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ORIGINAL PAPER

Corneal remodeling and spatial profiles following small incision lenticule extraction

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Abstract

Purpose To evaluate the three-dimensional corneal spatial profiles following small incision lenticule extraction (SMILE) based on corneal asphericity, thickness, and volume.

Materials and methods Eighty-three eyes in 83 patients who underwent SMILE were examined before and 1 and 6 months after surgery. The asphericity of the anterior and posterior corneal surfaces was analyzed. Corneal volume (CV) was measured in corneal regions measuring 3.0 mm, 5.0 mm, and 7.0 mm in diameter. Mean corneal thickness (CT) values were acquired at the apex (0.0 mm) and in four concentric radial zones from the apex (with diameters of 2.0, 4.0, 6.0, and 8.0 mm).

Results The mean anterior Q value increased from − 0.32 preoperatively to 0.67 at 1 month and 0.62 at 6 months postoperatively. The mean posterior Q value decreased from − 0.30 preoperatively to − 0.26 at 1 month and to − 0.25 at 6 months postoperatively. The CV increased by 0.05 ± 0.06 mm^3 (1.40%), 0.06 ± 0.11 mm^3 (0.83%), and 0.09 ± 0.17 mm^3 (0.73%) along the radial zones with respective diameters of 3.0 mm, 5.0 mm, and 7.0 mm. The CT increased by 6.02 ± 6.48 μm (1.36%) at the apex and then decreased with increasing distance from the center, i.e., to 5.52 ± 6.31 μm (1.20%) at 2.0 mm, 4.72 ± 6.55 μm (0.92%) at 4.0 mm, 4.47 ± 7.86 μm (0.75%) at 6.0 mm, and 4.86 ± 10.31 μm (0.70%) at 8.0 mm. No correlations were observed between changes in CV and CT and refractive fluctuation between 1 month and 6 months postoperatively.

Conclusions The corneal profile displayed a less oblate shift on the anterior surface; however, the posterior surface showed a slight backward shift during the postoperative period. The CV and CT steadily increased after surgery and mainly within the operative zones. Refraction remained stable postoperatively and was not affected by the corneal remodeling.

Keywords Small incision lenticule extraction · Corneal remodeling · Spatial profiles · Refraction · Corneal thickness

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Introduction

Small incision lenticule extraction (SMILE) is a newer method for correction of refraction in patients with myopia and myopic astigmatism [1–3]. SMILE uses a femtosecond laser to create a refractive lenticule and then remove it [4–6]. Compared with laser-assisted in situ keratomileusis (LASIK), SMILE has been shown to induce less keratocyte apoptosis, proliferation, and inflammation [7, 8]. Recent spectral-domain optical coherence tomography studies have revealed significant epithelial thickening during wound healing after SMILE [9, 10], but there is no evidence of postoperative refractive stability being affected by the observed epithelial remodeling. However, it is still not known how the spatial distribution of the corneal profile changes during remodeling postoperatively or how it affects the refractive status and clinical results of surgery.

The Scheimpflug system has enabled three-dimensional (3D) evaluation of the cornea and pachymetric mapping. By investigating tomographic parameters such as corneal thickness (CT) and corneal volume (CV), several corneal diseases, such as keratoconus, can be diagnosed more easily [11]. Moreover, corneal remodeling after refractive correction can be described by pachymetric mapping [12].

The aim of this study was to examine the remodeling of the cornea after SMILE. We investigated corneal asphericity, the spatial CT profile, and CV distribution and compared the 3D corneal changes at 1 and 6 months postoperatively.

Materials and methods

Study population

The right eyes of 83 healthy subjects (32 male, 51 female) were enrolled in this prospective study. Refraction had been stable for at least 2 years in all subjects, and the preoperative central corneal thickness (CCT) was more than 480 μm in all eyes. None of the patients had a history of other ocular surgeries. Full preoperative ophthalmic evaluations were performed to ensure no current or past ocular disease or any systemic illness other than refractive error.

The study was approved by the ethics committee at Tianjin Eye Hospital, Tianjin Medical University, and was conducted in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients who participated in the study at their first visit.

