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Intraocular pressure fluctuation range and correction after small incision lenticule extraction

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飞秒激光小切口角膜基质透镜取出术后眼压波动的范围与校正

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摘要

目的:探讨低、中、高度近视患者飞秒激光小切口角膜基质透镜取出术(SMILE)后正常眼压(IOP)波动范围的变化,探索术后眼压(IOP_{post})校正的新方法。

方法:前瞻性病例研究。纳入 2018-03/2019-09 在青岛大学附属医院接受 SMILE 治疗的近视患者 79 例 158 眼,分为低度近视(A)、中度近视(B)和高度近视(C)组。24h 眼压采用非接触式眼压计(NCT)和 Goldmann 眼压计(GAT)测量。记录术前 3d 和术后 6mo 等效球差(SE)、中央角膜厚度(CCT)、角膜横径(WTW)、角膜曲率、角膜体积(CV)、中央 3mm 直径范围内角膜体积(CCV_{3mm})与 CV 之比、切削 CV(△CV)与 CV 的比值。统计分析术后 NCT 测量值(NCT_{post})与各因素的相关性,并通过分阶段多元线性回归分析建立 IOP_{post} 表达模型。

结果:NCT 和 GAT 测得的眼压无差异($P>0.05$),但 3 组眼压有差异($P<0.05$)。NCT 的 IOP_{post} 范围:A 组为 8~17mmHg,B 组为 7~16.3mmHg,C 组为 7.7~14.3mmHg。GAT 的 IOP_{post} 范围为 8~17mmHg。IOP_{post} 的昼夜波动范围<6mmHg。IOP_{post} 双眼差值为 0~4mmHg。建立分阶段多元回归模型:$NCT_{post校正(A)}=0.349\times NCT_{post}+4.137\times CCV_{pre3mm}-1.533$;$NCT_{post校正(B)}=0.477\times NCT_{post}+3.643\times CCV_{post3mm}-1.125$;$NCT_{post校正(C)}=0.638\times NCT_{post}+3.426\times CCV_{post3mm}-0.716$。

结论:SMILE 术后 NCT 和 GAT 测得的眼压均低于术前。患者手术前后角膜体积变化率越大,术后眼压值越低。中央 3mm 直径范围内角膜体积是评价 SMILE 术后眼压的重要指标,从而指导术后用药。

关键词:飞秒激光小切口角膜基质透镜取出术;近视;眼压;昼夜眼压波动;校正

Abstract

• AIM: To investigate changes in the normal intraocular pressure (IOP) fluctuation range after the small incision lenticule extraction (SMILE) in patients with low, moderate and high myopia and to explore new methods for postoperative IOP (IOP_{post}) correction.

• METHODS: In this prospective case series study, 79 patients (158 eyes) who underwent SMILE at the Affiliated Hospital of Qingdao University from March 2018 to September 2019 were involved, and they were divided into low myopia (A), moderate myopia (B), and high myopia (C) groups. The 24-hour IOP was measured by the non-contact tonometer (NCT) and Goldmann applanation tonometer (GAT). Spherical equivalent (SE), central corneal thickness (CCT), the horizontal corneal diameter (WTW), corneal curvature, corneal volume (CV), ratio of the central 3-mm diameter CV (CCV_{3mm}) to the total CV, and the ratio of the cutting CV (ΔCV) to the CV were measured 3d preoperatively and 6mo postoperatively. The correlation between the postoperative NCT measurements (NCT_{post}) and various factors was statistically analysed, and the IOP_{post} expression model was established by phased multiple linear regression analysis.

• RESULTS: The differences in IOP measured by NCT and GAT were not statistically significant ($P>0.05$), but the differences in IOP of the three groups were statistically significant ($P<0.05$). The IOP_{post} range by NCT were 8-17 mmHg in group A, 7-16.3 mmHg in group B, and 7.7-14.3 mmHg in group C. The IOP_{post} range by GAT were 8-17 mmHg. The IOP_{post} fluctuation was <6 mmHg. The IOP_{post} difference between the right eye and left eye was 0-4 mmHg. A staged multivariate regression model was established: $NCT_{post\ corrected(A)}=0.349\times NCT_{post}+4.137\times CCV_{pre3mm}-1.533$; $NCT_{post\ corrected(B)}=0.477\times NCT_{post}+3.643\times CCV_{post3mm}-1.125$; $NCT_{post\ corrected(C)}=0.638\times NCT_{post}+3.426\times CCV_{post3mm}-0.716$.

