• Clinical Research •

Vector analysis of Contoura Vision for the correction of myopia and myopic astigmatism

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Abstract

● **AIM:** To evaluate the visual outcomes of Contoura Vision (CV) with automatic eye tracking system in eyes with myopia and myopic astigmatism.

● **METHODS:** This prospective study included 160 eyes (80 patients) with moderate myopia and irregular astigmatism between January and August 2018. Subjects were randomly divided into CV group (80 eyes) that underwent CV femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) and a control group (80 eyes) that underwent wavefront-optimized FS-LASIK. Visual outcomes and astigmatic vector analysis were evaluated and compared between preoperatively and 3mo postoperatively.

● **RESULTS:** Basic details were similar in both groups (P>0.05). At 3mo postoperatively, uncorrected distance visual acuity was 20/16, 20/20, and 20/25 in 24, 76, and 80 eyes of patients in CV group, respectively. The CV group was better in predictability of astigmatism correction at 3mo postoperatively. In CV group, 64 eyes had deviation of astigmatic axis within 15° and 28 eyes had deviation of astigmatic axis within 5°, both were better than those in the control group. The number of eyes with residual astigmatism within 0.5 D were less in CV group (48 eyes) than the control group (40 eyes). Compared with the preoperative, C7 significantly reduced to 0.056±0.030 in CV group at 3mo after the procedure (P<0.05), and were significantly lower than those in the control group (P<0.05).

● **CONCLUSION:** CV with automatic eye tracking system is safe and effective for the correction of myopia and myopic astigmatism.

● **KEYWORDS:** vector analysis; irregular astigmatism; Contoura Vision

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INTRODUCTION

Femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) has become the current mainstream corneal refractive surgery because of its predictability and stability[1-3]. However, many subjects with uncorrected distance visual acuity (UDVA) greater than 1.0 after FS-LASIK complain about poor night vision, glare, and double vision. Excimer laser treatment of spherical myopia is more predictable than that of myopic astigmatism[4]. Studies have shown that every 1 deviation of the astigmatic axis results in a loss of correction of 3.3%[5]. Residual astigmatism less than 0.50 D has an impact on visual quality[6]. With the development of technology, wavefront- guided[7-8] and topography-guided[9-10] had been used in LASIK. The conventional treatment method is wavefront-guided LASIK, which aims to correct the aberration of the entire eye and is gradually less effective with age due to changes in eye adjustment[7-8]. Topography-guided LASIK have been reported to correct irregular cornea. It has showed advantages for improved visual quality with less induction of high order aberrations (HOAs)[9-10]. In recent years, Alcon presented the innovative Contoura Vision (CV) technique based on the WaveLight refractive Suite. The studies by Motwani[11-13] have demonstrated the efficacy of CV in correcting low-order aberrations and HOAs caused by corneal asymmetry. This study aimed to observe changes of astigmatism and corneal irregularity after correction of low-to-moderate myopia with asymmetrical corneal astigmatism using automatic iris tracking and CV technology and to investigate the safety and effectiveness of this surgical procedure.

Commonly used parameters to assess efficiency of corneal refractive surgery including residual astigmatism, spherical equivalent, and cylindrical lens power were used as the

quantitative indices. Moreover, vector analysis that added factors impacting axial direction and lens power can be used to comprehensively evaluate the change of astigmatism after corneal refractive surgery and assess surgery efficacy[14-15]. In the vector analysis based on the Alpins method[16], accurate Cartesian coordinates provide accurate magnitude and axial direction of surgical-induced astigmatism (SIA), preoperative astigmatism, target astigmatism, and postoperative astigmatism.

SUBJECTS AND METHODS

Ethical Approval The study was approved by the local ethics committee of Liuzhou Worker's Hospital, China, and all patients signed an informed consent form during the initial visit. The study was conducted in accordance with the principles of the Declaration of Helsinki. The data are available in the ResMan research manager and the ChiCTR approved number is ChiCTR1900026855.