The eyes were divided into a low myopia group (n = 36) and a high myopia group (n = 47) to analyze the effects of differing amounts of refractive correction on corneal remodeling after SMILE. The spherical equivalent (SE) for surgical correction of refraction ranged from − 2.50 to − 5.95 D (mean − 4.40 ± 0.92 D) in the low myopia group and from − 6.00 to − 8.63 D (mean − 7.10 ± 0.79 D) in the high myopia group. Table 1 shows the patient demographics in the low and high myopia groups.

Surgical technique

SMILE was performed using a VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) with 130 nJ of energy. The refractive lenticule diameter was set at 6.0–6.5 mm with a 0.1-mm transition zone for correction of astigmatism. The cap diameter was 1.0 mm larger than the lenticule, and the cap thickness was 120 μm. The incision length was set at 3.0 mm, with the position at 12 o'clock. A minimum lenticule thickness of 10–15 μm was designed. Ofloxacin 0.3% eye drops (Tarivid; Santen Pharmaceutical Co., Ltd., Osaka, Japan) was administered four times daily for 3 days postoperatively. Fluorometholone 0.1% eye drops (Flumetholon; Santen) was also administered four times daily for the first 2 weeks postoperatively and then decreased to once every 2 weeks.

Measurements and data acquisition

The corneal asphericity (Q value), CT, and CV were measured automatically using a Scheimpflug tomography system (Pentacam; Oculus GmbH, Wetzlar, Germany). All measurements were performed just after a blink to minimize the effect of a change in tear film on the study data. Acceptable maps had at least 10.0 mm of corneal coverage with no extrapolated data in the central 9.0-mm zone.

The Q value within the 6-mm corneal diameter was assessed on both the anterior and posterior surfaces of the cornea. We calculated the CV of three different sized circles centered on the apex using the Pentacam software. These circles had diameters of 3.0 mm, 5.0 mm, and 7.0 mm (CV3, CV5, and CV7, respectively).

The CT at the apex was measured and recorded as the CCT. CT values were also measured in 2.0-mm

Table 1 Demographic information of patients in the low and high myopia groups

Group	*N*	Age (years)	*S* (D)	*C* (D)	SE (D)	LT (μm)
Low	36	25.30 ± 6.24	− 4.05 ± 0.87	− 0.71 ± 0.75	− 4.40 ± 0.92	85.58 ± 14.98
High	47	23.51 ± 4.25	− 6.66 ± 0.88	− 0.86 ± 0.72	− 7.10 ± 0.79	126.55 ± 14.09

S spherical diopter, *C* cylinder diopter, *SE* spherical equivalent, *D* diopters, *LT* lenticular thickness

increments from the center of the apex (CCT) to a diameter of 8.0 mm in order to determine a continuous range of CT. These measurements were referred to as CT0, CT2, CT4, CT6, and CT8, with each number corresponding to the diameter of the measured area in millimeters. Measurements were taken preoperatively and at 1 month and 6 months postoperatively.

Statistical analysis

The statistical analysis was performed using SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). The results are shown as the mean and standard deviation. The Kolmogorov–Smirnov test was used to confirm the normality of the data samples. Preoperative and postoperative values in different corneal regions were compared by one-way analysis of variance (ANOVA), and differences between groups were determined by Bonferroni ANOVA. The differences between values obtained at 1 month and those obtained at 6 months were compared using paired *t* tests and the low and high refraction groups were compared using independent *t* tests. A P value < 0.05 was considered statistically significant.

Results

Study population and characteristics

Eighty-three myopic right eyes of 83 patients (32 male, 51 female) underwent myopic SMILE refractive surgery for intended myopic spherical correction ranging from − 1.75 D to − 8.50 D (mean ± SD, − 5.53 ± 1.57) and cylinder ranging from 0.00 to − 3.00 D (− 0.79 ± 0.73). The mean age of the entire patient population at the time of surgery was 24 (range 18–39) years. The mean SE of the surgical refractive correction was − 5.93 ± 1.58 D, and the mean thickness of the refractive lenticule was 108.78 ± 24.99 (range 53–156) μm. No serious intraoperative or postoperative complications occurred in either study group. All patients were followed up at 1 month and 6 months postoperatively.