• CONCLUSION: The IOP measured by NCT and GAT after SMILE was lower than that measured before surgery. For different patients, the greater the rate of change in CV before and after surgery, the lower the IOP_{post}. $CCV_{post3mm}$ is an important index for evaluating IOP after SMILE and thus guide postoperative medication administration.
• KEYWORDS: small incision lenticule extraction; myopia; intraocular pressure; diurnal IOP fluctuation; correction
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INTRODUCTION

In recent years, with the growing number of people with myopia, the incidence of the primary open angle glaucoma (POAG) is increasing, and as the diopter step of myopia continues to rise, the probability of developing into POAG is higher[1-3]. Intraocular pressure (IOP) is currently the best indicator for evaluating the risk of glaucoma, and it is also the most effectively monitored indicator[4-5]. Corneal refractive surgeries have made great progress. Among them, small incision lenticule extraction (SMILE) has become a emerging mainstream surgical treatment for myopia. Due to its advantages of small incision, high safety and good biomechanical stability, SMILE has become more and more myopic patients' choices[6-8]. However, SMILE removes a complete stromal lens, which still causes a certain impact on the cornea, causing the tonometer's measurement value to change[9-10]. We need to accurately assess the 24-hour IOP changes of myopia patients with different diopter steps after SMILE. This has an important clinical application value for the timely diagnosis and treatment of potential POAG patients after SMILE. This study will observe the changes in IOP fluctuations of myopia patients with various refractive levels after SMILE, and respectively correct the IOP values after reduction, which will provide a reference for postoperative follow-up of myopia patients.

SUBJECTS AND METHODS

Ethical Approval The institutional review board at the Affiliated Hospital of Qingdao University approved this study protocol, which adhered to the tenets of the Declaration of Helsinki. All patients provided informed consent for surgery.

Objectives In this prospective case series study, 79 patients (158 eyes) who underwent SMILE surgery for correcting myopia and/or astigmatism at the Department of Ophthalmology, Affiliated Hospital of Qingdao University, from March 2018 to September 2019 were involved. Among them, there were 44 males and 35 females, aged between 18 and 35 (mean 22.3±4.3) years.

The inclusion criteria were as follows: 1) age: 18-35 years old; 2) refractive status: spherical equivalent (SE) ≤ -10.00 D, cylinder degree ≤ -5.00 D, refractive dioptre progression ≤ 0.5 D within 1y, and best corrected visual acuity (BCVA) ≥1.0. Patients were off soft contact lenses for at least 2wk, off rigid contact lenses for at least 4wk and off orthokeratology for at least 3mo; 3) ocular conditions: corneal transparency, normal corneal topography, no keratoconus tendency, calculated residual stromal bed after treatment ≥280 μm, and no dry eye and other ocular surface diseases; 4) IOP requirements: IOP_{pre} ≤21 mmHg.

The exclusion criteria were as follows: 1) ocular diseases: glaucoma, suspected glaucoma, visual field damage, cup-to-disk ratio >0.3, active inflammatory reaction or infection of the eye, history of previous eye surgery, history of trauma, cataract affecting vision, fundus disease, *etc*.; 2) systemic diseases: diabetes, hyperthyroidism, systemic connective tissue disease, mental disorders, *etc*. The grouping criteria were as follows (Table 1).

Inspection Methods All patients underwent a conventional SMILE preoperative examination, including assessments for uncorrected distance visual acuities (UDVA) and corrected distance visual acuities (CDVA), general optometry, dilated optometry, 24-hour IOP (24-hour IOP measured at 2:00, 6:00, 10:00, 14:00, 18:00, and 22:00), slit-lamp microscopy, corneal topography and a fundus examination. The follow-up period was 6mo. The UDVA, CDVA, general optometry, 24-hour IOP, and corneal topography were reviewed at 1wk, 1, 3mo and 6mo after SMILE surgery. This study used the 6mo postoperative data for statistics.

1) Vision: UDVA and CDVA before and after surgery were measured using a standard logarithmic visual acuity chart. A five-point recording method was used; 2) Optometry: A NIDEK AR-1 computer refractometer was used to check the patient's dioptre, which was combined with manifest refraction results and converted to an spherical equivalent (SE); 3) IOP value: Perform the non-contact tonometer (NCT, NT-510, Canon, Japan) inspection first, followed by the goldmann applanation tonometer (GAT, Haag-Streit, Bern, Switzerland) inspection, with an interval of 15min. During the NCT measurement, patients were required to relax, avoid blinking and holding their breath, and gaze at the indicator light. For each eye, the arithmetic average of the 3 measurement values was taken, and the difference between the measured values was less than 3 mmHg. Before GAT measurement, the subject's eyes were drunk with 0.5% tetracaine for surface anesthesia. After 0.25% sodium fluorescein solution was dripped, three measurements were made. The difference between the measured values is required to be less than 1 mmHg, and the average value is taken; 4) Corneal topography: The Oculus Pentacam three-dimensional anterior segment analyser was used to observe the front and back corneal surface morphology. The corneal volume (CV) before and after surgery, the central 3 mm-diameter CV (CCV_{3mm}), horizontal corneal diameter (WTW), and corneal curvature (Kf, Ks, Km) were recorded. Eyes were maintained, in a good state of tear film in a dark room before

