

Corneal Surface Irregularity and Surgically Induced Astigmatism Changes in the Small Incision Versus Microincision After SMILE

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Abstract

Background: To evaluate the corneal surface irregularity and surgically induced astigmatism changes in the small incision versus microincision after small incision lenticule extraction (SMILE) surgery.

Methods: A total of 70 eyes of 35 patients with myopia who underwent SMILE surgery were enrolled in this retrospective study. Patients were divided into two groups according to the incision size (small incision, 4.0 mm or microincision, <2.5 mm) and subjected to a standard ophthalmologic examination preoperatively. The changes in corneal topographic and surface irregularities were evaluated using a TMS-4N topographer during a 6-month follow-up period.

Results: According to Friedman's ANOVA test, there were statistically significant changes in SRI, SAI, and IOP between two groups during a 6-month follow-up (all $p < 0.001$). At last follow-up, SRI values less than 0.50 D were shown 27 eyes (75%) in the small incision group and 28 eyes (82%) in the microincision group; SAI values less than 0.50 D were shown 22 eyes (61%) in the small incision group and 18 eyes (53%) in the microincision group (all $p < 0.001$).

Conclusions: SMILE procedures, using both small incisions and microincisions, are safe and effective surgical options for patients with low to high myopia and provide stable postoperative biomechanical properties and superior postoperative visual outcomes.

Background

Refractive surgery is the most commonly used method for the correction of refractive errors, and it can help achieve spectacle or contact lens independence. However, while refractive surgery is popular, it is associated with the prevalence of postoperative complications, such as ocular dryness [1], corneal ectasia [2], and pain [3]. Today, procedures such as small incision lenticule extraction (SMILE) are widely used to correct myopia with less postoperative dryness and pain [4, 5]; these procedures offer superior biomechanical stabilities compared to other types of refractive surgeries [6].

Denoyer et al. [7] subjectively compared the outcomes of two different types of corneal refractive surgery methods and found that the SMILE procedure is associated with a lower incidence of dry eye symptoms and corneal nerve damage than laser-assisted in situ keratomileusis (LASIK). In contrast, Shah et al. [8] found that 38.9% of patient eyes were dryer than they were before the SMILE surgery using a self-reported symptom questionnaire. Cetinkaya et al. [9] subjectively evaluated the occurrence of dry eye symptoms after SMILE surgery and found that there were no differences regarding the incision size; however, they found that a larger incision could make the procedure more convenient.

Recently, an objective, noninvasive method to determine corneal surface irregularities has been widely used for the qualitative and quantitative analysis of disorders of tear film stability in the anterior segment. De Paiva et al. [10] showed that the surface regularity index (SRI) and surface asymmetry index (SAI) were effective in objectively assessing the tear stability in patients with tear film dysfunction. The corneal topographer (TMS-4N), based on the Hartmann test with Placido-based topography, Fourier analysis, and the optical aberration theory, produces evaluation maps of the anterior corneal surface [11]. This retrospective study aimed to evaluate corneal surface irregularity and surgically induced astigmatism (SIA) changes in the small incision versus microincision after SMILE surgery.

Materials And Methods

Thirty-five patients (70 eyes) who underwent SMILE between July 2015 and January 2017 at the Department of Ophthalmology, Peking Union Medical College Hospital, Beijing, China were included in this retrospective study. Among them, 18 patients (36 eyes) and 17 patients (34 eyes) underwent bilateral SMILE with small incision (4 mm) and microincision (2 mm or 2.5 mm) hinge width, respectively. Based on the definition of myopia, two eyes in the small incision group and one eye in the microincision group had low myopia (-3 to 0 D), 15 eyes in the small incision group and 17 eyes in the microincision group had moderate myopia (-6 to -3 D), and 19 eyes in the small incision group and 16 eyes in the microincision group had high myopia (more than -6 D). The study protocol followed the guidelines of the Declaration of Helsinki, which was approved by the Institutional Review Board for Human Studies of the Peking Union Medical College Hospital Institutional Ethics Committee. Written informed consent was obtained from all the patients before the commencement of the study.

