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

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Abstract

Background: To evaluate the visual outcomes of Contoura Vision with automatic eye tracking system in eyes with myopia and myopic astigmatism. Methods: In this prospective study, 40 consecutive patients (80 eyes) with moderate myopia and irregular astigmatism were included from January to August 2018 at Liuzhou Worker Hospital. Subjects were randomly divided into an experimental group (40 eyes) that underwent Contoura Vision FS-LASIK and a control group (40 eyes) that underwent wavefront-optimized FS-LASIK. Target refractions of all subjects were plano. Visual outcomes and astigmatic vector analysis were evaluated and compared between preoperatively and 3 months post-operatively. Results: The preoperative spherical and cylindrical refractive errors were similar in both groups (P>0.05). At 3 months postoperatively, cumulative uncorrected distance visual acuity (UDVA) was 20/16, 20/20, or 20/25 in 30 %, 95%, 100 % of patients in the experimental group, respectively. The experimental group was better than the control group in predictability of astigmatism correction at 3 months after operation. In the experimental group, 80% of eyes had deviation of astigmatic axis within 15° and 35% of 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 0.5D were higher in the experimental group (60%, 24 eyes) than the control group (50%, 20 eyes). Compared with the preoperative, C7 significantly reduced to 0.056±0.030 in the experimental group at 3 months after the procedure (P<0.05), and were significantly lower than those in the control group (P<0.05). Conclusion: Contoura Vision with automatic eye tracking system was safe and effective for the correction of myopia and myopic astigmatism.

Background

Femtosecond laser-assisted in situ keratomileusis (FS-LASIK) has become the current mainstream corneal refractive surgery because of its predictability and stability [1-2]. 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 [3]. Studies have shown that every 1° deviation of the astigmatic axis results in a loss of correction of 3.3% [4]. Residual astigmatism less than 0.50D has an impact on visual quality [5]. The conventional treatment method is wavefront aberration-guided excimer laser in situ keratomileusis (LASIK), which aims to correct the aberration of the entire eye and is gradually less effective with age due to changes in eye adjustment [6]. In recent years, the Alcon company presented the innovative Contoura Vision technique based on the WaveLight refractive Suite. The studies by Manoj et al. [7-8] have demonstrated the efficacy of Contoura Vision in correcting low-order aberrations and high-order aberrations 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 Contoura vision 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 (SE) 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 [9-10]. In the vector analysis based on the Alpins method [11], accurate Cartesian coordinates provide accurate magnitude and axial direction of surgical-induced astigmatism (SIA), preoperative astigmatism, target astigmatism and postoperative astigmatism.

Methods

1. Methods

1.1 Patients

This study was designed as a prospective cohort study. Forty subjects (80 eyes) who underwent myopia laser treatment in our hospital from January to August 2018 were selected and randomly divided into two groups: the experimental group included 20 subjects (40 eyes) who underwent automatic iris-tracking and topography-guided FS- LASIK (Contoura Vision), and the control group included 20 subjects (40 eyes) who underwent automatic iris-tracking LASIK. The inclusion criteria were as follows: ① subjects aged between 18 and 35 years; ② preoperative corneal topography showed a difference in refraction greater than 1.25D 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 15 daysor oxygen-permeable hard contact lens for over 3 months; and ④ subjects with a refraction less than -6.00D in sphere or -4.00D in cylinder. The exclusion criteria were as follows: ① subjects with keratoconus; ② subjects with history of previous ocular surgery or combined systemic disease; and ③ subjects with corneal scars or corneal lesions.

1.2 Method

1.2.1 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 total third order 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. The study was approved by the local ethics committee of Liuzhou Worker' Hospital, China, and all patients signed an informed consent form during the initial visit.

1.2 .2 Surgical procedure

All procedures were performed by the same experienced ophthalmologist. 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 experimental group underwent topography-guided keratomileusis in the EX500. The topographic neutralizing treatment (TNT) method[12] 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 high-order aberrations. 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.

1.2.3 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 3 weeks followed by polyethylene glycol ophthalmic solution (Alcon, USA) 4 times a day for 4 weeks.