Table 1　Baseline characteristics of the study subjects

Parameters	Group A (n=53)		Group B (n=65)		Group C (n=40)		F	P
	$\bar{x}\pm s$	range	$\bar{x}\pm s$	range	$\bar{x}\pm s$	range		
Age (y)	21.6±3.4	18-30	22.9±4.6	18-35	22.4±4.3	18-34	1.427	0.243
SE (D)	-2.594±0.526	-1.00- -3.00	-4.277±0.777	-3.25- -6.00	-6.919±0.478	-6.25- -8.00	534.653	<0.001
CCT (μm)	543.55±20.57	480-591	548.86±29.60	487-598	556.95±16.93	506-595	2.578	0.079
Kf (D)	42.14±1.22	39.8-44.7	42.20±1.34	40.0-44.7	42.23±1.24	40.3-44.6	0.164	0.834
Ks (D)	43.33±1.23	40.4-45.4	43.47±1.50	40.6-46.1	43.84±1.30	42.2-46.2	1.692	0.187
Km (D)	42.73±1.67	40.3-45.0	42.82±1.39	40.3-45.2	43.04±1.22	41.3-45.3	0.66	0.518
WTW (mm)	11.95±0.36	11.3-12.8	11.64±0.34	11.0-12.4	11.87±0.39	11.4-12.6	1.844	0.163
CCV_{3mm} (mm^3)	3.92±0.16	3.5-4.3	3.96±0.22	3.5-4.6	4.00±0.16	3.7-4.3	2.007	0.138
CV (mm^3)	60.86±2.52	55.9-65.5	61.88±3.25	56.1-70.7	62.09±2.50	58.2-65.6	2.692	0.071

SE:Spherical equivalent; CCT: Central corneal thickness; WTW: The horizontal corneal diameter; CV: Corneal volume; Low myopia group (group A) (53 eyes): -1.00 D≤SE≤-3.00 D; Moderate myopia group (group B) (65 eyes): -3.00 D <SE≤-6.00 D; High myopia group (group C) (40 eyes): -6.00 D<SE ≤-8.00 D; Spherical equivalent: Spherical mirror + 1/2 cylinder mirror (SE = DS + 1/2 DC).

Table 2　Comparison of IOP_{pre}, IOP_{post} and Pentacam-corrected IOP in each group　　mmHg

Parameters	Group A			Group B			Group C		
	$\bar{x}\pm s$	t	P	$\bar{x}\pm s$	t	P	$\bar{x}\pm s$	t	P
3d before surgery	15.92±2.08			16.35±2.16			16.60±1.77		
6mo after surgery	10.57±1.68	55.428	<0.001	10.32±1.54	69.247	<0.001	10.01±1.40	66.140	<0.001
Ehlers method	15.49±1.42	3.741	0.001	16.33±2.07	-0.300	0.764	17.94±1.64	-6.081	<0.001
Shah method	14.30±1.32	14.937	<0.001	14.82±1.64	10.875	<0.001	15.82±1.43	4.419	<0.001
Dresden method	13.56±1.33	22.723	<0.001	13.93±1.50	19.279	<0.001	14.64±1.37	15.362	<0.001
Kohlhaas method	13.46±1.62	26.710	<0.001	13.84±1.58	24.128	<0.001	14.29±1.71	19.092	<0.001
Orssengo/pye method	13.64±2.58	18.449	<0.001	13.31±1.87	23.481	<0.001	13.70±1.81	22.412	<0.001

the examination, and the average of the 3 measurement values was taken for the study. The above checks were performed by an experienced technician.

Surgical Methods　A VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) was used for surgical refractive corrections in all patients. The thickness of the corneal cap was set to 120 μm, the diameter was 7.8 mm, the lens diameter was 6.7 mm, the thinnest edge was 15 μm, and the astigmatism transition zone was 0.1 mm. The patient was placed in supine position, and the eye was anaesthetized. According to the surgical parameters, the posterior surface of the lens was first scanned and cut laterally. Then, the front surface of the lens was scanned, and the 2 mm edge of the corneal cap was scanned. After the end of the scan, the substrate lens was bluntly separated and completely removed. All procedures were performed by the same surgeon.

Postoperative Medication　Postoperatively, all the patients received 0.5% levofloxacin eye drops for 7d and 0.1% fluorometholone eyedrops for 2wk. Sodium hyaluronate eye drops were used for more than 4wk.

Statistical Methods　A prospective series of case studies was included in this study. Data analysis was performed using SPSS 22.0 statistical software. Normally distributed data are represented by the $\bar{x} \pm s$. Repeated measures analysis of variance was used to compare 24-hour IOP measurements before and after surgery. Pearson or Spearman correlation analysis was used to analyse the correlation between the IOP_{post} measurements and various influencing factors. Phased multiple linear regression analysis was used for IOP_{post} measurements and various influencing factors and to obtain a correction formula for the IOP_{post}. The difference was statistically significant at $P<0.05$.

RESULTS

Comparison of IOP_{pre}, IOP_{post} and Pentacam-corrected IOP　A paired t-test was used in Table 2. The IOP_{post} corrected by Ehlers was higher than the IOP_{pre} in patients with high myopia, and the IOP_{post} corrected by Ehlers was lower than the IOP_{pre} in patients with low myopia ($P<0.01$). There was no significant difference between the IOP_{pre} and IOP_{post} corrected by Ehlers in patients with moderate myopia (t = -0.300, P = 0.764). The NCT_{post} and Pentacam-corrected IOPs (Dresden, Orssengo, Shah, and Kohlhaas) were significantly decreased in each group, and the difference was statistically significant ($P<0.01$).

Comparison of the 24-hour IOP of the Left and Right Eyes　The difference between the two eyes preoperatively was 0-5 (mean 2.16±1.48) mmHg, and the difference between the two eyes postoperatively was 0-4 (mean 1.70±1.24) mmHg, indicating that the difference between the two eyes postoperatively was smaller than that before surgery.