Patients enrolled in the study underwent SMILE surgery for the correction of myopia and myopic compound astigmatism. All patients demonstrated at least 1 year of stable refraction before undergoing refractive surgery, with a follow-up period of at least 6 months postoperatively. The exclusion criteria included amblyopia, ocular pathology, retinal disorders, previous ocular surgery, or insufficient

follow-up. Patients were required to discontinue the use of soft contact lenses for at least 2 weeks and rigid gas-permeable lenses for at least 4 weeks prior to surgery.

Preoperative examination

All patients underwent a routine standard ophthalmologic examination preoperatively. The investigation included manifest refraction, cycloplegic refraction, slit-lamp examination, ultrasound pachymetry, dilated funduscopy (Optos California, Marlborough, MA, USA), and intraocular pressure (IOP) measurement using a Goldmann applanation tonometer. Uncorrected distance visual acuity (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 (CCT) was measured by ultrasonic pachymetry (TOMEY Ltd, Aichi, Japan), in which each measurement was the average of five consecutive measurements. Corneal topography was measured by TMS-4N (TOMEY, Erlangen, Germany). For high myopia, the macular and optic thickness was measured by Topcon DRI OCT Triton (Topcon, Corp., Tokyo, Japan), and visual field assessments were performed using Octopus 900 perimeter (Haag-Streit Inc, Koenig, Switzerland).

Surgical procedure

All surgical procedures targeted individuals with emmetropia and were performed by the same experienced surgeon (Y.L.). Topical anaesthesia was administered with 0.5% proparacaine (Alcaine, Alcon-Couvreur, Puur-Sint-Amands, Belgium, USP). SMILE surgery was performed by VisuMax Femtosecond Laser Platform (Carl Zeiss, Meditec AG, Germany, 500-kHz repetition rate). A small curved interface cone was used during each surgical procedure. The anterior and posterior surfaces of lenticules (spiral-out and spiral-in patterns, respectively) were followed by a side cut of the cap. The options value of power and spot distances for lenticule creation were 140 nJ and 4.30 μm , respectively. VisuMax Femtosecond Laser ablation options for SMILE surgery were as follows: 6.0–6.5-mm lenticule diameter; 110–120- μm cap thickness; 4-mm (small incision) or 2–2.5-mm (microincision) hinge width at 120 degrees for lenticule extraction; and 7.5–7.6-mm cap diameter with 90-degree side cut angle. A spatula was inserted through the side cut over the roof of the refractive lenticule to dissect this plane, followed by 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, Texas, USA) was administered for 4 times/day for one week. Flumetholone (0.1% fluorometholone, Santen Pharmaceutical, Osaka, Japan) was used for 4 times/day during the second week, after which the frequency was decreased to once per day each week for 1 month. Finally, topical eye drops of 0.5% antibiotic (Ofloxacin, Santen Pharmaceutical, Osaka, Japan) were administered 4 times/day for 2 weeks.

Postoperative evaluation

Patients were followed up 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). Polar SIA was analysed by the polar value analysis method [12].

Statistical analysis

Data were recorded in an Excel spreadsheet (Microsoft, Redmond, Washington, USA), and statistical analyses were performed using SPSS for MAC version 25.0 (IBM SPSS, Somers, New York, USA). The normality of the data was tested with the Shapiro–Wilk test. If the data were not normally distributed, the Wilcoxon rank–sum test and Mann–Whitney test were performed. Friedman's Analysis of variance (ANOVA) with the Bonferroni correction was applied when data did not show normal distribution. Fisher exact or chi-square test (asymptotic, Yates corrected, or exact permutation as appropriate) for categorical variables. P-values <0.05 were considered significant.

Results

All 70 eyes were available for postoperative evaluation during 6 months after SMILE. The maximum diameter of the optical zone was 6.43 ± 0.15 mm. In the small incision and microincision groups, the mean and standard deviation (SD) value of the spherical equivalent (SE) were -6.22 ± 1.65 D and -6.21 ± 1.78 D ($p = 0.786$), respectively; the SRI values were 0.20 ± 0.19 D and 0.19 ± 0.16 D, respectively; the SAI values were 0.30 ± 0.10 D and 0.32 ± 0.10 D, respectively; and there were no statistically significant differences in the preoperative demographic data between the two groups. More details are shown in Table 1.