General Data This study was designed as a prospective cohort study. Eighty subjects (160 eyes) who underwent myopia laser treatment in the Department of Ophthalmology of Liuzhou Worker's Hospital from January to August 2018 were selected and randomly divided into two groups: CV group included 40 subjects who underwent automatic iris-tracking and topography-guided FS-LASIK, and the control group included 40 subjects who underwent automatic iris-tracking LASIK. The inclusion criteria were as follows: 1) subjects aged between 18y and 50y; 2) preoperative corneal topography showed a difference in refraction greater than 1.25 D in the anterior corneal surface between the upper and lower portions (a 5-mm area in the central corneal area was selected); 3) subjects who stopped wearing soft contact lenses for at least 15d or oxygen-permeable hard contact lens for over 3mo; 4) subjects with a refraction less than -6.00 D in sphere or -4.00 D in cylinder; 5) the preoperative central corneal thickness (CCT) was more than 480 μm; 6) estimated postoperative residual stromal bed thickness was no less than 280 μm or the corneal ablation depth was no more than 50% of the thinnest corneal thickness. Patients who had anterior segment abnormalities such as keratoconus or corneal ectasia, recurring eye disease such as iritis or herpetic keratitis, severe dry eye, or systemic disease such as diabetes or hyperthyroidism, were not included.

Methods

Preoperative examination The preoperative routine examination included UDVA, best corrected distance visual acuity (CDVA), intraocular pressure, slit lamp biomicroscopy, fundus examination and measurement of corneal thickness. Special preoperative and postoperative examinations were performed by using Topolyzer and Oculyzer (Alcon, USA). Topolyzer scans were performed in natural light, and 8 consistent topographic maps of anterior corneal surface were selected and transmitted into the EX500 excimer laser. Oculyzer scans were performed in a dark room, and the absolute value of the vertical coma (C7), horizontal coma (C8) and 3rd total coma in the 4-mm area was obtained from the Zernike polynomial modes. The corneal index of surface variance (ISV) and the corneal index of vertical asymmetry (IVA) were examined in the refraction mode.

Surgical procedure All procedures were performed by the same experienced ophthalmologist (Lin Y). The WaveLight FS200 femtosecond laser (Alcon, USA) was used to create the corneal flap with a depth of 120 μm and diameter of 8.5 mm. The corneal flap hinge were located 90° superiorly. The diameter of optical zone ablation was 6.5 mm. The subjects in the CV group underwent topography-guided keratomileusis in the EX500. The topographic neutralizing treatment (TNT) method[15] which includes a comprehensive analysis of the results of manifest refraction and Topolyzer examination to adjust the actual laser correction degree was used during surgery. In the surgical design, appropriate diopter compensation should be considered for the spherical aberration that may be caused by elimination of HOAs. After the surgical design was completed, corneal ablation was performed using the automatic iris tracking system. The subjects in the control group underwent automatic iris-tracking LASIK in the EX500.

Postoperative pharmacotherapy Both groups of subjects were treated with levofloxacin ophthalmic solution (Santen, Japan) 4 times a day for a week and tobramycin dexamethasone ophthalmic solution (Alcon, USA) 4 times a day for a week. Then, the treatment continued with 0.1% fluorometholone ophthalmic solution (Santen, Japan) 3 times a day for 3wk followed by polyethylene glycol ophthalmic solution (Alcon, USA) 4 times a day for 4wk.

Observation parameters The following parameters were observed before and 3mo after surgery: UDVA, CDVA, autorefraction to verify spherical and cylinder power, corneal curvature, C7 and C8 by Topolyzer and ISV, IVA by Oculyzer.

Statistical Analysis SPSS 22.0 statistical software was used for statistical analysis. The χ^2 test was used to compare the quantitative data. The differences between C7, C8, ISV, and IVA within the same group were compared by repeated measures analysis of variance followed by least significant difference (LSD) *t*-tests for comparison of two means between different time points. Independent sample *t*-tests were used to compare the differences between the two groups. The astigmatism vector analysis between the eyes with different degrees of astigmatism before and 3mo after surgery was performed with the Alpins method[14] to calculate SIA, target corrected astigmatism (TIA), and spherical equivalent. Differences in preoperative and postoperative data were analyzed using the Wilcoxon rank sum test. $P<0.05$ was considered statistically significant.

RESULTS

General Data The demographic data of the 2 subject groups before surgery are shown in Table 1. There were no significant differences in age, sex, CCT, maximum keratometry (Kmax); minimum keratometry (Kmin), sphere, cylinder and CDVA between the two groups before surgery (P>0.05).