The IOP_{pre} of the right eye was 10-20.3 mmHg, with an average of 16.19±2.09 mmHg; the IOP_{pre} of the left eye was 11-21 mmHg, with an average of 16.30±2.03 mmHg, and the difference was not statistically significant (t = -0.895, P=0.371). Repeated measures analysis of variance showed a statistically significant difference in intraocular pressure

Table 3 Comparison of the 24-hour IOP values for the right eye and left eye in myopic patients after SMILE

(n=79, $\bar{x}\pm s$, mmHg)

Parameters	24h						Sum
	2:00	6:00	10:00	14:00	18:00	22:00	
OD	11.00±1.48	11.04±1.53	10.50±1.69	9.95±1.51	10.04±1.57	9.87±1.28	10.37±1.58
OS	10.78±1.47	10.91±1.67	10.76±1.82	10.01±1.62	9.89±1.44	10.04±1.48	10.39±1.64
Sum	10.90±1.48	10.98±1.60	10.63±1.76	9.98±1.56	9.96±1.50	9.96±1.39	10.38±1.61
t	0.929	0.518	-0.939	-0.265	0.668	-0.846	-0.215
P	0.356	0.606	0.351	0.792	0.506	0.400	0.830

Table 4 Changes in the range of IOP values before and after surgery in each group mmHg

Period	Groups	NCT		GAT		*t*	*P*
		$\bar{x}\pm s$	Range	$\bar{x}\pm s$	Range		
3d before surgery	Group A	15.92±2.08	11.0-21.0	15.69±2.09	10.0-20.0	1.451	0.148
	Group B	16.35±2.16	10.0-20.3	16.14±2.29	10.0-19.0	1.275	0.203
	Group C	16.60±1.77	12.7-21.0	16.32±1.99	11.0-21.0	1.584	0.115
	F	8.054		6.681			
	P	<0.001		0.001			
6mo after surgery	Group A	10.57±1.68	8.0-17.0	10.82±2.24	8.0-17.0	-1.587	0.114
	Group B	10.32±1.54	7.0-16.3	10.54±2.00	8.0-17.0	-1.839	0.067
	Group C	10.01±1.40	7.7-14.3	10.28±1.90	8.0-16.0	-1.802	0.073
	F	8.977		4.651			
	P	<0.001		0.010			

fluctuations in both eyes (F=24.903, P<0.001), and there was no interaction between the right and left eyes at any time point (F=0.888, P=0.477), indicating that time had no influence on the eyes.

According to the repeated measures variance analysis (Table 3), the multivariate test results showed that the IOP of the right eye (F=23.101, P<0.001), the IOP of the left eye (F=17.027, P<0.001), and the IOP at different time points after SMILE were significantly different, indicating that there was diurnal fluctuation in intraocular pressure. There was no interaction between the time points and the two eyes (F=1.474, P=0.202), indicating that time did not affect the eye. An analysis of variance of the IOP in the right eye and left eye for 24h showed that F=38.495 and P<0.001, indicating that there was a significant difference between the right eye and left eye 24-hour IOP in myopia patients after surgery. The IOP of the right eye and left eye were analysed with paired t-tests at each time point, indicating that there was no significant difference in the IOP of the right and left eyes at any time point in patients with myopia after SMILE (P>0.05).

Comparison of 24-hour IOP_{pre} and 24-hour IOP_{post} The differences in IOP measured by NCT and GAT were not statistically significant (P>0.05), but the differences in IOP of the three groups were statistically significant (P<0.05). The normal IOP range of 10-21 mmHg was not applicable to the IOP value after SMILE. The IOP_{post} range by NCT were 8-17 mmHg in group A, 7-16.3 mmHg in group B, and 7.7-14.3 mmHg in group C. The IOP_{post} range by GAT were 8-17 mmHg (Table 4). The IOP fluctuation before surgery was ≤8 mmHg, and the IOP fluctuation after surgery was ≤6 mmHg (Table 5).

Repeated measures analysis of variance was performed on the IOP values from before and after SMILE in patients with low myopia, which was listed in Table 6. The following IOP measured by NCT. The multivariate test results showed that the IOP_{pre} (F=14.814, P<0.001), IOP_{post} (F=4.432, P<0.001), and IOPs at different time points were significantly different and that there was no interaction between the preoperative and postoperative measurements at any time point (F=2.587, P=0.111), indicating that the effect of time does not vary for the preoperative and postoperative measurements. The analysis of variance before and after surgery showed that F=17.615 and P<0.001, indicating a significant difference between the IOP_{pre} and IOP_{post} measurements. A paired t-test was performed on the IOPs at each time point before and after surgery and showed that P<0.001, indicating that there was a significant difference between the IOP at each time point before and after surgery. Similarly, there was a significant difference between the preoperative and postoperative IOP measurements in patients with moderate and high myopia (group B: F=31.211, P<0.001; group C: F=80.121, P<0.001) (Table 7, Table 8).