One month after surgery, the mean SE was − 0.11 ± 0.30 D (range − 1.25 to + 0.75 D), and 77 (92.78%) of the 83 eyes were within ± 0.50 D. An uncorrected distance visual acuity of 20/20 or better was achieved in 79 (95.18%) of 83 eyes. However, the mean SE at 6 months was − 0.11 ± 0.13 D (range − 1.50 to + 0.50 D), and 82 (98.80%) of the 83 eyes were within ± 0.50 D at 6 months postoperatively (Fig. 1). Furthermore, an uncorrected distance visual acuity of 20/20 or better was achieved in 78 (93.98%) of 83 eyes.

Corneal asphericity

The mean anterior Q value increased from − 0.32 preoperatively to 0.67 by 1 month and to 0.62 by 6 months postoperatively; the difference between the values obtained at these follow-up time points was significant ($t = 4.866$, $P < 0.001$, paired *t* test). The shape of the anterior corneal surface became less oblate in the 1 month to 6 months postoperatively.

The mean posterior Q value decreased from − 0.30 preoperatively to − 0.26 by 1 month and to − 0.25 by 6 months postoperatively. Although the SMILE procedure does not involve the posterior surface of the cornea, there was an oblate shift in the posterior surface ($f = 4.273$, $P = 0.015$, ANOVA).

Corneal volume

The CV was observed to decrease with increasing refractive correction after SMILE. During the postoperative follow-up period, CV increased from 1 month to 6 months (Table 2). The increase in CV differed significantly according to region (ΔCV3, ΔCV5, ΔCV7; $f = 3.272$, $P = 0.040$, ANOVA). The CV

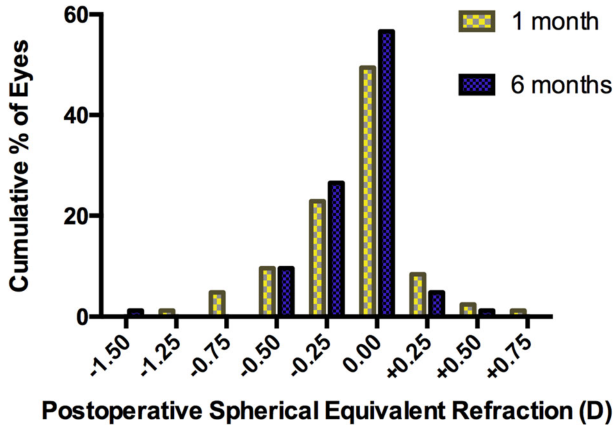

Fig. 1 Accuracy of refractive spherical equivalent after small incision lenticule extraction surgery

Table 2 Mean corneal volume and the changes at 3, 5, and 7 mm diameters from the corneal apex at 1- and 6-month follow-up appointments

	CV3 (mm^3)	CV5 (mm^3)	CV7 (mm^3)
1 month	3.33 ± 0.24	6.82 ± 0.42	12.74 ± 0.68
6 months	3.38 ± 0.24	6.87 ± 0.42	12.83 ± 0.69
Change (Δ)	0.05 ± 0.06	0.06 ± 0.11	0.09 ± 0.17
Change rate (Δ%)	1.40%	0.83%	0.73%

Change (Δ) = 6 months–1 month; change rate = (6 months–1 month)/1 month

increased by 0.05 ± 0.06 mm^3 (1.40%), 0.06 ± 0.11 mm^3 (0.83%), and 0.09 ± 0.17 mm^3 (0.73%) in the corneal regions measuring 3.0 mm, 5.0 mm, and 7.0 mm in diameter (Fig. 2). There were no significant differences in the CV changes by region between the low and high myopia groups (Table 4).