Vision and Refraction The UDVA in the CV group had 76 eyes (95%) of the eyes better than 20/20 after 1mo, which was maintained at the 3mo visit (Figure 1) and 60 eyes (75%) of eyes in control group (P<0.001). CDVA of 20/16 or better was measured for 12 eyes (15%) of control group eyes, compared to 24 eyes (30%) of CV group eyes (P<0.001).

Figure 2 depicts the CDVA between two groups at the 3mo visit. In the CV group, 48 eyes (60%) had an unchanged CDVA, 20 (25%) gained 1 line, and 8 (10%) gained 2 lines. Four eyes (5%) lost 1 line of CDVA, no one lost 2 lines, or more than 2 lines. In the control group, 52 eyes (65%) had an unchanged CDVA, 4 (5%) gained 1 line. Twenty eyes (25%) lost 1 line of CDVA, 4 eyes (5%) lost 2 lines or more. All differences were statistically significant at P<0.03, except the number of eyes with unchanged CDVA between two groups (P=0.21).

Changes in Corneal Parameters The ISV, IVA, and C7 in the CV group were significantly lower than those in the control group 3mo after surgery (Tables 2 and 3). At 3mo postoperative, the ISV and IVA in the CV group were significantly lower than those in the control group (t=13.19, 10.14 respectively, P=0.01, 0.01).

The TIA versus SIA vector scattergram showed no significant difference between CV group and control group (R^2=0.7649 and 0.5356, respectively; P=0.078, P=0.070; Figure 3). The TIA (2.16±0.89) and SIA (2.03±0.88) vectors in the CV group were not significantly different from that in the control group (2.32±0.82 and 2.08±0.83, P=0.0803 and 0.0841, respectively). In the CV group, 80% (64 eyes) of subjects had a deviation of astigmatism in the axial direction less than 15°, and 35% (28 eyes) of subjects had an axial deviation of less than 5°. These results were better than those in the control group (Figure 4). Figure 5 shows the percentage of eyes within ±0.25 D, ±0.50 D, and ±1.00 D of the intended plano cylinder after surgery. The difference was significant between the two groups (P<0.05).

Changes in Contrast Sensitivity The preoperative contrast sensitivity between two groups were similar. All spatial frequencies of contrast sensitivity of the CV group were higher than those of the control group 3mo after surgery (Table 4).

DISCUSSION

Some subjects undergoing LASIK still have visual problems such as poor night vision, glare, and blurred vision. Studies have shown that the root mean square after LASIK is 1.9-fold higher after surgery than before surgery[17]. Both spherical aberration and coma increased after surgery, and the spherical aberration increased 4-fold after surgery compared to before surgery. For corneal asymmetrical astigmatism, the refractive power of the cornea on the same meridian or on different meridians is different. Conventional LASIK may produce more optic aberrations which can seriously impair visual quality of subjects. At present, the individualized surgical methods mainly include wavefront aberration-guided or topographic-guided LASIK. The wavefront aberration-guided approach is focused on optic aberration of the whole eye, but it ignores the influence of tear film, pupils, and lens adjustment on aberrations[18-19]. Corneal topography-guided LASIK is more commonly used in subjects with ocular trauma or severe irregular corneal astigmatism[20-22] and is rarely reported in subjects with mild to moderate corneal irregular astigmatism in primary eyes. In this study, the automatic iris tracking system is designed according to the iris texture. The three-dimensional tracking mode effectively reduces the eye rotation caused

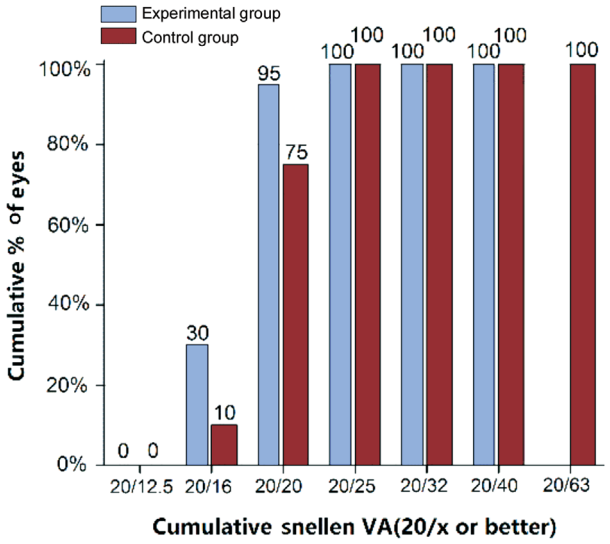

Figure 1 Uncorrected distance visual acuity at 3mo.