1.3. Observation parameters

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

1.4 Statistical analysis

SPSS 15.0 statistical software was used for statistical analysis. The $\chi 2$ 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 3 months after surgery was performed with the Alpins method [11] to calculate surgery-induced astigmatism (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).

Ethical approval

Ethical approval (the protocol of the study and informed consent) was obtained from the human Ethics Committee of the Fourth Affiliated Hospital of Guangxi Medical University. All the patients or their legal

guardians were given written informed consent. All procedures were in accordance with the Declaration of Helsinki.

Results

2.1 Study subjects

The demographic data of the 2 subject groups before surgery are shown in Table 1. There were no significant differences in age, sphere, cylinder and CDVA between the two groups before surgery (P>0.05).

2.2 Vision and refraction

With regards to efficacy, cumulative UDVA was 20/16, 20/20, or 20/25 in 30 %, 95%, 100 % of patients in the experimental group, respectively. The UDVA in the experimental group was better than the control group. The visual acuity distribution of the two groups 3 months after surgery is shown in Figure 1. In the experimental group, 24 eyes (60%) had an unchanged CDVA, 10 (25%) gained 1 line, and 4 (10%) gained 2 lines. 2 eyes (5%) lost 1 line of CDVA, no one lost 2 lines, or lost more than 2 lines (Figure. 2). In the control group, 26 eyes (65%) had an unchanged CDVA, 2 (5%) gained 1 line. 10 eyes (25%) lost 1 line of CDVA, 2 eyes (5%) lost 2 lines or more.

2.3 Changes in corneal parameters

The ISV, IVA, and C7 in the experimental group were significantly lower than those in the control group 3 months after surgery (see Table 2 and 3). The ISV and IVA in the experimental group were significantly lower than those in the control group (t was 13.19 and 10.07 respectively, P<0.05).

There were no significant differences in TIA and SIA between the two groups 3 months after surgery (P=0.40 and 0.35). The TIA and SIA analyses revealed that the experimental group was superior to the control group in astigmatism correction, and the experimental group was superior to the control group in prediction of astigmatism treatment (see Figure 3). In the experimental group, 80% (32 eyes) of subjects had a deviation of astigmatism in the axial direction less than 15°, and 35% (14 eyes) of subjects had an axial deviation of less than 5°. These results were better than those in the control group (see Figure 4). 60% of subjects (24 eyes) had residual astigmatism within 0.50D in the experimental group, which was better than 50% (20 eyes) in the control group (see Figure 5).

Discussion

Some subjects undergoing LASIK still have visual problems such as poor night vision, glare, and blurred vision. Studies have shown that the RMS after LASIK is 1.9-fold higher after surgery than before surgery [14]. 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 [15-16]. Corneal topography-guided LASIK is more commonly used in subjects with ocular trauma or severe irregular corneal astigmatism [17] 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 by the position change of the subject. Moreover, the system accurately adjusts the kappa angle to reduce the introduction of higher order aberrations（HOAs）[18-19].

Our study has shown that the UDVA was higher in the experimental group than in the control group 3 months after surgery. In the experimental group, 24 eyes (60%) had an unchanged CDVA, 10 (25%) gained 1 line, and 4 (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 Elahe et al. [20-21]. An automatic iris tracking system combined with myopia laser surgery significantly improves postoperative UDVA [22]. Ciccio [23] 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 experimental group was superior to the control group in ~~the therapeutic effect on~~ astigmatism correction, and the experimental group was superior to the control group in the prediction of astigmatism treatment. All subjects in experimental 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 [24]. 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 experimental group decreased significantly 3 months after surgery, and there were no significant differences in these parameters in the control group after surgery. In the experimental group, Contoura-assisted LASIK greatly improved the regularity of the corneal surface. Additionally, C7 decreased significantly in the experimental group 3 months 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. 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 [25] can improve surgical safety and effectiveness. In this study, there was no

significant difference in C8 between the experimental 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 high-order aberrations. 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 high order aberrations. Manoj et al. [7-8] 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, Contoura Vision topography-guided LASIK is designed to eliminate aberrations on the anterior surface of the cornea, and it effectively treats refractive errors to achieve stable BCVA in subjects [26].

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.