Corneal thickness

As seen in Table 3, the CT in all regions generally increased between 1 month and 6 months postoperatively (paired *t* test, $P < 0.000$). However, the amount of increase was not significantly different between the annuli ($f = 0.576$, $P = 0.680$, ANOVA). As shown in Fig. 3, the CT increased by 6.02 ± 6.48 μm (1.36%) in the central zone, and then decreased with increasing distance from the center, i.e., to 5.52 ± 6.31 μm (1.20%) at 2.0 mm, 4.72 ± 6.55 μm (0.92%) at 4.0 mm, 4.47 ± 7.86 μm (0.75%) at 6.0 mm, and 4.86 ± 10.31 μm (0.70%) at 8.0 mm. There were no significant differences in CT change by region between the low and high myopia groups.

Correlation analysis

The anterior *Q* value was negatively correlated with the preoperative SE ($r = -0.817$, $P < 0.000$), but no correlation was found for the posterior *Q* value. The changes in CV and CT between before surgery and 6 months after surgery showed a statistically significant positive linear association with the magnitude of preoperative refractive error and ablation depth (lenticule thickness for SMILE). However, no correlation was observed between the refractive fluctuation and the changes in CV and CT between 1 month and 6 months.

Discussion

In the present study, we evaluated several parameters that reflect remodeling of the cornea after SMILE. We aimed to explore the corneal changes that occur during healing of the wound postoperatively. We observed that the aspherical properties of the anterior corneal surface showed a less oblate shift from 1 month to

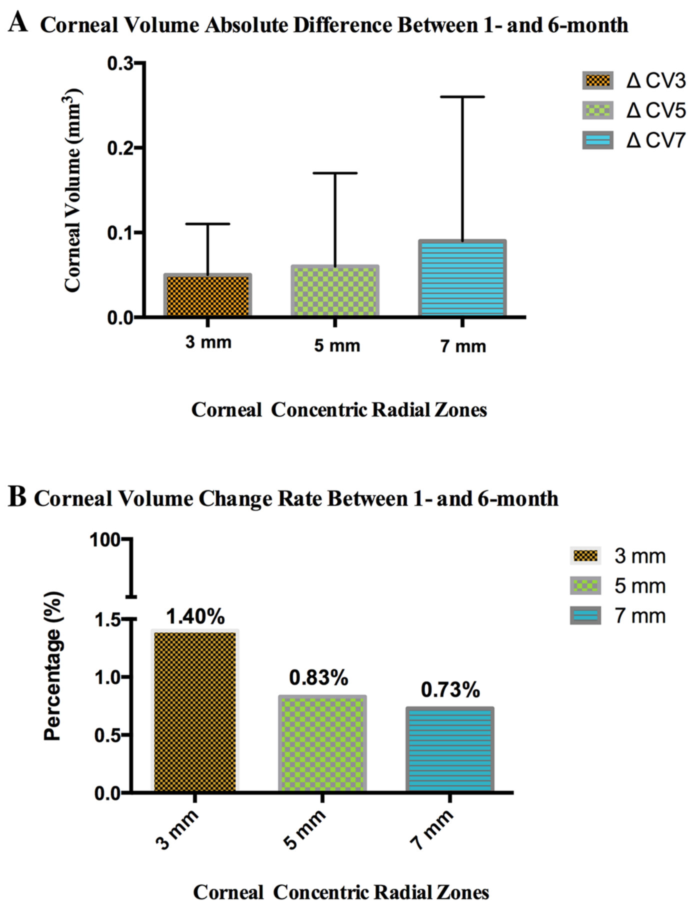

Fig. 2 Corneal volume distribution map showing the absolute difference (**a**) and rate of change (**b**) between measurements obtained on follow-up at 1 month and 6 months postoperatively

Table 3 Mean corneal thickness and the changes at 0, 2, 4, 6, 8, and 10 mm diameters from the corneal apex at 1- and 6-month follow-up appointments

	CT0 (μm)	CT2 (μm)	CT4 (μm)	CT6 (μm)	CT8 (μm)
1 month	450.30 ± 34.17	466.28 ± 33.57	518.48 ± 31.66	604.61 ± 30.96	704.14 ± 34.14
6 months	456.33 ± 33.90	471.80 ± 33.27	523.20 ± 31.46	609.08 ± 30.79	709.00 ± 33.82
Change (Δ)	6.02 ± 6.48	5.52 ± 6.31	4.72 ± 6.55	4.47 ± 7.86	4.86 ± 10.31
Change rate (Δ%)	1.36%	1.20%	0.92%	0.75%	0.70%