Table 1 Comparison of preoperative general data between the two groups

Parameters	Contoura Vision group	Control group
Age (y)	25.52±5.38	24.89±5.70
Sex, *n* (%)		
Female	11 (55)	10 (50)
Male	9 (45)	10 (50)
Preop. spherical power (D)	-5.74±1.20	-5.68±1.26
Preop. cylinder power (D)	-2.35±0.92	-2.50±0.90
BCVA	0.82±1.10	0.84±1.03
CCT (μm)	536.26±28.30	541.38±27.89
Kmin (D)	42.72±1.66	43.20±1.54
Kmax (D)	44.83±1.06	45.11±1.10

BCVA: Best corrected visual acuity; CCT: Central corneal thickness; Kmax: Maximum keratometry; Kmin: Minimum keratometry.

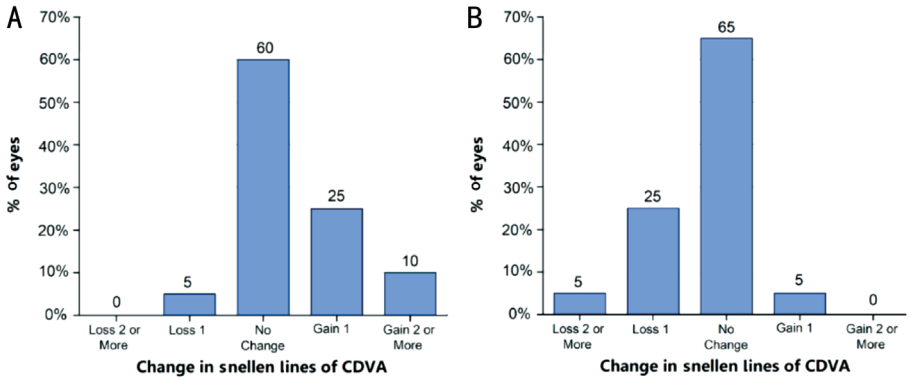

Figure 2 Corrected distance visual acuity at 3mo A: Contoura Vision group; B: Control group.

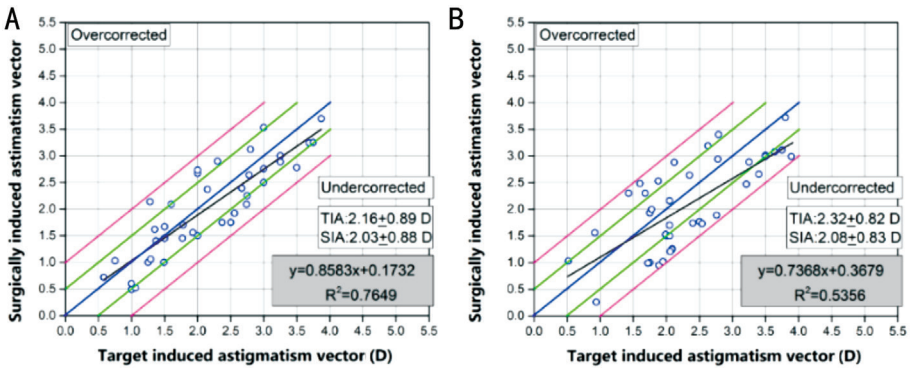

Figure 3 Postoperative changes in TIA and SIA A: Contoura Vision group; B: Control group. TIA: Target corrected astigmatism; SIA: Surgical-induced astigmatism.

