRK, respectively; Table 3), a postoperative UDVA of 20/40 or better in 94%, 98%, and 100%, respectively (SMILE, FS-LASIK, and T-PRK, respectively; Fig. 1), and 20/20 or better in 94%, 90%, and 94%, respectively (SMILE, FS-LASIK, and T-PRK; Fig. 1). In terms of the difference between postoperative UDVA and preoperative CDVA, 57% of the eyes showed no changes (62% of eyes in SMILE, 50% of eyes in FS-LASIK, and 58% of eyes in T-PRK), 22% of eyes were gain one or more lines (24% of eyes in SMILE, 24% of eyes in FS-LASIK, and 18% of eyes in T-PRK, respectively), and 18% of eyes were loss one lines (8% of eyes in SMILE, 24% of eyes in FS-LASIK, and 22% of eyes in T-PRK, respectively) after corneal refractive surgery (Fig. 2).

Discussion

The results from this retrospective, non-blind, case-series clinical study demonstrated that all corneal refractive surgery produced excellent visual and refractive outcomes in terms of refractive efficacy and safety. Nonetheless, our results suggest that all corneal refractive procedures had similar visual outcomes after surgery. In the analysis of UDVA and CDVA changes, a preoperative CDVA of 20/20 or better was seen in 100%, 100%, and 90% of eyes in SMILE, T-PRK, and FS-LASIK, respectively. Moreover, in terms of the difference between postoperative UDVA and preoperative CDVA, 57% of the eyes showed no changes, 22% of the eyes showed a gain one or more lines, 18% of eyes showed a loss one line.

Previously, Tobaigy et al. [21] and Scerrati et al. [22] suggested that the visual and refractive outcomes were better in surface ablation than stromal ablation. However, Kim et al. [23] reported that corneal stromal ablation surgery was superior to corneal surface surgery for high myopia. A longitudinal follow-up study concluded that corneal surface and stromal ablation surgery had similar efficacies for moderate myopia within 2 years, with a significantly superior efficacy in corneal surface ablation surgery after 4 years postoperatively. Meanwhile, the corneal stromal ablation surgery showed greater myopic regression 5 years postoperatively [24]. According to the current short-term follow-up results, there were superior outcomes in the early stage of corneal stromal ablation surgery and corneal lenticule extraction procedures than corneal surface ablation technique. Moreover, there were no statistically significant difference in efficacies within all procedures.

For this retrospective clinical study, we used the AKP analysis method [20] to evaluate the astigmatism changes after surgery, and found that according to this algorithm, corneal ablation was not significantly different within all procedures during the 6-month postoperative period. However, there was a statistically significant difference in AKP(+ 0) preoperatively. It means that corneal refractive surgery corrects the refraction error with changes to the corneal biomechanical properties by using the bitoric LASIK technique with an aspheric profile to create a smooth transitional zone between the treated and untreated cornea [25–27]. This ablation technique was achieved by balancing the negative and positive cylinder ablations, creating a more aspheric optical zone. Moreover, the optimized centration in the SMILE procedures

between the corneal vertex and optical zone center [28] were analyzed, and it was found that there was no significant difference in centration between SMILE and LASIK procedures [29].

There were also no major intraoperative or postoperative complications reported during the study period. Flumetholon was applied for the patients with minor postoperative symptoms such as visual fluctuation and dry eye which were temporary (resolved during 3 months postoperatively) and not significantly different in terms of their occurrence between all eyes included in this clinical study [30]. Of note, the efficacy, predictability, and safety outcomes of all procedures in the current case-series study after 6 months postoperatively were comparable with previously reported studies [17, 31].

We recognize that this retrospective clinical study has some limitations. This was a short-term follow-up study in which there was myopic regression after corneal refractive surgery for 10-year follow-up in a previous study [24]. Second, there was no evaluation of the visual quality (which may include increased occurrence of symptoms such as halos, glare, and starbursts) within groups. However, we noted that patients reported more uncomfortable symptom (such as fluctuation in vision) in SMILE or T-PRK treated eyes than in FS-LASIK-treated eyes at 1 and 3 months after surgery. However, these symptoms reportedly diminished, and there was no difference between the eyes by 6 months. These results are important when counseling patients before surgery and explaining what to expect after the procedure, factors that sometimes are more pertinent to the patient than scientific results. Finally, there were no statistically significant differences in refractive outcomes or efficacy after surgery in the early postsurgical period. On the contrary, the postoperative outcomes were significantly better for the corneal stromal ablation than the corneal surface ablation technique [23], and superior refractive outcomes were obtained in SMILE procedures which is a more surgeon-dependent surgical technique. Further understanding of the ablation algorithms of the femtosecond and excimer lasers with more advanced clinical trial studies to improve postoperative visual and refractive outcomes are needed.