Change (Δ) = 6 months–1 month; change rate = (6 months–1 month)/1 month

6 months after SMILE. The shift preserves normal corneal asphericity, which might be one of the reasons why SMILE could induce less spherical aberration [13]. This finding was in agreement with the results of previous studies that investigated postoperative changes in the curvature of the cornea and reported that the central cornea was steeper than the periphery after SMILE [14]. Kamiya et al. [15] compared corneal asphericity following wave front-guided LASIK and refractive lenticule extraction surgery (FLEx) and reported that changes in the Q value and number of fourth-order aberrations after FLEx were significantly less than those after wave front-guided LASIK. This suggests that FLEx induces a less oblate change in the corneal shape when compared with wave front-guided LASIK. The efficiency of the femtosecond laser is not influenced by the incident angle,

Table 4 Change in corneal volume at 3, 5, and 7 mm diameters from the corneal apex and change in corneal thickness at 2-mm increments from the corneal apex until a 8 mm diameter in both the low and the high myopia groups

	N	ΔCV3 (mm^3)	ΔCV5 (mm^3)	ΔCV7 (mm^3)	ΔCT0 (μm)	ΔCT2 (μm)	ΔCT4 (μm)	ΔCT6 (μm)	ΔCT8 (μm)
Low	36	0.04 ± 0.06	0.05 ± 0.10	0.09 ± 0.20	5.44 ± 6.24	4.92 ± 6.44	4.17 ± 6.94	4.06 ± 8.78	4.42 ± 11.80
High	47	0.05 ± 0.05	0.06 ± 0.11	0.09 ± 0.15	6.47 ± 6.69	5.98 ± 6.23	5.15 ± 6.28	4.79 ± 7.16	5.19 ± 9.13
t		− 1.361	− 1.065	− 0.555	− 0.711	− 0.758	− 0.675	− 0.418	− 0.337
P		0.785	0.565	0.248	0.716	0.965	0.801	0.512	0.392

Change (Δ) = 6 months–1 month; independent *t* tests

$^*P < 0.05$

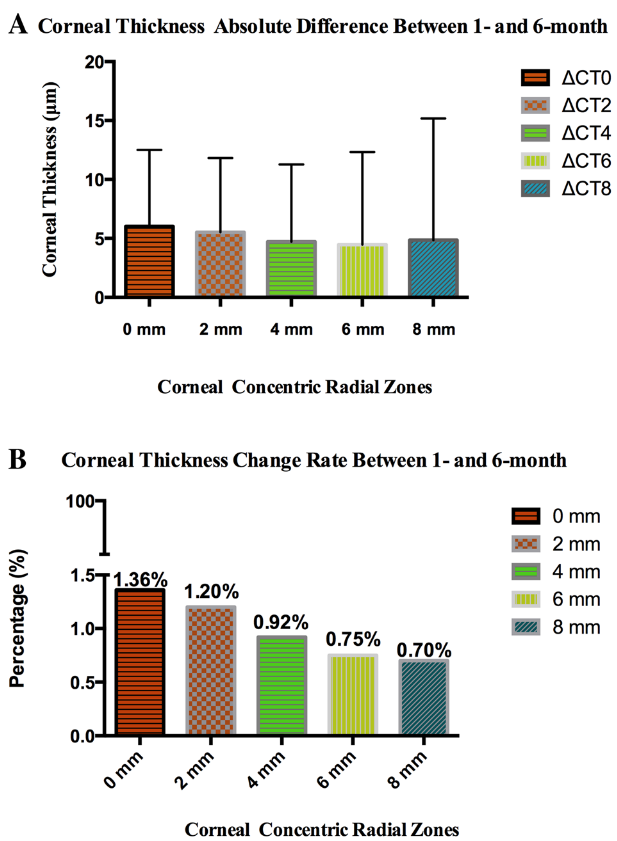

Fig. 3 Corneal thickness profile map showing the absolute difference (**a**) and rate of change (**b**) between measurements obtained on follow-up at 1 month and 6 months postoperatively

whereas regional variations occur as cosine effects during excimer laser ablations.