Abbreviations

uncorrected distance visual acuity (UDVA)、Femtosecond laser-assisted in situ keratomileusis (FS-LASIK)、spherical equivalent (SE)、surgical-induced astigmatism (SIA)、target corrected astigmatism (TIA)、corrected distance visual acuity (CDVA)、vertical coma(C7)、horizontal coma(C8)、index of surface variance (ISV) 、index of vertical asymmetry (IVA)、topographic neutralizing treatment (TNT).

Declarations

Declarations

- Consent for publication

Not applicable

- Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

- Competing interests

The authors declare that they have no competing interests in this section

- Funding

All funds come from the author’s own, no other financial support.

- Authors' contributions

YL and MY: Prepare and design experiments, carry out research, collect data, score. Analysis and interpretation of data; Writing papers; Statistical analysis; According to the editorial department's amendments. Line modification. SHJ: Prepare and design experiments, analyze and interpret data; revise the key results and conclusions in the paper. WJB, ZX and XX: Collecting data, analyzing and interpreting data; statistical analysis. All authors read and approved the final manuscript

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References

[1] Somani S, Tuan KA, Chernyak D. Corneal asphericity and retinal image quality: a case study and simulations. J Refract Surg, 2004, 20(5): S581-585.

[2] Amigó A, Bonaque-González S, Guerras-Valera E. Control of induced spherical aberration in moderate hyperopic LASIK by customizing corneal asphericity. J Refract Surg, 2015, 31(12):802-806. DOI: 10.3928/1081597X-20151111-03.

[3] Bailey MD, Zadnik K. Outcomes of LASIK for myopia with FDA-approved lasers. Cornea 2007; 26:246–254.

[4] Novis C. Astigmatism and toric intraocular lenses. Curr Opin Ophthalmol. 2000;11(1):47–50.

[5].Villegas EA□Alc6n E□Artal P□Minimum amount of astigmatism that should be corrected[J]□J Cataract Refract Surg□2014□40(1)□13-19□DOI□10□10160□jer$□2013□09□010□

[6].Dick HB , Kaiser S. Dynamic aberrometry during accommodation of phakic eyes with potentially accommodative lenses [J]. Ophthalmologe,2002,99(11):825-834. DOI:10.1007/s00347-002-0737-3.

[7].Manoj Motwani□The use of WaveLight® Contoura to create a uniform cornea: the LYRA Protocol. Part 3: the results of 50 treated eyes. Clinical Ophthalmology, 2017:11 915–921. http://dx.doi.org/10.2147/OPTH.SI33841

[8]. Manoj Motwani. The use of WaveLight® Contoura to create auniform cornea: the lYra Protocol. Part 1: the effect of higher-order corneal aberrations on refractive astigmatism. Clinical Ophthalmology, 2017:11 897–905. http://dx.doi.org/10.2147/OPTH.SI33839

[9].Eydelman MB, Drum B, Holladay J, Hilmantel G, Kezirian G, Durrie D, Stulting RD, Sanders D, Wong B. Standardized analyses of correction of astigmatism by laser systems that reshape the cornea. J Refract Surg 2006; 22:81–95

[10]. Arbelaez MC, Vidal C, Arba-Mosquera S. Excimer laser correction of moderate to high astigmatism with a non-wavefrontguided aberration-free ablation profile: six-month results. J Cataract Refract Surg 2009; 35:1789–1798

[11].Alpins NA. A new method of analyzing vectors for changes in

astigmatism. J Cataract Refract Surg. 1993;19:524–533.

[12]. Lin DT，Holland SR，Rocha KM，et a1，Method for optimizing topography-guided ablation of highly aberrated eyes with the ALLEGETI'O WAVE excimer laser[J]，J Refract Surg，2008，24(4)，S439，445，

[13]. Dan Z, Timothy J, J. Bradley R. JRS Standard for Reporting Astigmatism Outcomes of Refractive Surgery. Journal of Refractive Surgery. 2014; 30:654-659. doi:10.3928/1081597X-20140903-01

[14].Estber Moreno B，jesus m，Susana M，Rafael N, Lourdes L, Sergio B， Ocular aberrations before and after myopic corneal surgery: LASIK-induced changes measured with laser ray tracing[J]， Invest Ophthalmol Vis Sci, 2001,42，6，: 1396-1403.

