Investigation of Predictability and Influence factors of the Achieved Lenticule Thickness in Small Incision Lenticule Extraction

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Abstract

Background To evaluate the differences between the predicted and achieved lenticule thickness (ΔLT) after small incision lenticule extraction (SMILE) surgery and investigate relationships between ΔLT and refractive errors or lenticule depth in SMILE. Methods A total of 184 eyes from 184 consecutive patients who underwent SMILE were included in this prospective study. One eye for each patient was randomly selected and included for statistical analysis. An ultrasound pachymetry measurement and Scheimpflug camera corneal topography were obtained before and at 3 months after SMILE. The achieved lenticule thickness was calculated by comparing the preoperative examinations with postoperative examinations using ultrasound pachymetry and Pentacam software measurements. The pupil center and corneal vertex were selected as the 2 locations for measurement calculation on Pentacam. Analysis of variance (ANOVA) was performed to compare mean pachymetry values using different instruments. An independent t test was performed to evaluate the difference in ΔLT between different cap thicknesses. Linear regression analyses were performed between the VisuMax readout lenticule thicknesses and the measured maximum corneal change, the preoperative spherical equivalent (SE) and each ΔLT. Results On average, the achieved lenticule thickness measured with ultrasound pachymetry was 13.02 ± 8.87 μm thinner than the VisuMax readout lenticule thickness. Linear regression analysis showed significant relationships between the predicted and each achieved lenticule thickness. The preoperative SE was significantly related to each ΔLT (ultrasound: R^2 =0.279; at corneal vertex: R^2 =0.252; at pupil center R^2 =0.246). The ΔLT measured by ultrasound pachymetry was significantly smaller in the thick cap group (cap thickness above 120 μm) than in the thin cap group ($P < 0.01$). Conclusions An overestimation of achieved lenticule thickness was found in this study. The ΔLT was related to the preoperative SE correction. Furthermore a lager ΔLT was found under a thin cap.

Introduction

Small incision lenticule extraction (SMILE) was first described by Sekundo et al. and Shah et al. in 2011 for the treatment of myopia and myopic astigmatism.[1, 2] Compared with Excimer laser surgery, SMILE is an “all-in-one” surgery that involves the creation of an intrastromal lenticule and a peripheral incision in one step using a femtosecond laser and manual extraction of the lenticule later. In this way, SMILE surgery avoids or minimizes errors associated with excimer laser ablation, such as stromal hydration,[3] laser fluence,[4–6] environmental temperature, and relative humidity.[7] Therefore, the thickness of the intrastromal lenticule created at the beginning of the surgery determines the safety and accuracy of SMILE surgery. A close consistency would be expected between the predicted and achieved lenticule thickness. However, previous studies have reported that there was still a difference between the predicted and achieved lenticule thickness (ΔLT). Reinstein et al.[8] detected a systematic overestimation of central lenticule thickness of approximately 8 μm. Luft et al.[9] also found that the predicted lenticule thickness was thicker than the achieved lenticule thickness, especially with higher myopic correction. As proposed by Reinstein this difference might be related to a postoperative expansion of the central cornea caused by corneal biomechanical redistribution after SMILE.

Based on this assumption, we hypothesized that the ΔLT was related to the lenticule thickness (ie refractive errors). Also, it has been demonstrated that the corneal biomechanics decrease from anterior to posterior within the central corneal region.[10–12]Therefore, we further hypothesized that a deeper lenticule would preserve more corneal biomechanics and decrease the overestimation of lenticule thickness.

Ultrasound pachymetry has been the gold standard in measuring corneal thickness. Scheimpflug imaging[13], as a new method, also allows the measurement of corneal thickness. The principle of Scheimpflug imaging uses optical sectioning of the cornea with maximum depth of focus.[14]

In the current study, we included a large number of patients to investigate the predictability between the VisuMax readout and achieved lenticule thickness measured at 3 months postoperatively. The aim of this study was to assess the ΔLT in SMILE using ultrasound pachymetry and Scheimpflug imaging and to investigate the associations of ΔLT with different refractive errors and different lenticule depths. To our knowledge, this is the first clinical study investigate the relationship between the ΔLT and lenticule depths.

Methods

This prospective study included 184 consecutive patients who underwent a SMILE procedure at the Eye Center, Second Affiliated Hospital, College of Medicine, Zhejiang University, from November 2017 to August 2018. This study followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Second Affiliated Hospital of Zhejiang University. Written informed consent was obtained from the subjects before participating in this study. Patients with the ocular pathology (eg, keratoconus) or a history of ocular surgery or trauma were excluded from participation in the study.

Each patient underwent an ophthalmologic examination, including manifest refraction spherical equivalent (MRSE), slit-lamp examination, ultrasound pachymetry measurement (Tomey SP–3000 pachymeter, Nagoya, Aichi-ken, Japan) and Pentacam imaging (Oculus Optikgeräte GmbH, Wetzlar, Germany). Ultrasound pachymetry and Pentacam scanning were performed preoperatively and at the 3-month follow-up.