Table 1
Preoperative and demographic data of patients.

Parameters	Group		P value
	Small incision (n = 36)	Microincision (n = 34)	
Age (y)	27.78 ± 6.22	25.65 ± 4.77	0.164
Sex (F/M) (n)	32/4	26/8	0.168 [†]
Preoperative SE (D)	-6.22 ± 1.65	-6.21 ± 1.78	0.786
Preoperative K _{ast} (D)	1.43 ± 1.84	1.27 ± 0.65	0.304
K _s (D)	43.96 ± 1.14	44.57 ± 2.05	0.153
K _f (D)	42.53 ± 2.07	43.28 ± 1.63	0.095
IOP (mmHg)	15.89 ± 3.18	15.76 ± 3.13	0.597
SRI (D)	0.20 ± 0.19	0.19 ± 0.16	0.805
SAI (D)	0.30 ± 0.10	0.32 ± 0.10	0.505
CCT (µm)	544.42 ± 35.91	541.15 ± 34.04	0.655
RBT (µm)	308.00 ± 26.64	295.82 ± 34.73	0.079
Optical zone (mm)	6.41 ± 0.19	6.44 ± 0.10	0.590
Efficacy index	0.97	0.88	0.145 [†]
y = years, F = female, M = male, SE = spherical equivalent, D = diopters, K _{ast} = keratometric astigmatism, K _s = steepest keratometry, K _f = flattest keratometry, IOP = intraocular pressure, SRI = surface regularity index, SAI = surface asymmetry index, CCT = central corneal thickness, RBT = residual bed thickness.			
[†] Chi-square test for the comparison of variables between two groups.			

The objective of the surgery was to achieve emmetropia in all the patients; a comparison of cumulative data on postoperative UDVA and preoperative CDVA is shown in Fig. 1. At the most recent follow-up visit, the UDVA was 20/20 or better in 92.9% of the cases (n = 65) and 20/40 or better in 98.6% of the cases (n = 69). The efficacy index was 0.97 in the small incision group and 0.88 in the microincision group, respectively (p = 0.09; Table 1).

According to Friedman's ANOVA test, there were statistically significant differences in SRI, SAI, and IOP during a 6-month follow-up (all p < 0.001; Table 2). The preoperative SRI increased from 0.20 ± 0.19 D to 0.33 ± 0.23 D, SAI increased from 0.30 ± 0.10 D to 0.49 ± 0.22 D, IOP reduced from 15.89 ± 3.18 mmHg to 11.84 ± 3.14 mmHg in the small incision group (p < 0.001); SRI increased from 0.19 ± 0.16 D to 0.37 ± 0.25 D, SAI increased from 0.32 ± 0.10 D to 0.50 ± 0.28 D, IOP reduced from 15.76 ± 3.13 mmHg to 12.77 ± 1.61 mmHg in the microincision group (p < 0.001) 1 month after SMILE surgery. There were no additional significant changes in any other parameters during the remaining follow-up period. Further details are shown in Table 2.

Table 2
Changes of IOP and corneal surface irregularity after SMILE surgery.

Parameters	Preoperative		1 month		3 months		6 months		P value [†]
	Small incision	Microincision							
SRI (D)	0.20 ± 0.19	0.19 ± 0.16	0.33 ± 0.23*	0.37 ± 0.25*	0.30 ± 0.22*	0.31 ± 0.26*	0.32 ± 0.20*	0.34 ± 0.34*	< 0.001
SAI (D)	0.30 ± 0.10	0.32 ± 0.10	0.49 ± 0.21*	0.50 ± 0.28*	0.48 ± 0.17*	0.45 ± 0.19*	0.46 ± 0.15*	0.54 ± 0.32*	< 0.001
IOP (mmHg)	15.89 ± 3.18	15.76 ± 3.13	11.84 ± 3.14*	12.77 ± 1.61*	11.58 ± 2.09*	12.17 ± 2.12*	11.34 ± 2.23*	12.00 ± 1.60*	< 0.001

SRI = surface regularity index, SAI = surface asymmetry index, D = diopters, IOP = intraocular pressure, post-op = postoperative.
*P value was statistically significant difference between baseline and postoperatively by Wilcoxon rank-sum test (p < 0.001).
[†]Friedman's Analysis of variance (ANOVA) with the Bonferroni correction for the comparison of corresponding values between groups during a 6-month follow-up.