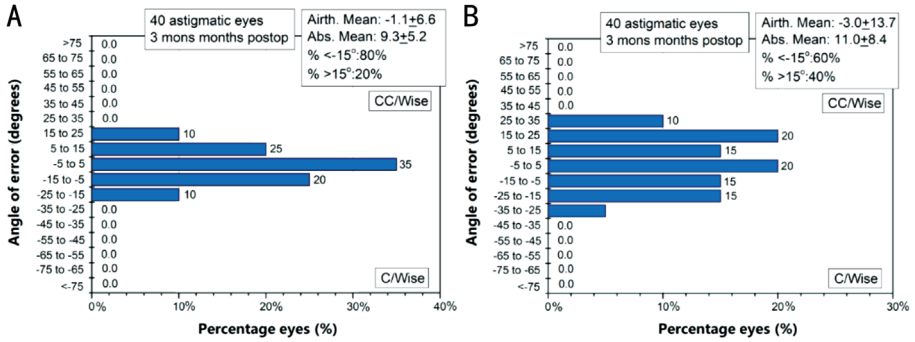

Figure 4 Axial direction changes of astigmatism in subjects 3mo after surgery A: Contoura Vision group; B: Control group.

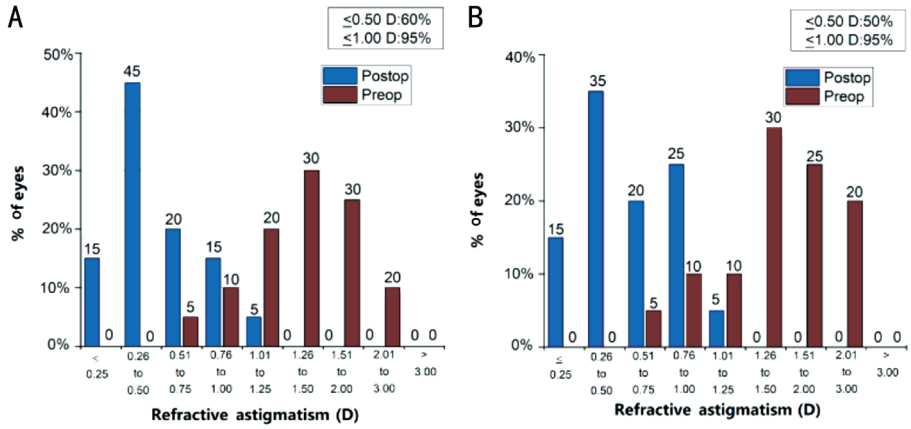

Figure 5 Changes in degree of astigmatism in subjects 3mo after surgery A: Contoura Vision group; B: Control group.

by the position change of the subject. Moreover, the system accurately adjusts the kappa angle to reduce the introduction of HOAs[23-24].

Our study has shown that the UDVA was higher in the CV group than in the control group 3mo after surgery. In the CV group, 48 eyes (60%) had an unchanged CDVA, 20 (25%)

Table 2 Preop. and postop. changes of corneal ISV, IVA

Parameters	ISV			IVA		
	Contoura Vision group	Control group	*P*	Contoura Vision group	Control group	*P*
Preop.	27.85±3.20	28.03±2.83	0.23	0.29±0.04	0.28±0.05	0.21
Postop. 1mo	6.24±3.47	25.98±9.15	0.02	0.18±0.06	0.27±0.06	0.02
Postop. 3mo	5.68±3.02	25.50±8.25	0.01	0.16±0.08	0.28±0.07	0.02
t^a	12.35	1.33		8.36	1.40	
P^a	0.01	0.28		0.02	0.34	

ISV: Index of surface variance; IVA: Index of vertical asymmetry. [a]Comparison between preop. and postop. 3mo.

Table 3 Preop. and postop. changes of corneal 3rd total coma, C7, C8

Parameters	3rd total coma		C7		C8	
	Control group	Contoura Vision group	Control group	Contoura Vision group	Control group	Contoura Vision group
Preop.	0.267±0.049	0.291±0.033	0.165±0.051	0.170±0.048	0.051±0.036	0.048±0.040
Postop. 1mo	0.2926±0.062	0.105±0.077	0.181±0.066	0.077±0.017	0.063±0.055	0.045±0.046
Postop. 3mo	0.289±0.056	0.088±0.054	0.173±0.048	0.056±0.030	0.060±0.040	0.045±0.035
t^a	-1.221	5.45	-2.620	8.392	-0.603	-0.564
P^a	0.39	0.02	0.18	0.02	0.16	0.14

[a]Comparison between preop. and postop. 3mo.