Correlations Between IOP_{post} Measurements and Various Influencing Factors The IOP_{post} measurements of each group were positively correlated with IOP_{pre}, CCT_{post}, 3 mm/WTW,

Table 5　Changes in the 24h fluctuation range of IOP before and after surgery in each group mmHg

Period	Groups	NCT		GAT		t	P
		$\bar{x}\pm s$	Range	$\bar{x}\pm s$	Range		
3d before surgery	Group A	3.62±1.18	0.7-7.3	3.39±1.03	1.0-5.7	1.010	0.317
	Group B	3.53±1.04	1.3-5.7	3.41±1.08	0.7-6.3	0.738	0.463
	Group C	3.47±0.95	1.7-6.0	3.20±0.89	1.3-5.3	1.340	0.188
	F	0.235		0.614			
	P	0.790		0.537			
6mo after surgery	Group A	2.87±1.07	0.3-5.3	3.06±0.89	1.0-5.0	-0.973	0.335
	Group B	2.78±1.02	0.7-5.0	3.02±0.78	1.3-5.3	-1.384	0.171
	Group C	2.92±1.11	0.7-6.0	3.09±0.84	0.7-5.7	-0.488	0.628
	F	0.243		0.135			
	P	0.285		0.826			

Table 6　Changes in IOP 24h before and after SMILE in patients with low myopia ($n=53$, $\bar{x}\pm s$, mmHg)

Date	24h						Sum
	2:00	6:00	10:00	14:00	18:00	22:00	
3d before surgery	16.55±2.09	16.63±2.08	16.46±2.32	15.37±1.83	15.19±1.95	15.33±1.69	15.92±2.08
6mo after surgery	11.00±1.63	10.94±1.78	10.65±1.62	10.25±1.45	10.36±1.72	10.24±1.79	10.57±1.68
Sum	13.77±3.35	13.79±3.45	13.55±3.53	12.81±3.05	12.77±3.04	12.79±3.09	13.25±3.28
t	20.020	20.179	20.866	21.587	14.899	18.845	46.559
P	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 7　Changes in IOP values 24h before and after SMILE in patients with moderate myopia ($n=65$, $\bar{x}\pm s$, mmHg)

Date	24h						Sum
	2:00	6:00	10:00	14:00	18:00	22:00	
3d before surgery	17.10±2.22	17.01±2.26	16.71±1.93	15.61±1.97	15.69±2.08	15.96±2.05	16.35±2.16
6mo after surgery	10.90±1.41	10.97±1.45	10.37±1.71	9.92±1.51	9.82±1.50	9.97±1.25	10.32±1.54
Sum	14.00±3.62	13.99±3.58	13.54±3.66	12.76±3.35	12.75±3.46	12.97±3.45	13.33±3.55
t	23.036	20.763	27.933	24.411	22.787	28.452	59.172
P	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8　Changes in IOP values 24h before and after SMILE in patients with high myopia ($n=40$, $\bar{x}\pm s$, mmHg)

Date	24h						Sum
	2:00	6:00	10:00	14:00	18:00	22:00	
3d before surgery	17.69±1.61	17.95±1.93	17.13±1.62	16.00±1.57	15.81±1.89	16.40±1.50	16.60±1.77
6mo after surgery	10.42±0.99	10.77±1.57	10.31±1.92	9.27±1.44	9.26±0.97	9.58±0.84	10.01±1.40
Sum	14.02±3.82	14.33±3.98	13.53±3.83	12.56±3.68	12.42±3.55	12.97±3.59	13.38±3.83
t	40.261	31.441	29.506	29.853	42.729	34.071	66.140
P	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

CV_{post}, $CCV_{post3mm}$, and $CCV_{post3mm}/CV_{post}$ ($P<0.05$; Table 9), and negatively correlated with WTW ($P<0.05$; Table 9). There was no significant correlation with corneal curvature$_{post}$, ΔCV, and ΔIOP ($P>0.05$).

Correction Formula for IOP_{post} Measurements　The IOP 6mo postoperatively was used as a dependent variable, and the SE_{pre}, CCT_{post}, WTW, 3 mm/WTW, CV_{post}, $CCV_{post3mm}$, $CCV_{post3mm}/CV_{post}$ were used as independent variables. A staged multivariate regression model (stepwise method) was established for each group of IOP_{post} measurements. $NCT_{post\ corrected\ (A)} = 0.349 \times NCT_{post} + 4.137 \times CCV_{pre3mm} - 1.533$ ($F=17.165$, $P<0.01$), adjusted $R^2=0.383$; $NCT_{post\ corrected\ (B)} = 0.477 \times NCT_{post} + 3.643 \times CCV_{post3mm} - 1.125$ ($F=41.819$, $P<0.01$), adjusted $R^2=0.561$; $NCT_{post\ corrected\ (C)} = 0.638 \times NCT_{post} + 3.426 \times CCV_{post3mm} - 0.716$ ($F=69.858$, $P<0.01$), adjusted $R^2=0.779$.