Corneal surface irregularity changes in the small incision versus microincision during a 6-month follow-up are shown in Table 3. A total of 32 eyes (88%) in the small incision group and 32 eyes (94%) in the microincision group, SRI values less than 0.50 D; 36 eyes (100%) in the small incision group and 34 eyes (100%) in the microincision group, SAI values less than 0.50 D, preoperatively. During a 6-month follow-up, 27 eyes (75%) in the small incision group and 28 eyes (82%) in the microincision group, SRI values less than 0.50 D; 22 eyes (61%) in the small incision group and 18 eyes (53%) in the microincision group, SAI values less than 0.50 D (all p < 0.001).

Table 3
SRI and SAI changes in the small incision versus microincision during a 6-month follow-up.

Parameters	Preoperative		1 month		3 months		6 months		P value
	Small incision	Microincision							
< 0.50 D in SRI no. (%)	32 (88%)	32 (94%)	26 (72%)	26 (76%)	28 (78%)	27 (79%)	27 (75%)	28 (82%)	< 0.001
< 0.50 D in SAI no. (%)	36 (100%)	34 (100%)	23 (64%)	23 (68%)	23 (64%)	26 (76%)	22 (61%)	18 (53%)	< 0.001

SRI = surface regularity index, SAI = surface asymmetry index, D = diopters.

Table 4 shows the results of polar SIA changes after SMILE surgery. The combined mean polar values for SIA changed in astigmatic of polar value of net astigmatism (AKP) [AKP(+ 0) and AKP(+ 45)] were not statistically significantly different between two groups during various postoperative visits.

Table 4

Polar value analysis of astigmatism changes after SMILE during various postoperative visits.

Parameter	Group		P value
	Small incision	Microincision	
Pre-op			
AKP(+0)	1.43 ± 1.84	1.27 ± 0.65	0.304
AKP(+45)	0	0	1.000
Post-op 1 month			
AKP(+0)	0.15 ± 0.45	0.13 ± 0.53	0.634
AKP(+45)	-0.03 ± 0.38	-0.04 ± 0.51	0.801
Post-op 3 months			
AKP(+0)	0.01 ± 0.39	0.01 ± 0.57	0.916
AKP(+45)	-0.01 ± 0.47	0.01 ± 0.55	0.953
Post-op 6 months			
AKP(+0)	0.01 ± 0.44	0.15 ± 0.46	0.204
AKP(+45)	-0.16 ± 0.41	0.02 ± 0.50	0.098
Change			
△AKP(+0)	-1.41 ± 1.87	-1.12 ± 0.70	0.716
△AKP(+45)	-0.16 ± 0.41	0.02 ± 0.50	0.098
SMILE = small incision lenticule extraction, 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.			

Discussion

SMILE surgery is a popular corneal refractive surgical procedure that can both reduce the risk of iatrogenic dry eye disease (DED) and improve the overall outcome. This indicates that refractive surgery has evolved through the reduction of the limitations related to preoperative ocular dryness. However, some patients have experienced transient dryness of eye after refractive surgery, whereas others have reported severe symptoms over a long period [1, 5, 7, 9, 13]. Moreover, DED can affect visual quality and visual function, meanwhile tear film instability and ocular surface damage lead to visual disturbances [14]. In the current study, we evaluate corneal surface irregularity and polar SIA changes after SMILE surgery, and found that incision size does not influence the postoperative visual and refractive outcomes.