Conclusions

In summary, our case-series, non-blinded, retrospective clinical study suggests that all the corneal refractive surgery are able to provide excellent visual outcomes for myopia and myopic compound astigmatism, in terms of visual and refractive predictability, efficacy, and safety. Moreover, other groups suggested that SMILE is a refractive technique that is more surgeon-dependent compared with other types of corneal refractive surgery [31]. There were no statistically significant differences in visual or refractive outcomes within any procedure in the current study. Regarding the flap-related healing process, the outcomes were superior in SMILE and FS-LASIK than T-PRK. However, the SMILE procedure needs a thicker cornea for lenticule extraction than FS-LASIK in equally myopic patients.

Abbreviations

SMILE: small-incision lenticule extraction; FS-LASIK: femtosecond laser-assisted *in situ* keratomileusis; T-PRK: transepithelial photorefractive keratectomy; UDVA: uncorrected distance visual acuity; CDVA:

corrected distance visual acuity; AKP: astigmatic polar value of net astigmatism; CCT: central corneal thickness; RBT: residual bed thickness

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Peking Union Medical College Hospital (China) and followed the tenets of the Declaration of Helsinki. A written and informed consent was obtained from all participants.

Consent for publication: Not applicable.

Availability of data and materials: Available from the corresponding author on reasonable request.

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Authors' contributions

Conceived and designed the experiments: J.P. and Y.L.

Performed the experiments: Y.L.

Collected and analyzed the data: J.P.

Contributed regents/materials/analysis tools: J.P. and Y.L.

Wrote the paper: J.P.

Critical revision of the manuscript: J.P.

All the authors have read and approved the final manuscript.

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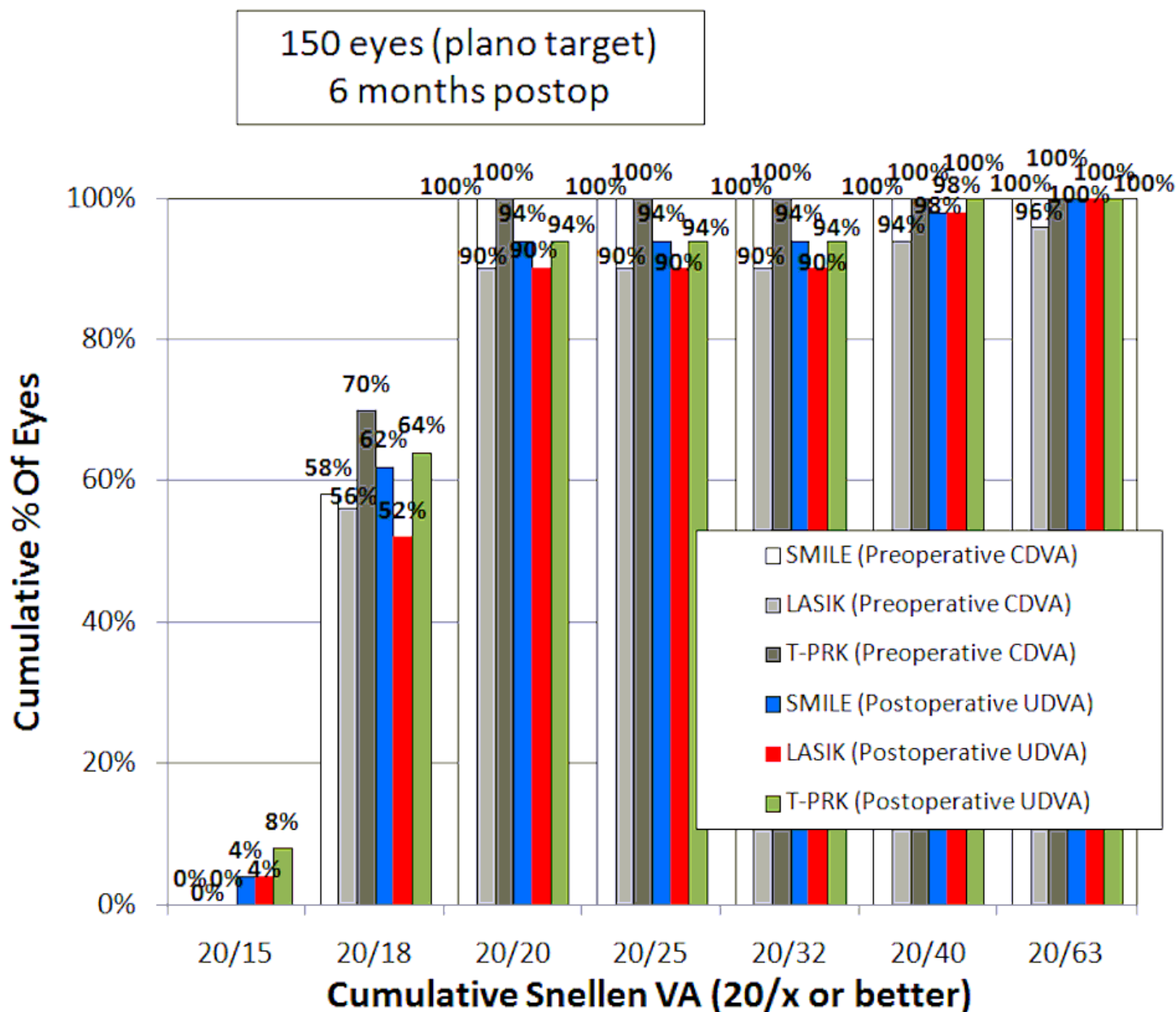
Figures