[15].Dick HB , Kaiser S. Dynamic aberrometry during accommodation of phakic eyes with potentially accommodative lenses [J]. Ophthalmologe,2002,99(11):825-834. DOI:10.1007/s00347-002-0737-3.

[16]. Xiong ning, Liu yi, Wang ping. Theraperutic effect of wavefront-guided laser in situ keratomileusis for myopic astigmatism. Rec Adv Ophthalmol, 2007:27，6，，452-454.

[17]. Duan sufang, Liu jing, Li xiuhong, Liu zhenghua, Song zixuan, Liu xiangling. Clinical study of topography guided off-flap Epi-LASIK in treating traumatic corneal astigmatism. Int Eye Sci, 2014:14，9，，1620-1623.

[18]. Zhang jun, Zheng li, Zhao xia, Xu yang, Lin hanjun, Mao hongqian. Clinical study of the contoura automatic location tracking system for correction of ametropia with mild irregular astigmatism. Chin J Optom Ophthalmol, 2018,20(4):216-221. DOI:10.3760/cma.j.issn.1674-845X.2018.04.005.

[19]. Chen kaijian, Bai ji, Liu ting, Ye jiaxin, Kan qiuxia, Liu lina.The effectiveness of topography guided FS-LASIK in treating asymmetric corneal astigmatism. Chin J Optom Ophthalmol, 2016，18(7):394-398.

[20]. ElAHE, Ghanem AA, Saleh SM. Wavefront-optimized ablation versus topography-guided customized ablation in myopic LASIK: comparative study of higher order aberrations. Ophthalmic Surg Lasers Imaging, 2011,42(4):314-320.

DOI:10.3928/15428877-20110421-01

[21]. Liu B, Chen W, Shao DW. Using Laser Sight Astrapro Planner 2.2Z software incorneal topography-guided laser in situ kertomileusis for myopia with asymmetric corneal shaper [J]. Int J Ophthalmol, 2014, 7(3):452-456.

DOI:10.3980/j.issn.2222-3959.2014.03.12.

[22]. Lin keji, Chen jun, Lin wen, Lin xiaodong, Zhou yueming, Zheng liangdin. Efficacy of iris lacation to femtosecond combined wavefront guided LASIK for myopic and astigmatism. Int Eye Sci, 2016,16 (6):1057-1060.

[23].Ciccio AE, Durrie DS, Stahl JE, Schwendeman F. Ocular cyclotorsion during customized laser ablation. J Refract Surg 2005; 21:S772–S774

[24]. Lin qiaoya, Li xuexi, Hu jun. The effect of astigmatic axes' changes by deviation of head and cyclotorsion in LASIK. Chin J Pract Ophthalmol, 2012,30(8):941-944.

[25].Lin DT, Holland SR, Rocha KM, et al. Method for optimizing topography-guid ablation of highly aberrated eyes with the Allegetto wave excimer laser(J)J Refract Surg, 2008,24(4):S439-445.

[26]. Manoj Motwani. The use of WaveLight Contoura to create a uniform cornea: the LYRA Protocol. Part 2: the consequences of treating astigmatism on an incorrect axis via excimer laser(Clinical Ophthalmology, 2017:11 907–913.http://dx.doi.org/10.2147/OPTH.SI33840

Tables

Table 1. Comparison of preoperative general data between the two groups

Parameter	experimental group	control group	t	*P* value
Age/years	25.52±5.38	24.89±5.70	-1.44	>0(05
Preoperative spherical power / D	-5.74±1.20	-5.68±1.26	1.37	>0(05
Preoperative cylinder power / D	-2.35±0.92	-2.50±0.90	1.61	>0(05
BCVA	0.82±1.10	0.84±1.03	1.25	>0(05

Table 2. Preoperative and postoperative changes of corneal ISV, IVA

	ISV		IVA	
	experimental group	control group	experimental group	control group
Before surgery	27.85±3.20	28.03±2.83	3.67±2.11	3.81±2.23
3 months after surgery	5.68±3.02	25.50±8.25	0.89±0.54	3.98±1.94
t	12.35	1.33	9.22	1.45
P	<0.05	>0.05	<0.05	>0.05