DISCUSSION

At present, the safety, effectiveness, stability, and predictability of SMILE correction for myopia and/or astigmatism have been widely recognized[11-12]. The femtosecond

Table 9 Correlations between IOP_{post} measurements and corneal parameters and their differences in each group *r*

Groups	IOP_{pre}	CCT_{post}	WTW	3 mm/WTW	CV_{post}	$CCV_{post3mm}$	$CCV_{post3mm}$/ CV_{post}
Group A	0.616[a]	0.785[a]	-0.395[a]	0.407[a]	0.307[a]	0.731[a]	0.633[a]
Group B	0.650[a]	0.613[a]	-0.282[a]	0.301[a]	0.515[a]	0.635[a]	0.373[a]
Group C	0.811[a]	0.442[a]	-0.570[a]	0.501[a]	0.410[a]	0.630[a]	0.382[a]

a: $P<0.05$.

laser is the shortest pulse laser that humans have built under laboratory conditions. It rapidly ionizes the corneal tissue to form a hot plasma, vaporizes the corneal tissue and generates expanded blisters and CO_2 bubbles. The corneal tissue is thus separated so that the complete stromal lens can be cut out of the corneal tissue[13].

Accurate evaluation of the IOP after SMILE is essential for the diagnosis and treatment of potential glaucoma patients[9]. The Goldmann applanation tonometer (GAT) is still considered the gold standard for tonometers[14]. However, the GAT is an applanation tonometer, and corneal thickness, corneal curvature, tear film stability, and corneal stroma elasticity may all influence the measurement of intraocular pressure[15]. At present, NCT is designed based on the Imberk-Fick principle. Its automatic microcomputer sensor calculates the intraocular pressure value according to the time required for the light to reflect from the corneal surface and flatten the 3.6 mm-diameter area of the central corneal area[16-17]. NCT does not require surface anaesthesia and does not touch the cornea[18]. It is suitable for large-scale screening of potential glaucoma patients, especially for patients who have undergone myopic surgery. In this study, we found that there was no statistical difference between the IOP measured by NCT and GAT ($P>0.05$). Animal experimental studies have shown that the eyeball structure and aqueous humour circulation are not affected by corneal refractive surgery and that the IOP will not change significantly[19]. However, the cornea is not an ideal plane. Because of changes in the central corneal volume, corneal curvature, corneal biomechanics, *etc.*, after SMILE, the force required to flatten the cornea of the same area is reduced, and the postoperative IOP value is lower than the true value[20]. Thus, the IOP evaluation standard[21], in which 10-21 mmHg is the normal IOP range, the binocular difference is ≤5 mmHg and the diurnal IOP fluctuation is ≤ 8 mmHg, is no longer appropriate.

LASIK changes the curvature of the front surface of the cornea through the ablation of the corneal stroma with an excimer laser, thereby changing the refractive power of the cornea to achieve the purpose of correcting vision[22]. Iatrogenic corneal dilatation is a vision-threatening complication after LASIK and is associated with weakened corneal mechanical strength[22-23]. Previous studies have found that the Pentacam correction formula by Ehlers is more reliable in the correction of IOP after LASIK and EK. The Ehlers method uses 545 μm as the standard corneal thickness; for every 15 μm increase or decrease, the IOP increases or decreases by 1 mmHg, respectively[24]. Follow-up after LASIK found that corneal thickness was related to preoperative and postoperative IOP[25]. The greater the preoperative CCT and cutting depth, the greater the postoperative IOP reading changes were[26-27]. The incision in SMILE is only 2 mm, and a corneal cap is made instead of a corneal flap. The collagen fibre damage is significantly reduced, the integrity of Bowman's membrane and the anterior stroma layer is better preserved, and the corneal elasticity is better maintained[9-10,28]. The SMILE matrix lens has a diameter of 6.5-7.0 mm and has no transition zone. The changes in the shape of the peripheral cornea are significantly less than those in LASIK. It greatly reduces the changes in corneal biomechanics[12,23]. Thus, it is possible to reduce the effect on IOP measurements. It can be seen that SMILE is different from previous procedures in terms of surgical design, corneal biomechanical changes, *etc.* Therefore, the previous LASIK IOP-corrected formula cannot be applied to the evaluation of IOP after SMILE.

This study found that the IOP_{post} corrected by Ehlers was higher than the IOP_{pre} in patients with high myopia and that the IOP_{post} corrected by Ehlers was lower than the IOP_{pre} in patients with low myopia. There was statistical significance ($P<0.01$). There was no significant difference between the IOP_{pre} and IOP_{post} corrected by Ehlers in patients with moderate myopia ($t = -0.300$, $P=0.764$). It was considered that the Ehlers correction for the assessment of IOP in patients with moderate myopia after SMILE is relatively reliable. The NCT_{post} and Pentacam-corrected IOPs (Dresden, Orssengo, Shah, and Kohlhaas) were significantly decreased in each group, and the difference was statistically significant ($P<0.01$). Therefore, it is believed that Pentacam's IOP correction formula is insufficient to correct the IOP after SMILE. Li *et al*[29] obtained the following formula: IOP after SMILE = NCT_{post} + 0.389 NCT_{pre} - 0.431 SE - 4.61815. However, at present, the evaluation of IOP after SMILE remains to be further studied.