Surgical Procedure

All SMILE procedures were performed by the same surgeon (YYB) using the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany). The routine procedures of the SMILE surgery have been described in a previous study.[15] In this study, the laser cut energy index was 155 nJ; the intended cap thickness was 110 μm to 140 μm; the programmed optical zone diameter was between 6.1 and 6.5 mm; and the diameter of the cap was 1 mm larger than the diameter of the lenticule. The optical zone and cap thickness were selected on the basis of the pupil diameter and percent tissue alert (PTA). A recommended nomogram adjustment was implemented for all subjects. To achieve emmetropia, the nomogram adds

10% correction of spherical refractive, as suggested by the manufacturer and as is the similar experience of other surgeons.[16, 17] The predicted lenticule thickness, following the nomogram adjustment, was displayed by the VisuMax software and recorded for statistical analysis.

Postoperative Treatment Regimen

Patients were instructed to wear plastic shields for 7 nights. The Levofloxacin eye drops (Cravit; Santen Pharmaceutical Co Ltd., Osaka, Japan) and 0.1% Fluorometholone eye drops (Santen Pharmaceutical Co Ltd., Osaka, Japan) were prescribed 4 times daily for 1 and 2 weeks, respectively. Preservative-free artificial tears were prescribed 4 times a day for a month. The patients were followed up at 1 day, 1 week and 1 and 3 months. Pentacam scanning and ultrasound pachymetry were performed at the 3-month postoperative visit.

Achieved Lenticule Thickness Calculation

The achieved lenticule thickness data were calculated by comparing the pre- and postoperative examinations with Pentacam software and ultrasound pachymetry measurement, respectively. Noncontact assessment (Pentacam) was consistently performed first. The rotating Pentacam Scheimpflug camera measures corneal thickness normal to the anterior surface tangent[18]. The pachymetry values were provided at 3 points[19], including the corneal vertex, pupil center and thinnest point. During the examination, the automatic release mode was used.[20] In this study, the intended treatment center was the corneal vertex. Since the position of the thinnest point of cornea varies greatly from person to person. The corneal vertex and pupil center were selected as the two locations to calculate the achieved lenticule thickness.

When corneal thicknesses were measured by ultrasound pachymetry, all patients underwent topical anesthesia using proparacaine 0.5% (Alcaine; Alcon-Couvreur n.v., Puurs, Belgium), and an average of 10 consecutive measurements was obtained in each eye. For ultrasound pachymetry measurements, a default velocity of 1640 m/s was used.

Statistical Analysis

In our study, only one eye for each patient was randomly selected and included for statistical analysis to ensure that the measurements from eyes can be treated as independent.[21] All statistical analyses were performed using the SPSS software package, version 16.0 (SPSS Inc., IBM, USA). The Kolmogorov-Smirnov normality test was used to assess the normal distribution of data. One-way analysis of variance (ANOVA) with post hoc Bonferroni test was performed to compare mean pachymetry values using different instruments, both preoperatively and postoperatively. Agreement was evaluated using Bland-Altman charts, in which the achieved lenticule thickness between the measurements are plotted against their mean.[22] The 95% limits of agreements (LoA) of the bias were calculated as the mean ± 1.96 standard deviations. Linear regression analysis was performed, and the coefficient of determination (R^2) was calculated to investigate the correlation between the predicted and achieved lenticule thickness, between the preoperative spherical equivalent and ΔLT. An independent t test was performed to evaluate the difference in ΔLT between different cap thicknesses. *P* values less than 0.05 were considered statistically significant.

Results

A total of 184 myopic eyes of 184 patients (93 men and 91 women) with a mean age of 24.24 ± 6.28 years (range: 18 to 42 years) who underwent SMILE surgery were analyzed preoperatively and 3 months postoperatively. No intraoperative or postoperative complications were encountered during the follow-up. The mean preoperative spherical equivalent (SE) refractive error was –5.34 ± 1.63 diopters (D) (range: –9.38 to –1.5 D). The mean SE of the surgical refractive correction was –5.85±1.79 D (range: –10.2 to –1.65 D). The mean preoperative and treated cylinder errors were both –0.65±0.57 D (range: –2.75 to 0 D).

The programmed optical zone was selected on the basis of the pupil diameter and PTA. The optical zone diameter was 6.1 mm in 3 eyes (1.6%), 6.2 mm in 2 eyes (1.1%), 6.3 mm in 4 eyes (2.2%), 6.4 mm in 10 eyes (5.4%), and 6.5 mm in 165 eyes (89.7%). The programmed cap thickness was 110 μm in 24 eyes (13.0%), 120 μm in 87 eyes (47.3%), 130 μm in 61 eyes (33.2%), 135 μm in 6 eyes (3.3%), and 140 μm in 7 eyes (3.8%). The programmed mean minimum thickness at the edge of the lenticule was 11.88 ± 3. 07 μm (range: 10 to 30 μm).

Predictability and Stability

At 3 months postoperatively, uncorrected distance visual acuity (UDVA) was 20/20 or better in 178 eyes (96.7%). All of the eyes (100%) that underwent SMILE surgery had a postoperative UDVA of 20/30 or better. The linear regression analysis of attempted SE versus achieved SE refraction at 3 months after SMILE is shown in Figure 1. The predictability of SMILE surgery at 3 months postoperatively is displayed in Figure 2. At the 3 month follow-up, 99% (183) of the eyes and 100% (184) of eyes were within ±0.5 and ±1.0 D. The postoperative SE was 0.02 ± 0.17 D (range: –0.75 to 0.5 D).