Table 4 Preop. and postop. changes of contrast sensitivity

Parameters	3.0 cpd		6.0 cpd		12.0 cpd		18.0 cpd	
	Control group	Contoura Vision group	Control group	Contoura Vision group	Control group	Contoura Vision group	Control group	Contoura Vision group
Preop.	1.79±0.20	1.81±0.17	1.85±0.13	1.86±0.015	1.54±0.12	1.55±0.16	1.19±0.12	1.19±0.15
Postop. 3mo	1.67±0.13	1.72±0.15	1.64±0.19	1.67±0.17	1.38±0.15	1.42±0.11	0.87±0.13	0.95±0.18

gained 1 line, and 8 (10%) gained 2 lines. This is superior to improvements in the control group. This suggests that the automatic iris tracking system combined with Contoura technology is superior to conventional surgery in terms of postoperative visual acuity. The findings in this study are consistent with the findings of El Awady *et al*[25] and Liu *et al*[26]. An automatic iris tracking system combined with myopia laser surgery significantly improves postoperative UDVA[27]. Ciccio *et al*[28] suggested that 68% of subjects had an eye rotation greater than 2° when transitioning from the sitting position to the supine position. Rotation greater than 2° during LASIK will affect astigmatism and aberrations if not corrected. Our study has shown that the CV group was superior to the control group in astigmatism correction, and the CV group was superior to the control group in the prediction of astigmatism treatment. All subjects in CV groups had a deviation of astigmatism axial direction less than 15°. This indicates that active rotation tracking eyeball shifting reduce the positional deviation of LASIK on the cornea and avoid irregular SIA[29]. The automatic iris tracking system in Contoura surgery is based on the theory that the positions of the corneal apex and the center of the limbus remain unchanged before and during surgery. This system estimates the corneal apex position by detecting the position of the center of the cornea, and it estimates the positions of the pupil center and corneal apex by detecting the center of the pupil and improves the accuracy of the tracking.

ISV and IVA are parameters that reflect the regularity of the corneal surface. Our results have shown that ISV and IVA in the CV group decreased significantly 3mo after surgery, and there were no significant differences in these parameters in the control group after surgery. In the CV group, Contoura-assisted LASIK greatly improved the regularity of the corneal surface. Additionally, C7 decreased significantly in the CV group 3mo after surgery in our study. In contrast, they did not change significantly in the control group. In contrast, they did not change significantly in the control group. Previous studies found that Contoura-assisted LASIK induced significantly less vertical coma and spherical aberration[30-31]. The results of Kim *et al*[31] induced corneal coma was significantly low in the Contoura-assisted LASIK. We believe that the TNT technique that was used in the Contoura surgical design to neutralize irregular astigmatism while incorporating astigmatism and spherical changes that may occur in LASIK surgery into surgical design can improve surgical safety and effectiveness. In this study, there was no significant difference in C8 between the CV group and the control group after operation. Intraoperative iris tracking and positioning technology is used to reduce coma difference caused by inaccurate adjustment of kappa angle and off-center ablation. Contoura is a new concept

that applies corneal topography-guided customized ablations to subjects with primary eyes (normal cornea). On one hand, it treats low-order aberrations (such as myopia and astigmatism). On the other hand, it treats the subject's own HOAs. Contoura software accurately provides the subject's astigmatism and its axis direction, although astigmatism and its axis may differ from manifest refection results. In the control group, C7 and C8 have no significantly difference compare with preoperative. Symmetric ablation will not eliminate HOAs. Motwani[12-13] found that the HOAs were directly modifying the lower-order astigmatism. So effective elimination of higher-order phase difference can improve visual quality. Their results are consistent with our results. Based on the morphology of the anterior surface of the cornea, CV topography-guided LASIK is designed to eliminate aberrations on the anterior surface of the cornea, and it effectively treats refractive errors to achieve stable CDVA in subjects[32].

In summary, automatic iris tracking combined with Contoura technology is a safe and effective procedure to treat mild and moderate corneal irregular astigmatism. However, this study is limited by its small sample size and short-term follow-up. Thus, clinical studies with larger sample sizes and long-term observations are needed to verify the results.

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