Pathologically elevated IOP is the main risk factor for glaucoma, and large IOP fluctuations are independent risk factors for progressive damage to the optic nerve. In this study, repeated measures analysis of variance showed that there was no statistically significant difference between the right and left eyes, both before and after surgery. There were significant differences in IOP at different time points during the day before and after surgery in patients with low myopia, moderate myopia, and high myopia. Studies have shown that the IOP_{post} range by NCT are from 8-17 mmHg in group A, 7-16.3 mmHg in group B, and 7-14.3 mmHg in group C. The IOP_{post} difference between the two eyes is 0-4 mmHg, and the diurnal IOP fluctuation after the operation is less than 6 mmHg; both are decreased compared with the preoperative values. With an increase in the preoperative refractive power, the postoperative IOP value decreases.

This study found that the higher the IOP_{pre}, the larger the CV, the higher the SE, the thicker the base lens, and the smaller the corneal diameter, the greater the change in IOP measurements after surgery. In addition, the statistical results show that the greater the CV change rate before and after surgery, the lower the IOP_{post} measurement. The preoperative CV was not consistent among patients. When the surgical lens volume was the same, the postoperative corneal rigidity changes were different, and the IOP_{post} measurements varied. The patients were divided into three groups according to the SE level. The IOP_{pre} measurement value and the CCV_{post} can be used to roughly predict the IOP_{post} measurement of each group, which is convenient to evaluate the actual IOP after surgery and guide postoperative hormone medication administration. The results of this study have important clinical significance for the diagnosis and treatment of patients with potential glaucoma after SMILE with different refractive levels before surgery.

There are some limitations in this study. There are differences between tonometers, and different designs in corneal cap thickness and optical area diameter in surgical parameters will affect the changes of corneal biomechanical factors after the operation, subsequently affecting the size of the IOP measurement[30-31]. The prediction of IOP after SMILE is still to be further studied by increasing the sample size.

In summary, factors such as the IOP_{pre} and cutting volume should be considered when assessing the IOP_{post}. The IOP_{post} value is lower than the real value and may be evaluated relative to the normal IOP range of 7-17 mmHg, a binocular difference of ≤4 mmHg, and a diurnal IOP fluctuation ≤6 mmHg. The greater the IOP_{pre} value, the larger the CV, the smaller the corneal diameter, the higher the degree of myopia, the larger the surgical removal of the stromal lens, the greater the change in IOP_{post} measurements. For different patients, the greater the change in CV before and after surgery, the lower the IOP_{post} measurement. CCV_{3mm} is an important indicator in the evaluation of IOP measurements after SMILE, and it is of great significance the administration of medication after SMILE. The correction of IOP after SMILE remains to be further explored.

REFERENCES

1 Lan YW, Chang SY, Sun FJ, Hsieh JW. Different disc characteristics associated with high myopia and the location of glaucomatous damage in primary open-angle glaucoma and normal-tension glaucoma. *J Glaucoma* 2019;28(6):519-528

2 Tham YC, Aung T, Fan Q, Saw SM, Siantar RG, Wong TY, Cheng CY. Joint effects of intraocular pressure and myopia on risk of primary open-angle glaucoma: the Singapore epidemiology of eye diseases study. *Sci Rep* 2016;6:19320

3 Kwon J, Sung KR, Jo J, Yang SH. Glaucoma progression and its relationship with corrected and uncorrected intraocular pressure in eyes with history of refractive corneal surgery. *Curr Eye Res* 2018;43(9):1136-1144

4 Ma YZ, Ma YP, Feng CL, Shen MQ, Yuan YZ. Ocular biometric parameters are associated with non-contact tonometry measured intraocular pressure in non-pathologic myopic patients. *Int Ophthalmol* 2020;40(2):431-437

5 Chiam N, Baskaran M, Li Z, Perera S, Goh D, Husain R, Khor CC, Cheng CY, Aung T, Vithana EN. Social, health and ocular factors associated with primary open-angle glaucoma amongst Chinese Singaporeans. *Clin Exp Ophthalmol* 2018;46(1):25-34

6 Sánchez-González JM, Alonso-Aliste F. Visual and refractive outcomes of 100 small incision lenticule extractions (SMILE) in moderate and high myopia: a 24-month follow-up study. *Graefe's Arch Clin Exp Ophthalmol* 2019;257(7):1561-1567

7 Qin B, Zhao J, Li M, Yao P, Zhou X. The comparison of visual outcomes, aberrations, and Bowman's layer micro-distortions after femtosecond laser small-incision lenticule extraction (SMILE) for the correction of high and moderate myopia and myopic astigmatism. *BMC Ophthalmol* 2019;19(1):138

8 Zhu X, Zou L, Yu M, Qiu C, Chen M, Dai J. Comparison of postoperative visual quality after SMILE and LASEK for high myopia: a 1-year outcome. *PLoS One* 2017;12(8):e0182251

9 Wang KJ, Wang WW, Tsai CL, Wang IJ. Intraocular pressure changes in eyes with small incision lenticules and laser *in situ* keratomileusis. *Clin Exp Optom* 2019;102(4):399-405

10 Shen Y, Su XJ, Liu X, Miao HM, Fang XJ, Zhou XT. Changes in intraocular pressure values measured with noncontact tonometer (NCT), ocular response analyzer (ORA) and corvis scheimpflug technology tonometer (CST) in the early phase after small incision lenticule extraction (SMILE). *BMC Ophthalmol* 2016;16(1):1-8