Assessment corneal thickness

The preoperative and postoperative mean corneal pachymetry values are summarized in Table 1. The mean predicted central lenticule thickness of the VisuMax readout was 106.55 ± 23.24 μm (range 60 to 155 μm). Three months postoperatively, the achieved mean lenticule thickness measured by ultrasound pachymetry was 93.53 ± 20.39 μm (range 46 to 139 μm). The achieved lenticule thickness measured using Pentacam software was 89.89 ± 20.47 μm (range 43 to 135 μm) at the corneal vertex and 90.30 ± 20.54 μm (range 42 to 134 μm) at the pupil center. No significant difference was detected between repeated measurements before and after surgery (Table 1). Additionally, there was no significant difference between the 3 individual achieved lenticule thicknesses (ANOVA, $P = 0.175$). The VisuMax readout lenticule thickness was significantly thicker than all of the achieved lenticule thicknesses measured with ultrasound pachymetry and Pentacam software (ANOVA, $P<0.001$). On average, the VisuMax readout lenticule thickness was 13.02 ± 8.87 μm (range: –9 to +33 μm) thicker than the achieved lenticule thickness measured with ultrasound pachymetry. Linear regression detected significant relationships between the VisuMax readout lenticule thickness and all of the achieved lenticule thicknesses (Figure 3A-C). Figure 4 shows the linear regression analysis comparing the ultrasonic measured lenticule thickness with the preoperative SE ($R^2 = 0.279$). Linear regression also detected significant relationships between the preoperative SE and both of the ΔLT values measured with Scheimpflug methods (at corneal vertex: $R^2 = 0.252$; at pupil center $R^2 = 0.246$). In contrast, the preoperative central stromal thickness was not a significant determinant for the change in the ΔLT.

Table 1. Mean Preoperative and Postoperative Pachymetry of Subjects (μm).

Parameter	Preoperative	Postoperative
Ultrasound pachymetry	547.05±27.34	453.52±30.62
Corneal Vertex	545.46±25.60	455.30±29.70
Pupil Center	545.96±25.63	455.38±29.85
P Value*	0.736	0.798

Mean ±SD, n = 184; * ANOVA test.

To investigate the relationship between the ΔLT and cap thickness, we divided the whole sample into two subsets (based on the 50th percentile of cap thickness): eyes with a cap thickness less than or equal to 120 μm (n = 110) and eyes with a cap thickness greater than 120 μm (n = 74). The ultrasound measurements showed that ΔLT in the thick cap group (cap thickness above 120 μm) was significantly smaller than that in the thin cap group (Table 2). However, no significant difference was found with Scheimpflug measurements between different cap thickness groups.

For corneal pachymetry compared to ultrasound, a bias was shown by the Scheimpflug method (Table 3). In the present study, central corneal thickness before SMILE surgery was measured thinner by Scheimpflug imaging compared to ultrasound. The opposite tendency was obtained after SMILE surgery. The Bland-Altman analysis showed a tendency that the evident bias usually shows at extreme values of central corneal thickness (above 550 μm or under 420 μm) in both Scheimpflug measurement comparisons with ultrasound pachymetry (Figure 5).

Table 2 The changes of ΔLT in different cap thickness group (μm).

Parameters	≤120 μm cap group (n=110)	120 μm cap group (n=74)	*P*
Predicted Lenticule Thickness	108.38 ± 22.64	103.84 ± 24.01	0.194
ΔLT			
Ultrasound Pachymetry	14.71 ± 8.96	10.51 ± 8.15	0.001*
Corneal Vertex	17.33 ± 8.85	15.68 ± 8.92	0.217
Pupil Center	16.79 ± 8.56	15.46 ± 8.91	0.311

Mean ±SD; * Statistically significant at $P \leq 0.05$; ΔLT: difference between predicted and achieved lenticule thickness.

Table 3 Pentacam measurements VS ultrasound pachymetry measurements (μm).

Parameters	Bias	SD	95% Limits of Agreement (μm)		
			Upper	Lower	Width
Preoperative cornea pachymetry					
Corneal Vertex	-1.59	7.80	13.70	-16.88	30.58
Pupil Center	-1.09	7.64	13.87	-16.06	29.93
Postoperative cornea pachymetry					
Corneal Vertex	2.07	6.46	14.73	-10.60	25.34
Pupil Center	2.15	6.51	14.91	-10.61	25.52

Difference (bias) in cornea thickness measurements was calculated as Pentacam measurements minus ultrasound pachymetry (i.e., a negative difference indicated a thinner reading on Pentacam compared to ultrasound). (Mean ±SD, n = 184).

Discussion

Myopia correction is accomplished through intrastromal lenticule extraction by femtosecond laser in SMILE surgery. Therefore, the predictability of lenticule thickness is the key to the accuracy of the SMILE procedure. The present study examined the relationship between the predicted and achieved lenticule thickness in eyes that had undergone SMILE for myopia and myopic astigmatism using the VisuMax femtosecond laser system.