Furthermore, we observed that the *Q* value of the posterior corneal surface increased from − 0.30 preoperatively to − 0.26 at 1 month and to − 0.25 at 6 months postoperatively, and showed a slight backward shift during the postoperative follow-up period. This finding is consistent with the results of two recent studies of posterior corneal elevation that found a slight backward shift in the central cornea after SMILE [16, 17]. Overall, our results and those of previous studies indicate that SMILE produces a much safer posterior corneal surface than conventional surgical procedures.

In the present study, both the CT and CV contributed to the 3D model constructed to illustrate the profile of the cornea after SMILE. Both the CT and CV increased between 1 month and 6 months after SMILE. There could be several explanations for this thickening. In addition to the significant epithelial

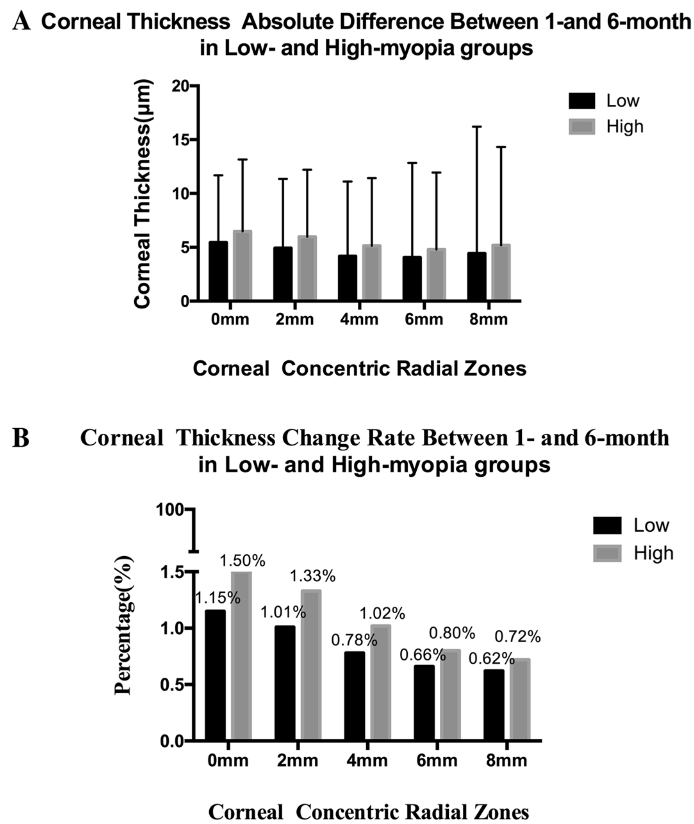

Fig. 4 Corneal volume distribution map showing the absolute difference (**a**) and rate of change (**b**) between measurements obtained on follow-up at 1 month and 6 months postoperatively in low and high myopia groups

hyperplasia already documented to occur during the 6 months after surgery [9, 18], the space between the two layers and wound healing at the interface might also contribute to the increases in CT and CV. In a previous study of the ultrastructural changes and corneal wound healing after SMILE, we found that the interface of the extracted lenticule appeared to be adherent to mucus secretions [19]. We speculated that mucus secretion at the interface might affect the CT and CV measurements postoperatively. Most of the previous research on morphologic changes in the cornea postoperatively have focused on CT. However, some findings, e.g., for postoperative CCT, have varied according to a number of factors. Cennamo et al. [20] found a decrease in central and paracentral CT after photorefractive keratectomy (PRK), whereas Sabetti et al. [21] reported an increase in CCT over time. Kozak et al. [22] described an increase in CCT between 1 week and 6 months postoperatively in eyes that had undergone LASIK or PRK. Meanwhile, Diniz et al. [23] reported a significant decrease in the CV in regions with a diameter of 3 mm, 5 mm, or 7 mm over time after LASIK and. Rosa et al. [24] found a decrease in CCT and CV after PRK. We cannot explain these inconsistencies between the studies. To the best of our knowledge, the Pentacam, which is mostly used to measure CCT and CV, has a reproducibility of ± 5 μm and ± 0.3 mm, respectively [3, 25], which is greater than the region of the very small changes we observed during the postoperative period.