11 Han T, Xu Y, Han X, Zeng L, Shang J, Chen X, Zhou X. Three-year outcomes of small incision lenticule extraction (SMILE) and femtosecond laser-assisted laser *in situ* keratomileusis (FS-LASIK) for myopia and myopic astigmatism. *Br J Ophthalmol* 2019; 103(4):565-568

12 Titiyal JS, Kaur M, Shaikh F, Gagrani M, Brar A, Rathi A. Small incision lenticule extraction (SMILE) techniques: patient selection and perspectives. *Clin Ophthalmol* 2018;12:1685-1699

13 Chen LY, Manche EE. Comparison of femtosecond and excimer laser platforms available for corneal refractive surgery. *Curr Opin Ophthalmol* 2016;27(4):316-322

14 Galgauskas S, Strupaite R, Strelkauskaite E, Asoklis R. Comparison of intraocular pressure measurements with different contact tonometers in young healthy persons. *Int J Ophthalmol* 2016;9(1):76-80

15 Ramm L, Herber R, Spoerl E, Raiskup F, Pillunat LE, Terai N. Intraocular pressure measurement using ocular response analyzer, dynamic contour tonometer, and scheimpflug analyzer corvis ST. *J Ophthalmol* 2019;2019:1-9

16 Nuyen B, Mansouri K. Detecting IOP fluctuations in glaucoma patients. *Open Ophthalmol J* 2016;10(1):44-55

17 Yildiz A, Yasar T. Comparison of Goldmann applanation, non-contact, dynamic contour and tonopen tonometry measurements in healthy and glaucomatous eyes, and effect of central corneal thickness on the measurement results. *Med Glas (Zenica)* 2018;15(2):152-157

18 Erdogan H, Akingol Z, Cam O, Sencan S. A comparison of NCT,

Goldman application tonometry values with and without fluorescein. *Clin Ophthalmol* 2018;12:2183-2188

19 Cheng WB, Liu LJ, Yu SS, Jing Y, Zuo T, Cui T, Zhang H, Ma JN, Wei PH, Hao WT, Lap-Ki Ng A, Pak-Man Cheng G, Chi-Pang Woo V, *et al*. Real-time intraocular pressure measurements in the vitreous chamber of rabbit eyes during small incision lenticule extraction (SMILE). *Curr Eye Res* 2018;43(10):1260-1266

20 Hosny M, Aboalazayem F, El Shiwy H, Salem M. Comparison of different intraocular pressure measurement techniques in normal eyes and post small incision lenticule extraction. *Clin Ophthalmol* 2017; 11: 1309-1314

21 Wu AM, Wu CM, Young BK, Wu DJ, Chen A, Margo CE, Greenberg PB. Evaluation of primary open-angle glaucoma clinical practice guidelines. *Can J Ophthalmol* 2015;50(3):192-196

22 Guo H, Hosseini-Moghaddam SM, Hodge W. Corneal biomechanical properties after SMILE versus FLEX, LASIK, LASEK, or PRK: a systematic review and Meta-analysis. *BMC Ophthalmol* 2019;19(1): 1-20

23 Osman IM, Helaly HA, Abou Shousha M, AbouSamra A, Ahmed I. Corneal safety and stability in cases of small incision lenticule extraction with collagen cross-linking (SMILE xtra). *J Ophthalmol* 2019;2019: 1-10

24 Li H, Wang Y, Dou R, Wei PH, Zhang JM, Zhao W, Li LY. Intraocular pressure changes and relationship with corneal biomechanics after SMILE and FS-LASIK. *Invest Ophthalmol Vis Sci* 2016;57(10): 4180

25 Jethani J, Dave P, Jethani M, Desai Y, Patel P. The applicability of correction factor for corneal thickness on non-contact tonometer measured intraocular pressure in LASIK treated eyes. *Saudi J Ophthalmol* 2016;30(1):25-28

26 De Bernardo M, Capasso L, Caliendo L, Vosa Y, Rosa N. Intraocular pressure evaluation after myopic refractive surgery: a comparison of methods in 121 eyes. *Semin Ophthalmol* 2016;31(3):233-242

27 Ajazaj V, Kacaniku G, Asani M, Shabani A, Dida E. Intraocular pressure after corneal refractive surgery. *Med Arch* 2018;72(3):341

28 Reinstein DZ, Archer TJ, Gobbe M. Small incision lenticule extraction (SMILE) history, fundamentals of a new refractive surgery technique and clinical outcomes. *Eye Vis* 2014;1(1):1-12

29 Li H, Wang Y, Dou R, Wang L, Wei PH, Zhao W, Li LY. Analysis of intraocular pressure measurement and the influencing factors after small incision lenticule extraction. *Zhonghua Yan Ke Za Zhi* 2016;52(1): 22-29

30 Liu Q, Yang XN, Lin LM, Liu ML, Lin HQ, Liu F, Xie Y, Lam DSC. Review on centration, astigmatic axis alignment, pupil size and optical zone in SMILE. *Asia Pac J Ophthalmol* 2019;8(5):385-390

31 Liu T, Yu T, Liu LN, Chen KJ, Bai J. Corneal cap thickness and its effect on visual acuity and corneal biomechanics in eyes undergoing small incision lenticule extraction. *J Ophthalmol* 2018;2018:1-7