In the present study, we found that the VisuMax readout was thicker than the achieved lenticule thickness by a mean of 13.02 ± 8.87 μm (range: −9 to +33 μm). Previous studies have reported results similar to those in our study. Reinstein et al.[8] assessed the stromal thickness in 70 eyes from 37 patients before and 3 months after SMILE surgery using Artemis high frequency digital ultrasound. These authors found that the achieved lenticule thickness was 8.2 ± 8.0 μm (range: −8 to +29 μm) thinner than the VisuMax readout on average. Luft et al.[9] followed 42 eyes from 21 patients for 1 year and observed that the difference between attempted and measured reduction of central stromal thickness was smallest at the 6-week timepoint using spectral-domain optical coherence tomography. The achieved lenticule thickness was thinner than the predicted lenticule thickness by a mean of 9.8 ± 7.8 μm (range −5 to +30 μm). An overestimation of the achieved lenticule thickness in the SMILE procedure was consistently found in previous studies.

However, divergent results were reported by several comparative studies on the relationship of predicted and achieved lenticule thickness. Reinstein et al.[8] speculated that the difference between the predicted and achieved lenticule thickness was a systematic difference that was similar for both low and high myopia. Zhou et al.[17] also indicated that the degree of myopia had no effect on the difference between the predicted and achieved lenticule thickness. On the other hand, Luft et al.[9] found that the discrepancy between the attempted and achieved lenticule thickness was significantly dependent on the amount of surgical refractive correction. A study by Liang et al.[23] assessed lenticule thickness accuracy in 190 eyes from 96 patients and divided them into 3 groups according to preoperative manifest refraction spherical equivalent. These authors also found that the discrepancy between the attempted and achieved lenticule thickness (ΔLT) was significantly smaller in the moderate myopia group (9.7 ± 6.4 μm) than in the high myopia group (12.3 ± 8.8 μm) and the superhigh myopia group (17.9 ± 6.9 μm). In the present study, our results were in accordance with those reported by Luft et al[9]. Linear regression analysis showed that the ΔLT was significantly related to the preoperative spherical equivalent correction.

In the present study, the ΔLT obtained with ultrasound was significantly larger under a thin cap ($P < 0.01$). To our knowledge, this study is the first to show that the change in ΔLT might be related to the depth of the lenticule in SMILE surgery. Reinstein et al.[8] proposed that the central stroma might expand after SMILE surgery as a result of tension release of the stromal collagen lamellae disrupted after the extraction of the lenticule. This expansion might cause a potential gap between the bottom lamellae of the cap and the top lamellae of the residual bed. Roberts and Dupps[24]also proposed that peripheral thickening may exert a lateral tension at the ablation margin that produces central flattening.

This phenomenon might be related to the redistribution of corneal tension, as lenticule creation and extraction may reduce cohesive tensile strength. Randleman et al. demonstrated that the cohesive tensile strength decreases from anterior to posterior within the central corneal region, and the anterior corneal stroma directly adjacent to Bowman’s layer had the highest cohesive tensile strength.[10] Therefore, a superficial lenticule tended to lose more cohesive tensile strength compared to a deeper lenticule. As the lateral tension increases, the central stroma might expand more, and the gap between the bottom lamellae of the cap and the top lamellae of the residual bed might also increase.

However, no significant differences were found with Scheimpflug measurements between the different lenticule depths groups. The Bland–Altman analysis showed a bias for the mean difference of corneal thickness before and after SMILE surgery when comparing the Scheimpflug techniques to ultrasound. The differences in the acquisition methods should be considered as a factor in the systematic bias. Previous studies reported that the differences in corneal thickness measurements between Scheimpflug techniques and ultrasound pachymetry were statistically significant; the measurements acquired by optical modalities are not directly interchangeable with ultrasound pachymetry measurements.[25, 26]

A personal nomogram for SMILE surgery was also found in previous studies. Liang et al.[16] suggested adding 11% correction of SE to the nomogram for SMILE surgery. Zhou et al.[17] adjusted the mean treated SE up to −6.30±2.00 D when the mean preoperative SE was −5.96±1.97 D in SMILE surgery. Reinstein et al.[8] also reported that a mean under correction of −0.78 D would be expected if he did not change the nomogram. In this study, the nomogram adds 10% correction of spherical refractive to achieve emmetropia. At 3 months postoperatively, the mean postoperative SE was 0.02 ± 0.17 D (range: −0.75 to 0.5 D). Only 14% of patients showed slight postoperative hyperopia between +0.14 D to +0.50 D (Figure 2). Therefore, we concluded that the change in the nomogram was appropriate. The change in the nomogram might be related to the overestimation of the achieved lenticule thickness, which might be explained by the corneal remodeling after SMILE and epithelium growth postoperatively.

The shortcoming of this study was that we did not evaluate changes in epithelial thickness. As previous studies reported, the epithelial thickness increased after SMILE surgery.[27–30] Luft et al.[28] found that the average central epithelial thickness was 109.3% of the preoperative thickness at 3 months after surgery, which increased by a mean of 5.9 ± 3.3 μm (range 0.7 to 11.4 μm). Reinstein et al.[8] also found that at 6 months after SMILE, the central epithelial thickness was 15.0 ± 5.2 μm (range: 5 to 30 μm) thicker than the preoperative thickness. This finding might be the reason that our study showed a larger discrepancy between the predicted and achieved lenticule thickness than the results of Reinstein et al.[8] and Luft et al.[9] Luft et al. analyzed the attempted and measured reduction of central stromal thickness and found that the slope of the regression line was 0.89, which indicated that the lenticule thickness was overestimated by approximately 10%.[9] In our study, the slope of the regression line was between 0.81–0.82, using ultrasound and Pentacam software, respectively. The underlying reasons for this difference might be postoperative corneal epithelium growth.

Conclusions

In conclusion, an overestimation of the achieved lenticule thickness was evident in this study. Furthermore, the changes in the ΔLT were related to the preoperative spherical equivalent correction and lenticule depth. Corneal expansion might be the reason for the relatively large mismatch between the predicted and achieved lenticule thickness. Further research is needed to substantiate this hypothesis.

Abbreviations

ANOVA: Analysis of variance; D: Diopters; LoA: Limits of agreements; PTA: Percent tissue alert; SE: Spherical equivalent; SD: Standard deviation; SMILE: Small incision lenticule extraction; UDVA: uncorrected distance visual acuity; ΔLT: The differences between the predicted and achieved lenticule thickness.

Declarations

Ethics approval and consent to participate

This study followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Second Affiliated Hospital of Zhejiang University. Written informed consent was obtained from the subjects before participating in this study.

Consent for publication

Not applicable

Availability of data and material

The datasets used 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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Authors' contributions

FW participated in the design of the study, analyzed the data and drafted the manuscript. HFY collected the data. XYC performed the statistical analysis. YBY designed the study, analyzed the data and revised the manuscript. All authors read and approved the final manuscript.

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Figures

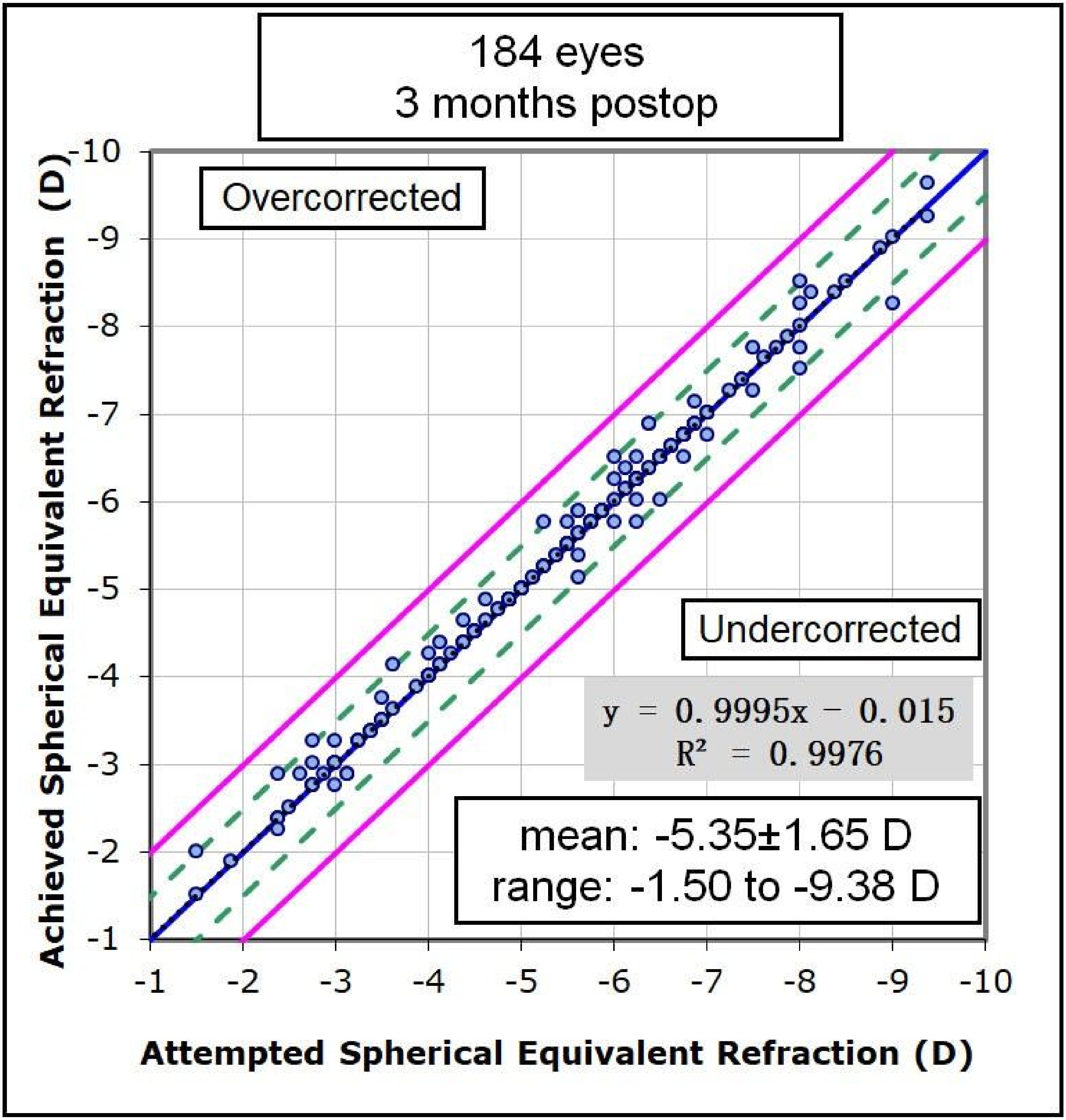

Figure 1

Figure 1. Achieved versus attempted changes in spherical equivalent at 3 months follow-up for 184 patients.

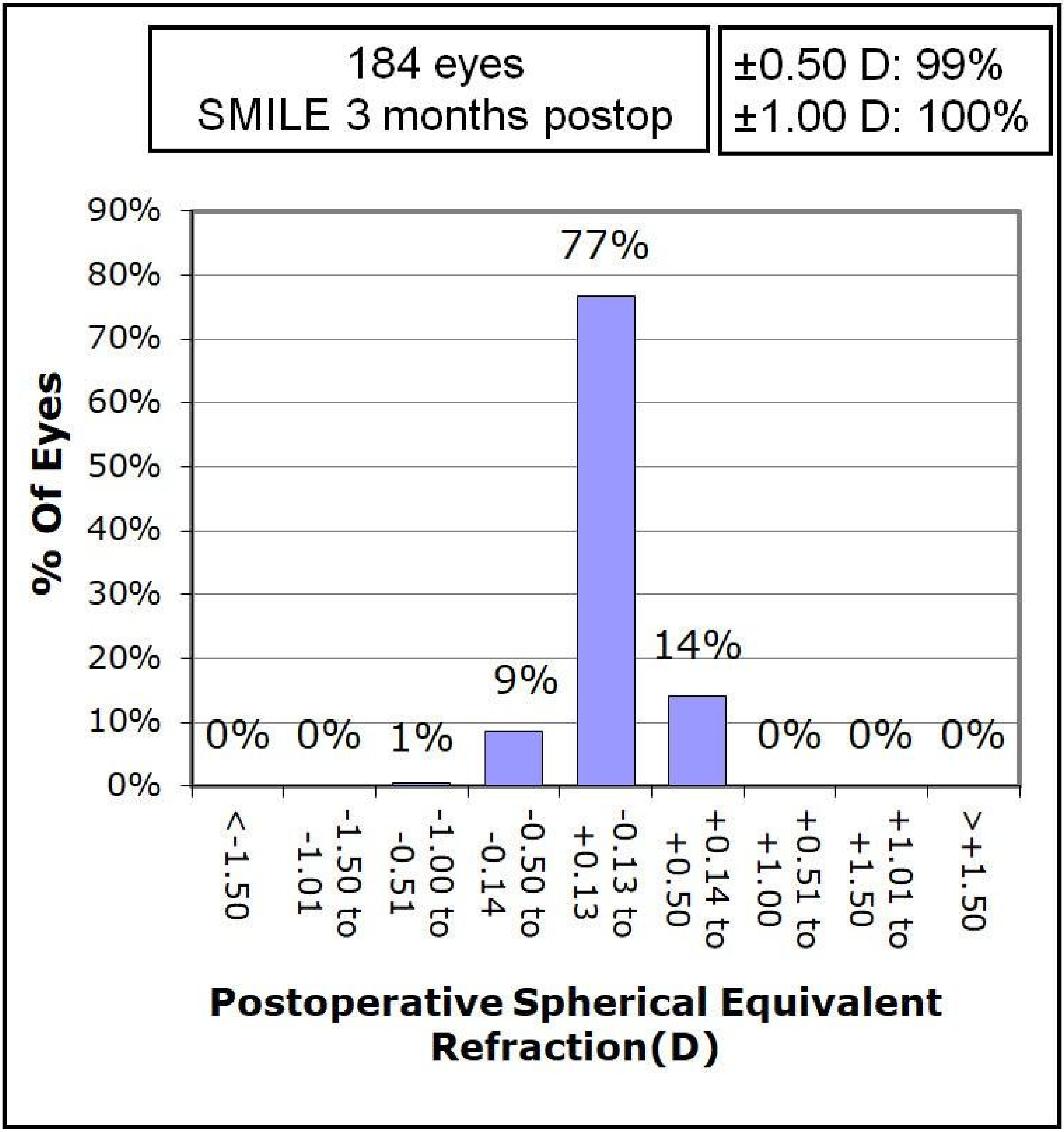

Figure 2

Figure 2. Accuracy of spherical equivalent refraction for 184 patients at 3 months after SMILE surgery.

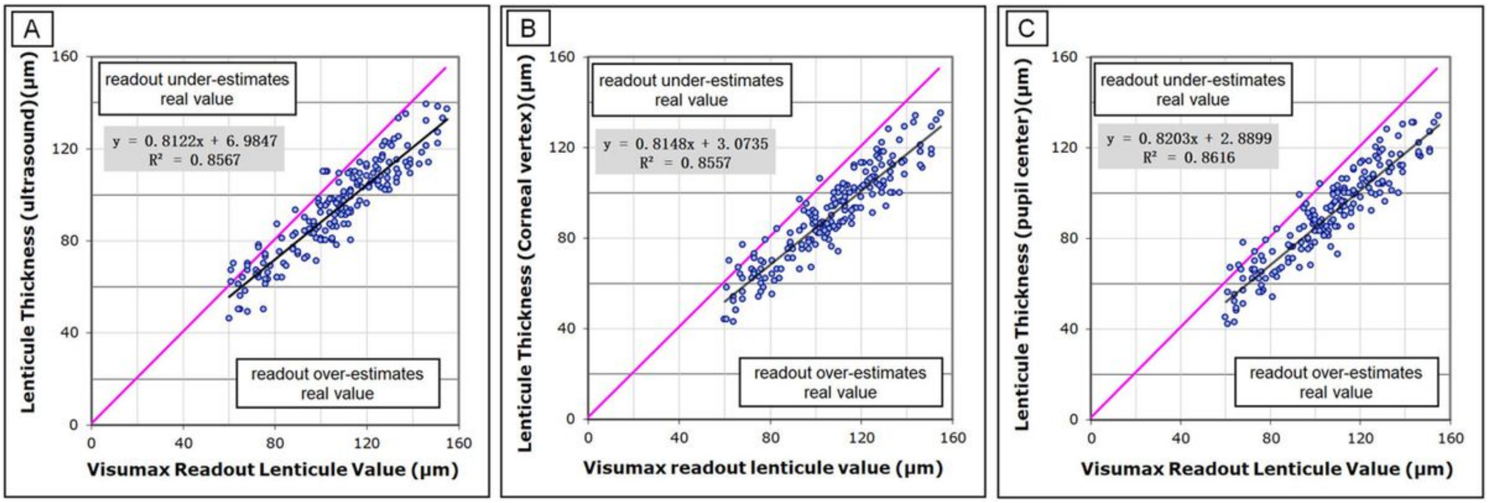

Figure 3

Figure 3. Correlation between the predicted and achieved lenticule thickness measured with ultrasound pachymetry. (A). Correlations between predicted and achieved lenticule thickness measured with Pentacam software at the corneal vertex (B) and the pupil center (C). The regression equations and coefficients of determination (R2) are displayed. The red dotted line indicates a slope of 1.

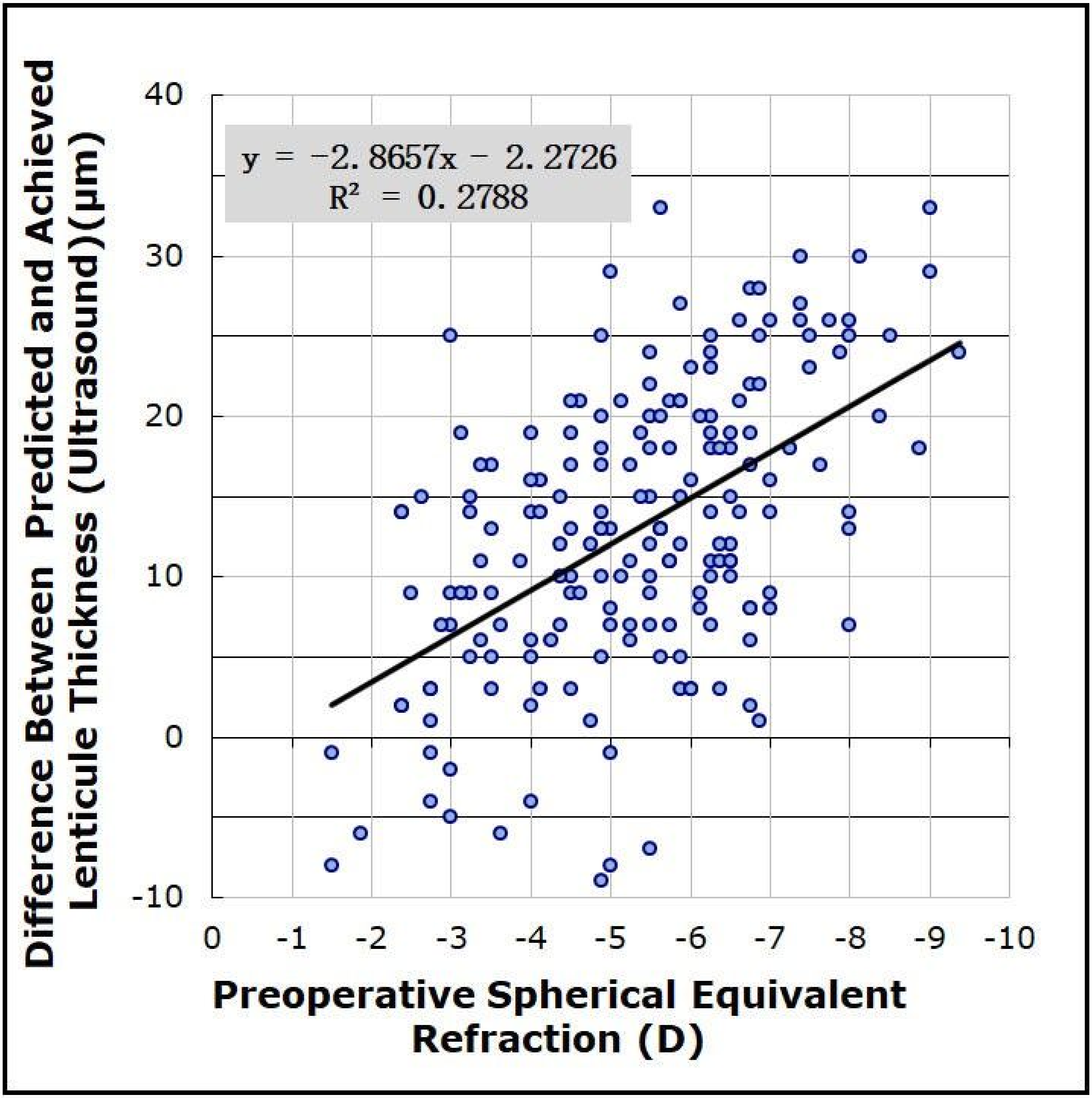

Figure 4

Figure 4. Associations of the preoperative spherical equivalent refraction and the difference between predicted and achieved lenticule thickness measured with ultrasound pachymetry. The regression equations and coefficients of determination (R2) are displayed.

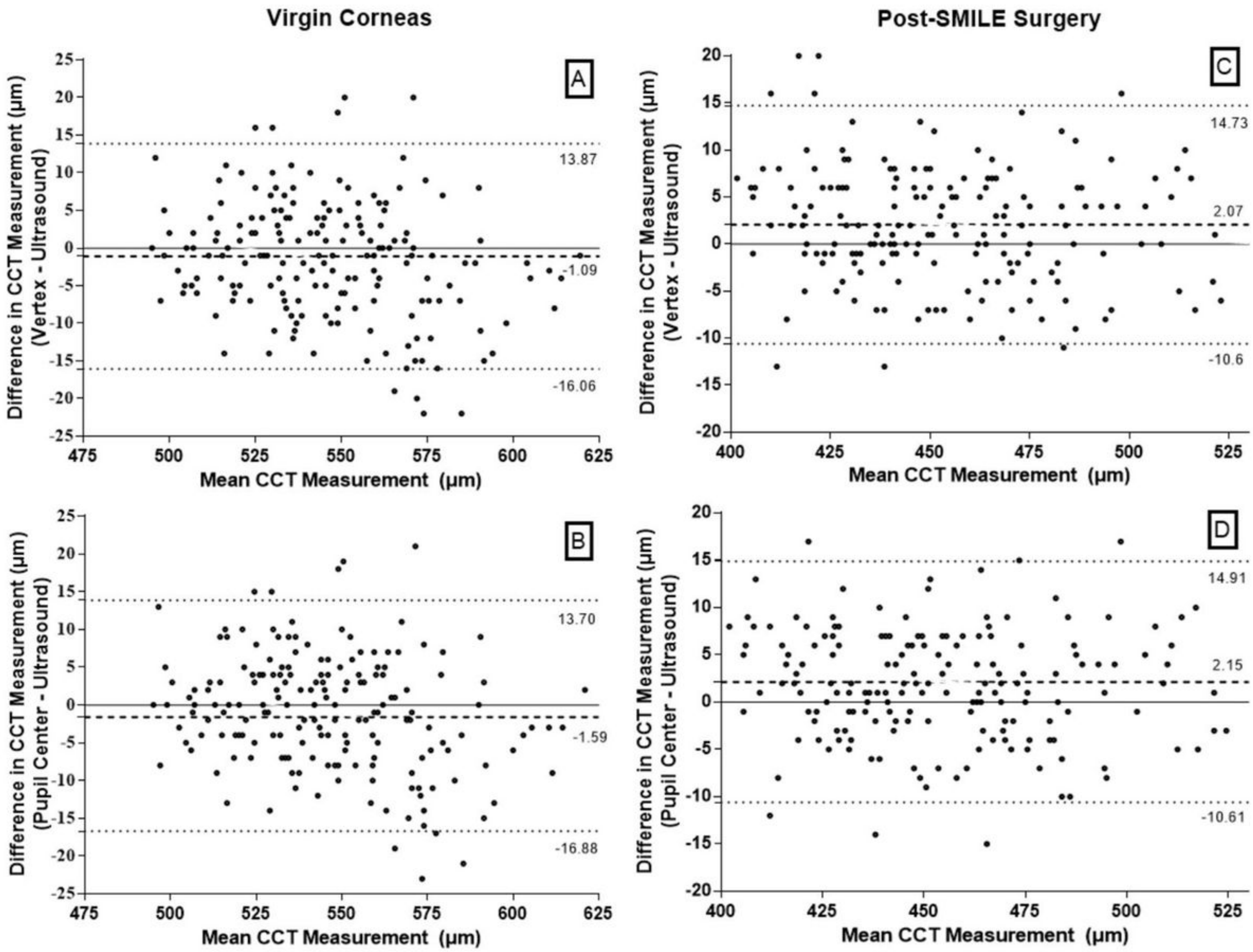

Figure 5

Figure 5. Bland–Altman charts displaying the difference between Scheimpflug Imaging and Ultrasound. In Virgin and post-SMILE refractive surgery corneas, Bland–Altman charts displaying the difference for central corneal thickness measurements. The pupil center and corneal vertex were selected as the 2 locations for measurement calculation on Pentacam. A negative difference indicates a thinner reading on Pentacam compared to ultrasound. Bias (dashed line) ± 95% limits of agreement (dotted line) are displayed (Tables 3). (CCT: central corneal thickness).