The changes in CT and CV varied according to the corneal region measured. The greatest increase in the CV and CT was within the operative area (mostly at the center and mid-center) and the least was at the mid-periphery, especially at the edge of the cap (6.0–8.0 mm in diameter). This pattern of variation in CV and CT partly supports the negative meniscus-like lenticular model [26], which demonstrates more significant thickening at the center than at the mid-periphery. Central stromal expansion caused by biomechanical changes after SMILE may explain part of this phenomenon.

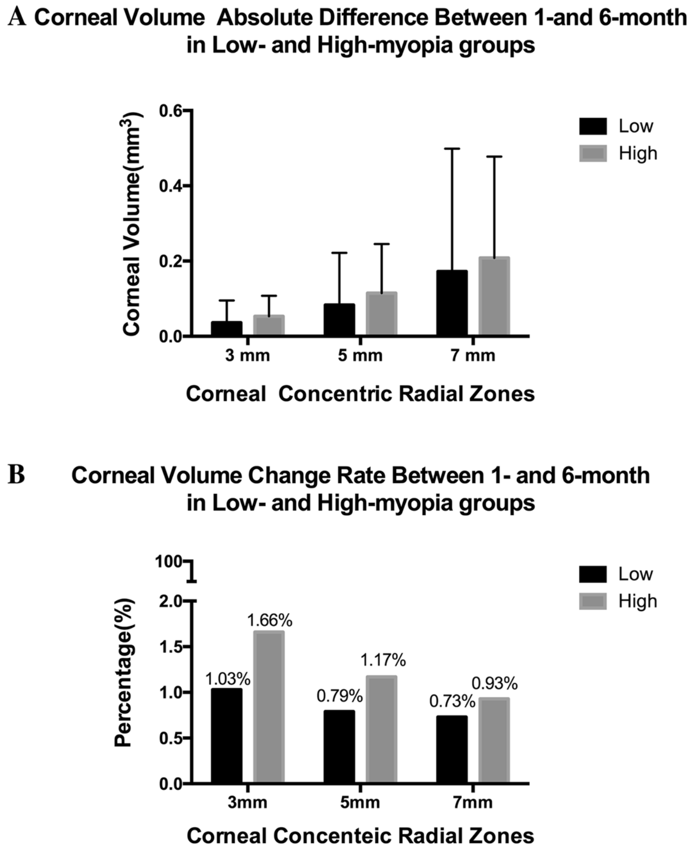

Fig. 5 Corneal thickness profile map showing the absolute difference (**a**) and rate of change (**b**) between measurements obtained on follow-up at 1 month and 6 months postoperatively in low and high myopia groups

In this study, we found that the postoperative changes in CV and CT were related to the amount of refractive correction by SMILE. However, no correlation was observed between refractive changes and the changes in CV and CT between 1 month and 6 months. It is worth noting that the greatest increase in CV and CT was only 1%, so the refraction remained stable during 6 months of follow-up. Furthermore, we also found that the CT and CV increased more in the high myopia group from 1 month to 6 months; however, these increases were not statistically significant. But it is encouraging to see that the difference between the values of the changes in CCT and CV in different groups cannot be neglected (Figs. 4, 5). The changes of CCT and CV in high myopia group were significantly higher than that in low myopia group. This may be related to the amount of treatment and a more obvious increase in CCT and CV in high myopia should be quite an obvious finding.

In conclusion, corneal remodeling and repair is a long-term process after a SMILE procedure. Corneal asphericity, volume, and thickness have a 3D spatial profile that change depending on regional characteristics. The central regions of the cornea showed obvious increases in volume and thickness, whereas the hyperplasia at the edge of the operative area remained inactive postoperatively. Despite the promising results of this study, histopathologic studies and long-term observations are required for further evaluation of corneal remodeling after the SMILE procedure.

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Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Tianjin Eye Hospital at Tianjin Medical University research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Conflict of interest All authors declare that they have no conflict of interest.

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