A stable and continuous tear film is essential for achieving an optically smooth surface. Currently, corneal topographical examinations have been shown to help assess the corneal surface irregularities in aqueous tear deficiency states by using indices such as the SRI and SAI [10]. The present study showed that there were statistically significant increases in the SRI from 0.20 ± 0.19 D to 0.33 ± 0.23 D in the small incision group, and from 0.19 ± 0.16 to 0.37 ± 0.25 in the microincision group; and in the SAI from 0.30 ± 0.10 D to 0.49 ± 0.21 D in the small incision, and from 0.32 ± 0.10 D to 0.50 ± 0.28 D in the microincision group 1 month after SMILE surgery with no additional significant changes during follow-up period. Regarding our results, there were statistically significant induced SRI values over 0.50 D as 25% in the small incision group and 18% in the microincision group; SAI values over 0.50 D as 39% in the small incision group and 47% in the microincision group, 6-month after SMILE surgery. It was reported that the 38.9% of patient' eyes were DED by a self-reported symptom questionnaire study [8]. A meta-analysis study reported that SMILE procedures did not have obvious superiority over femtosecond-assisted laser in situ keratomileusis, after revealing similar and acceptable objective parameters with SMILE, potentially resulting in milder subjective symptoms [13]. Further, we used the AKP analysis method [12] to evaluate the SIA changes and found that AKP(+0) showed statistically significant changes in both groups, and fluctuation in corneal surface irregularity outcomes masked changes of polar SIA values after SMILE surgery. This meant that the corneal wound healing processes influenced corneal surface irregularity and corneal polar SIA values during various postoperative visits.

In the current study, we found the refractive and visual outcomes 6 months after SMILE surgery for the patients with low to high myopia to be promising. UDVA was 20/20 or better in 97% of the eyes in the small incision group and 20/20 or better in 88% of the eyes in the microincision group. The preoperative CDVA was 20/18 or better in 36% of the eyes in the small incision group and 20/18 or better in 62% of the eyes in the microincision group. These results are similar to those demonstrated in a previous study after SMILE surgery for high myopia [15]. Superior efficacy index is shown in present study, and similar results (0.97) were reported by Sánchez-González et al. [16]

Schallhorn et al. [17] found that the CCT, ablation volume, and flap creation were influenced by the postoperative IOP. In the current study, a high steroid-induced IOP was observed (> 20 mmHg) in 8.57% of cases. In addition, SMILE procedures are associated with steroid-induced IOP in the early stage after surgery [18]. Moreover, eyes with high myopia are at a high risk of glaucoma and are difficult to diagnose at an early stage, especially after corneal refractive surgery [19]. On the contrary, IOP was a major factor used for monitoring, and it facilitates long-term follow-up of glaucoma, including characterisation of primary open-angle glaucoma (POAG). Na et al. [20] suggested that OCT was useful for the diagnosis of POAG through the evaluation of the peripapillary choroidal microvasculature dropout and retinal nerve fibre layer combined with hemifield visual field (VF) in high myopic eyes. Currently, there are no reported cases of VF loss and glaucoma symptoms during SMILE procedures.

The current study has several limitations. First, the statistical analysis showed that, more females were involved in current study, which could lead to a possible bias in the outcomes. Shehadeh-Mashor et al. [1] determined that the development of DED after refractive surgery was associated with age, sex, a lower preoperative refractive error, and LASIK procedures. Moreover, recent studies have reported the occurrence of clinical signs of DED, showing controversial results after SMILE surgery [4, 7, 13]. However, the tear stability analysis system was effective in assessing tear stability in DED and quantitatively evaluating the different types of DED by SRI and SAI [10, 21]. A large sample size to achieve more effective power should be considered in further investigation.

Conclusion

SMILE has become a popular surgical option with stable postoperative biomechanical properties and provides superior visual outcomes after surgery. Our data indicate that SMILE is a safe and effective refractive surgical option for patients with low to high myopia combined with high astigmatism, and favourable outcomes of astigmatism after SMILE procedures were noted.

Abbreviations

SMILE: small incision lenticule extraction; LASIK: laser-assisted in situ keratomileusis; SAI: surface asymmetry index; SRI: surface regularity index; SIA: surgically induced astigmatism; IOP: intraocular pressure; UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; AKP: astigmatic of polar value of net astigmatism; CCT: central corneal thickness; DED: dry eye disease; POAG: primary open-angle glaucoma.

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:

The datasets obtained and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests:

The authors declare that they have no competing interests.