Figure 1

Cumulative postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA).
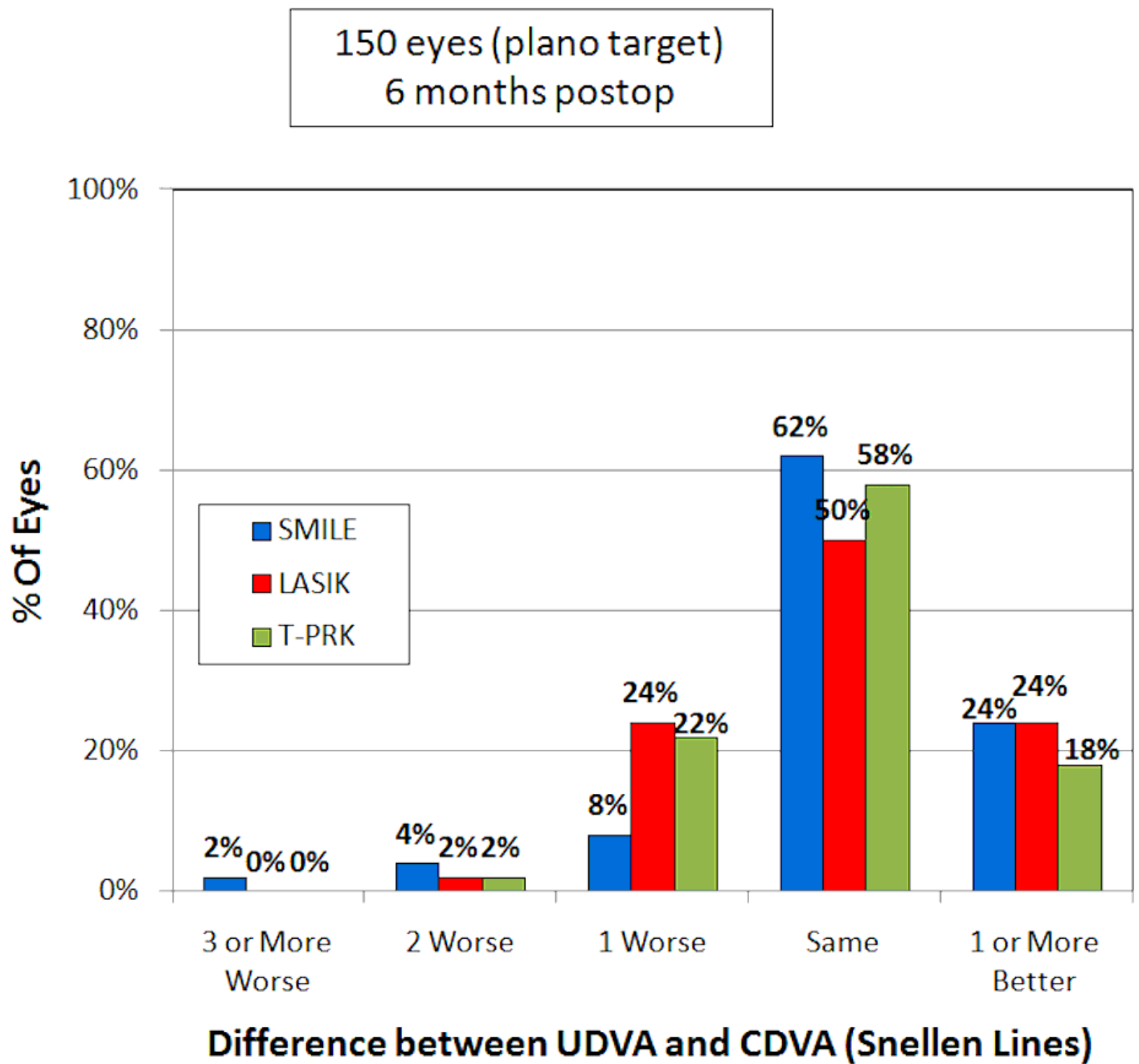
Figure 2

Difference between postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA).