

ORIGINAL ARTICLE

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A comparative study between the Schwind and Zyoptix XP microkeratomes

ABSTRACT

Objectives

To compare the flap thickness created by two different microkeratomes and its effect on visual outcomes.

Methods

This prospective study involved 32 eyes of 16 patients who underwent laser in situ keratomileusis (LASIK). Flap creation was randomly assigned to either the Schwind (110 µm) or Zyoptix XP (120 µm) microkeratome. Flap thickness was measured using the subtraction technique. Uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), low-contrast sensitivity, and aberrometry measurements were compared preoperatively and at 6 months postoperatively.

Results

The mean flap thickness was $97 \pm 13 \,\mu m$ (range, 81 to 116 μm) and 146 \pm 27 μm (range, 71 to 181 μm) using the Schwind and XP respectively. The mean deviation from the labeled predicted thickness was –13 $\pm\,13~\mu m$ and 26 $\pm 27 \,\mu \text{m}$ respectively, and this difference was statistically significant (p = 0.002). Three eyes had flap displacement, 1 had loose epithelium, and 1 had flap striae in the Schwind group. There were no complications in the XP group. At 6 months, 71% of eyes had UCVA of 20/20 or better in both groups. All eyes attained BCVA of 20/30 or better with spherical equivalent within ±1D of targeted emmetropia in both groups. Low-contrast sensitivity scores were higher in the Schwind group in most frequencies; however, the differences were not statistically significant. The mean change in the total higher-order aberration (HOA), trefoil, coma, quadrafoil was comparable between the groups. The mean change in spherical aberration was smaller (p = 0.03) in the Schwind (0.12 ± 0.35) than in the XP group (0.96 ± 1.3) .

Conclusion

Flap thickness was more predictable with the Schwind than the XP. Schwind flaps were thinner, which may have resulted in more flap complications. Vision and refractive results were similar for both groups. There was no statistically significant difference in HOA; however, spherical aberration was significantly lower in the Schwind.

Keywords: LASIK, Schwind Carriazo, Zyoptix XP, Microkeratome, Flap thickness

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LASER in situ keratomileusis (LASIK) is a widely accepted procedure in managing refractive errors. However, laser correction is limited by the patient's corneal thickness. The need to deliver correction for higher errors of refraction without compromising corneal strength has paved the way for newer-generation microkeratomes and other technologies that create thinner flaps making more corneal tissue available for correction.¹

There are different microkeratomes in use today. The main differences lie in the type of movement (straight, pivoting, or pendular), applanation of the cornea during cut(convex or planar), and position of the hinge (superior or nasal).

The Schwind Carriazo-Pendular (CP) microkeratome is pendular with convex applanation. It produces a superior hinge. This convex applanation provides a nearly constant pressure on the cornea during the cutting process, producing almost uniform thickness throughout the flap area. The constant pressure applied by the CP is presumed to lower the risk of buttonhole compared with planar applanation microkeratomes in which the central pressure is higher than the peripheral.²

The Zyoptix XP (XP) is a pivot microkeratome with planar applanation. It produces a meniscus-formed flap, which is thinner in the center and thicker in the periphery. The keratome cuts in a constant plane, which produces a smoother corneal bed, thus also suggesting less chance of a buttonhole.³⁻⁴

Evaluating flap thickness and quality created by different keratomes is important. With an instrument that offers greater predictability in flap thickness, the surgeon can reasonably estimate residual bed thickness and avoid ectasia. The shearing force due to differences in keratome movement and bed contour may affect visual results and induce unwanted aberrations. Flap complications such as buttonholes, displacement, and striae may occur with overly thin, friable flaps.

This study compared the differences in outcomes (flap-thickness reproducibility, vision, contrast sensitivity, and higher-order aberrations) of LASIK between Schwind CP microkeratome and Zyoptix XP microkeratome.

METHODOLOGY

This is a prospective, randomized, subject-masked, comparative clinical study of 32 eyes of 16 patients seen in a single center from July 2008 to February 2009.

The research protocol followed the guidelines of the Helsinki Declaration and was approved by the hospital's ethics review board. All patients were fully informed of the nature and details of the procedure. The scope of the study, including all the risks and benefits involved, were explained. Informed consent was obtained from all participants.

To be included, patients must:

- be at least 18 years old;
- have myopia with or without astigmatism in both eyes, but with stable refraction;
- have stopped using soft contact lenses for at least 1 week or hard contact lens for at least 3 weeks;
- have estimated residual corneal-bed thickness of 280 µm and above;
 - be willing to undergo LASIK in both eyes. Excluded were patients who:
- have preexisting systemic diseases that could hinder wound healing;
 - are pregnant or lactating;
 - have active ocular inflammation and infection;
 - have a history of herpes simplex or herpes zoster keratitis;
- have signs of corneal pathologies, corneal warpage on topography;
 - have unstable refraction;
 - have had previous eye surgeries or eye trauma;
 - have cataract, glaucoma, or other optic-nerve diseases;
 - have retina pathologies;
 - will undergo PRK or LASEK.

All patients underwent refractive-screening protocol which included history taking, visual-acuity measurements, manifest and cycloplegic refractions, dim-light pupil-size determination, slitlamp examination, intraocular pressure check, ultrasonic pachymetry, Schirmer's testing, corneal topography using Orbscan IIz, Zywave undilated and dilated wavefront aberrometry measurements, and dilated-fundus examination.

All laser treatments for each eye were targeted for emmetropia using the personalized-treatment software planner (Bausch & Lomb, Rochester, NY, USA). The surgeries were performed by a single surgeon. The right eye was treated first. A randomization table was used to determine which eye would undergo flap creation using either CP microkeratome or XP microkeratome. The patients were blinded as to the type of microkeratome.

On the operative eye, asepsis and antisepsis technique with 10% betadine was applied around the lid and periorbital adnexa, followed by sterile draping of the eye and placement of the lid speculum. Pachymetry was done on the central cornea before placement of keratome. Flaps were created using either the CP or the XP microkeratome based on the randomization table. The flaps were lifted and pachymetry measurements were done on the dry stromal bed. The pachymeter automatically took 25 readings and the mean reading was recorded. To obtain the flap thickness per eye, the stromal-bed-thickness measurement was subtracted from the corneal thickness prior to flap cutting.

Laser ablation was performed using the Technolas 217z and the flap repositioned by floating and then dried.

Postoperative medications were gatifloxacin (Zymar, Allergan, Irvine, CA, USA) and 1% prednisolone acetate (Pred Forte, Allergan, Irvine, CA, USA) 4x a day for at least 2 weeks.

Examinations were scheduled at 1 day, 7 days, 1 month, 3 months, and 6 months postoperatively. Uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were measured at each postoperative visit. Contrast-sensitivity tests, topography, and aberrometry were performed at 1, 3, and 6 months follow-up.

Statistical data were collected and analyzed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) data-analysis tool pack. Two-tailed paired student ttest was performed with a significance level of p < 0.05. Means and standard deviations were also obtained. Visual acuity (VA) was expressed in the logarithm of minimum angle of resolution (logMAR) scale using a VA conversion chart.

RESULTS

Thirty-two eyes of 16 patients were included in the study. Six were male and 13 female, with a mean age of 34 ± 9.3 years (range, 21 to 48). The preoperative UCVA, spherical equivalent, and central pachymetry were similar in both groups (Table 1).

Flap thickness and complications

The mean flap thickness created was $97\pm13\,\mu\mathrm{m}$ (range, 81 to $116\,\mu$) using the CP and $146\pm27\,\mu\mathrm{m}$ (range, 71 to $181\,\mu\mathrm{m}$) using the XP. The mean deviation from the predicted thickness was $-13\pm13\,\mu\mathrm{m}$ and $26\pm27\,\mu\mathrm{m}$ for the CP and XP respectively. The difference between the groups was statistically significant (p=0.002). In the CP group, 3 eyes had flap displacement, 1 had loose epithelium and 1 had flap striae. There were no complications in the XP group. No evidence of ectasia was noted in all eyes.

Visual results

At 6 months postoperatively, UCVA was 20/20 in 93% and 86% of eyes in the CP and XP groups respectively. Mean UCVA was 20/20 (range, 20/15 to 20/20) in the CP and 20/25 (range, 20/15 to 20/30) in the XP groups. UCVA was 20/30 or better in all eyes in the 2 groups (Figure 1). The BCVA was 20/20 in 100% and 93% of eyes in the CP and XP groups respectively. Mean BCVA was 20/20 in both groups (range, 20/15 to 20/20). All eyes achieved BCVA of 20/25 (Figure 2). There was no statistical difference in the UCVA and BCVA in either group (p = 0.27 for CP and p = 0.16 for XP).

Preoperatively, the mean spherical equivalent was -4.50D and -4.70 in the CP and XP. The mean sphere was -4.00D in both groups. The mean cylinder was -0.9 and -0.8

Table 1. Preoperative parameters of the study population.

Parameters	Schwind	XP	р
Log MAR mean UCVA	1.37 ± 0.13	1.37 ± 0.14	0.46
	20/400	20/400	
Range	20/200 to CF 7ft	20/200 to CF 6ft	
Log MAR mean BCVA	1.0	1.0	
Range	20/15 to 20/20	20/15 to 20/20	
Mean spherical equivalent (D)	-4.58 ± 1.31	-4.72 ± 1.2	0.44
Range	−3 to −8.5	−3 to −8.1	
Central pachymetry (µm)	556 ± 40	554 ± 39	0.98
Range	503 to 629	504 to 635	

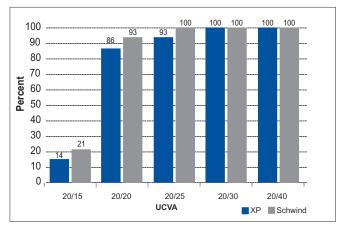


Figure 1. Uncorrected visual acuity (UCVA) at 6 months postoperatively.

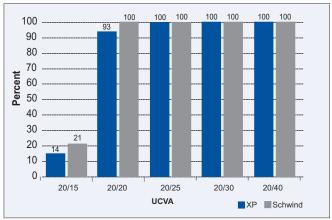


Figure 2. Best-corrected visual acuity (BCVA) at 6 months postoperatively.

respectively (Table 2).

At 6 months postoperatively, the mean spherical equivalent was -0.04D in the CP and -0.1 in the XP groups. The mean sphere was -0.02D and 0.03 and the mean cylinder was -0.1 and -0.27 respectively (Table 2).

At 6 months, contrast sensitivity both at photopic and mesopic conditions, with and without glare, were all measured at 1.5, 3, 6, 12, and 18 cycles/degree (cpd) (Figures 3 and 4). Contrast sensitivity was better in the

Table 2 . Refraction summary preoperatively and at 6 months postoperatively.

	Preoperative			6 months postoperatively		
	Mean (D)	Range (D)	p ¹	Mean (D)	Range (D)	p ¹
Sphere Schwind XP	-4.00 ± 1.3 -4.00 ± 1.4	-2.00 to -8.00 -2.00 to -7.50	0.27	-0.02 ± 0.04 0.03 ± 0.31	-0.25 to 1.00 -0.50 to 0.75	0.88
Cylinder Schwind XP	-0.90 ± 1.1 -0.80 ± 1.2	-4.25 to 0 -5.00 to 0	0.50	-0.10 ± 0.29 -0.27 ± 0.21	-1.00 to 0 -0.50 to 0	0.36
Spherical equivalent Schwind XP	-4.50 ± 1.3 -4.70 ± 1.3	-3.00 to -8.50 -3.00 to -8.00	0.44	-0.04 ± 0.29 -0.10 ± 0.31	-0.38 to 0.75 -0.50 to 0.63	0.65

¹Paired t-test

Table 3. Mean spherical and higher-order aberrations preoperatively and at 6 months postoperatively.

	Preoperative			6 months postoperatively		
	Schwind	ХР	р	Schwind	ХР	р
Spherical aberration (μm) Higher-order aberrations (μm)	1.56 ± 2.66 -0.12 ± 0.15	1.30 ± 2.62 -0.11 ± 0.15	0.35 0.86	0.12 ± 0.35 0.19 ± 0.31	0.96 ± 1.3 -0.01 ± 1.3	0.03 0.22

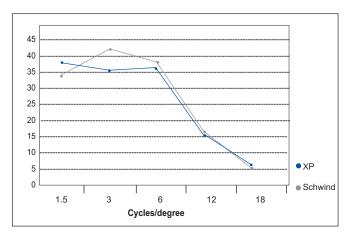


Figure 3A. Contrast-sensitivity scores under mesopic conditions without glare at 6 months.

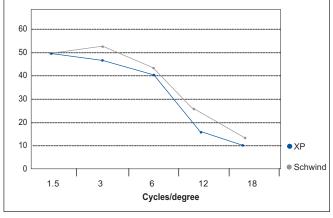


Figure 3B. Contrast-sensitivity scores under mesopic conditions with glare at 6 months.

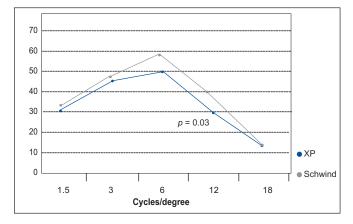


Figure 4A. Contrast-sensitivity scores under photopic conditions without glare at 6 months.

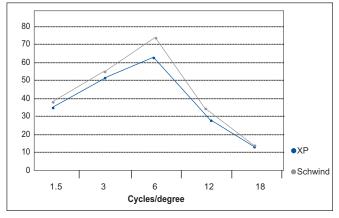


Figure 4B. Contrast-sensitivity scores under photopic conditions with glare at 6 months.

CP than in the XP group, but most measurements did not reach statistical significance except those under photopic conditions without glare at 12 cpd spatial frequency (p = 0.03).

At 6 months, 21% of eyes in the CP group gained 1 line compared with 14% in the XP group. Seven percent in the XP group lost 1 line compared with none in the CP group.

Higher-order aberrations

Preoperatively, mean spherical aberration was $-0.12~\mu m$ in the CP and $-0.11~\mu m$ in the XP groups. Mean total higher-order aberration was 1.56 and 1.30 respectively. The difference in the aberrations between the 2 groups was not statistically significant (Table 3).

At 6 months postoperatively, there was a smaller mean change of spherical aberration in the CP compared with the XP (Table 3), and the difference was statistically significant (p = 0.03). The total higher-order aberrations were similar in both groups. Mean change in the trefoil, coma, and quadrafoil were also comparable between the groups.

DISCUSSION

This prospective study compared contralateral eyes of the same patient that were randomized to receive flaps created either by a CP or an XP microkeratome during a wavefront-guided LASIK treatment for myopia or astigmatic myopia. Our data showed that the mean flap thickness (97 \pm 13 $\mu m)$ created by the Schwind microkeratome was thinner than the labeled predicted thickness (110 $\mu m).$ In contrast, the mean flap thickness (146 \pm 27 $\mu m)$ created with the XP microkeratome was thicker than predicted (120 $\mu m)$. These differences were statistically significant.

Thinner flaps have the advantage of preserving more untreated cornea; hence, the biomechanical integrity is less altered.^{5, 9} Thicker flaps may inadvertently increase risks of ectasia if the residual stroma is less than what the surgeon estimated it would be. On the other hand, studies also reported that thinner flaps were more difficult to manage and had greater tendency to develop flap striae, displacement, and irregular astigmatism.^{8, 10} The results of this study are consistent with these reports since only the thinner flaps in the CP group had flap problems. Despite the complications encountered, they did not affect visual outcomes in the CP group.

The difference in flap thickness did not seem to affect visual outcome. There were no statistical differences in the UCVA, BCVA, and contrast sensitivity in both groups.

In this study, the flap thickness exhibited an impact on the postoperative spherical aberration. Six months postoperatively, eyes with flaps created using the Schwind microkeratome had smaller mean change in spherical aberration. Spherical aberration, which is symmetrical to the visual axis of the eye, has been found to be substantially increased after LASIK.^{7, 11-12} It is hypothesized that flap thickness bears impact on the spherical aberration. Suggested sources of induced spherical aberration after LASIK included biomechanical responses and epithelial-thickness modulation during the wound-healing process. In our study, it was difficult to determine the exact cause of the difference in spherical aberration. Our data seemed to suggest that the thinner flaps created by the CP may be the only identifiable difference and, therefore, the most likely contributing factor.

In summary, CP-created flaps were thinner and showed more predictability than the XP, but they resulted in more complications. Total higher-order aberration was similar in both groups, but spherical aberration was increased in the XP group. Despite these differences, the vision and refractive results were similar for both groups.

We conclude that flap quality and thickness may affect flap handling and lead to complications, but have little or no effect on visual outcome.

We recommend that future studies should involve larger sample size and comparison of other mechanical microkeratomes or femtosecond lasers to determine if flap quality and thickness do play a role in visual outcome.

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