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None.

Authors' contributions:

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

Performed the experiments: Y.L.

Collect and analyzed the data: J.P. and M.W.

Contributed reagents/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

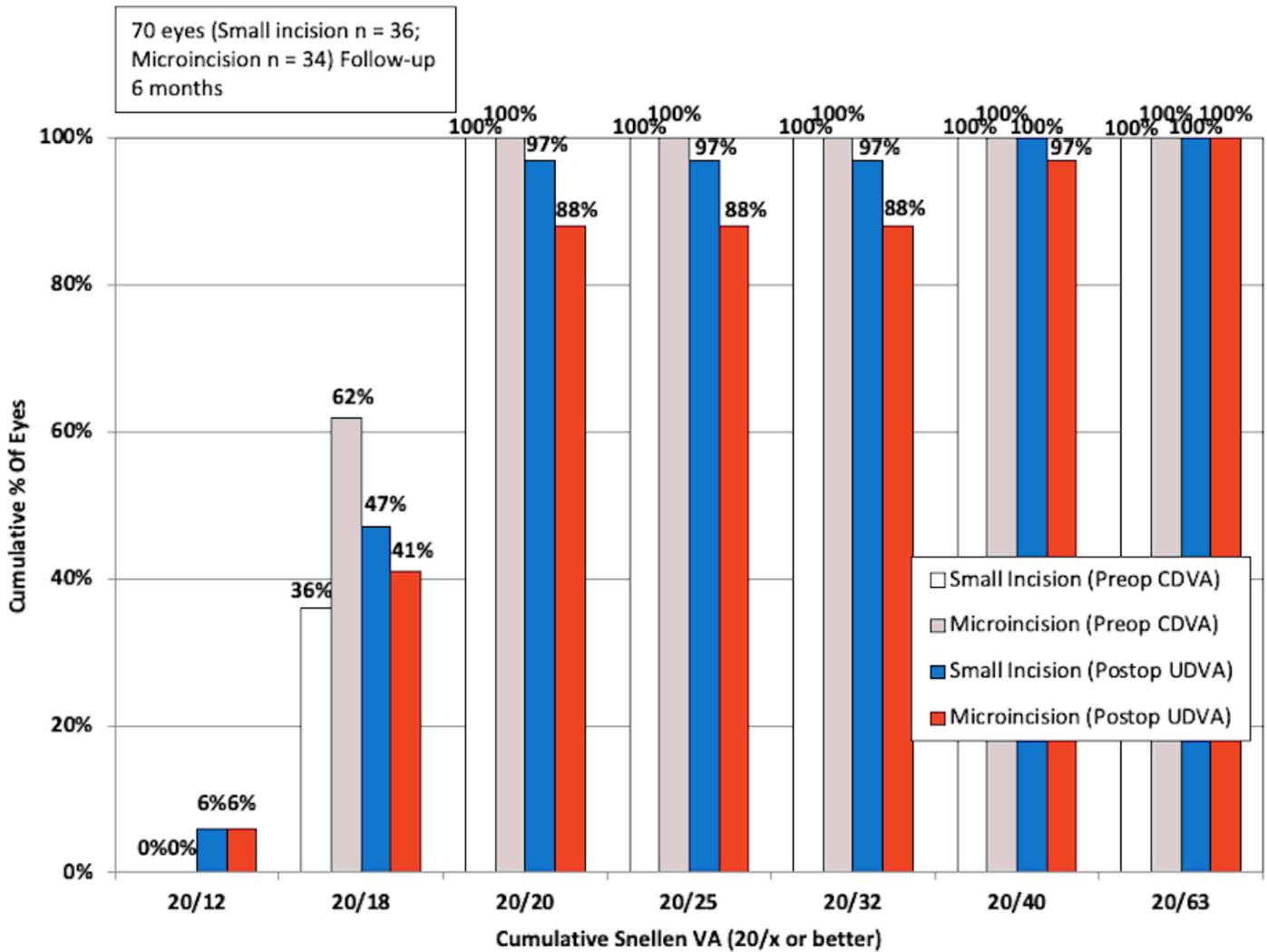


Figure 1

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