Table 3. Preoperative and postoperative changes of corneal 3nd total coma, C7, C8

	3nd total coma		C7		C8	
	control group	experimental group	control group	experimental group	control group	experimental group
Before surgery	0.267±0.049	0.291±0.033	0.165±0.051	0.170±0.048	0.051±0.036	0.048±0.040
3 months after surgery	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	-1.221	5.45	-2.620	8.392	-0.603	-0.564
P	>0.05	<0.05	>0.05	<0.05	>0.05	>0.05

Figures

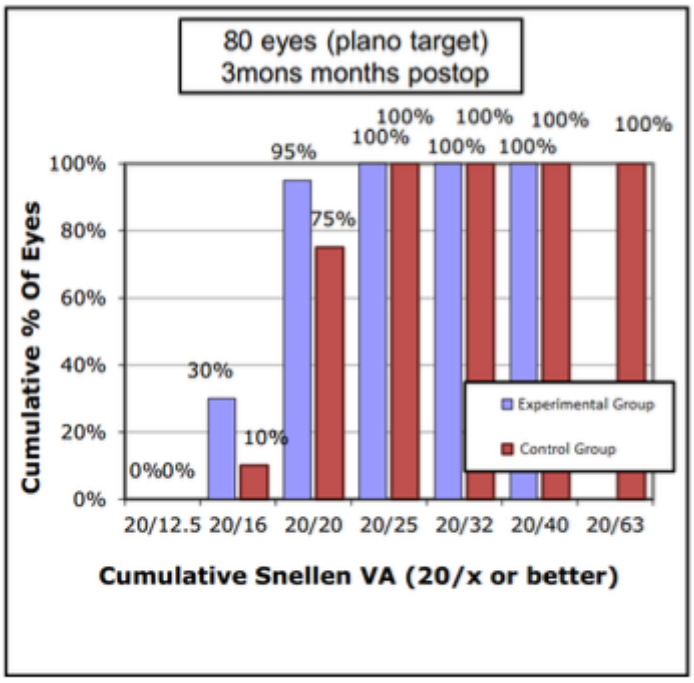

Figure 1

The visual acuity distribution of the two groups of subjects 3 months after surgery (A: experimental group and B: control group)

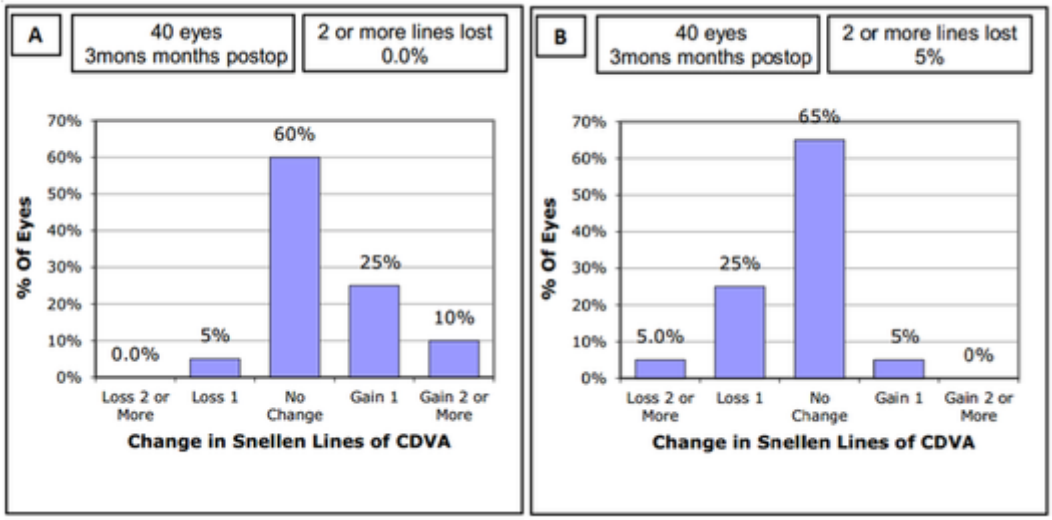

Figure 2

Changes in CDVA of the two groups of subjects 3 months after surgery (A: experimental group and B: control group)

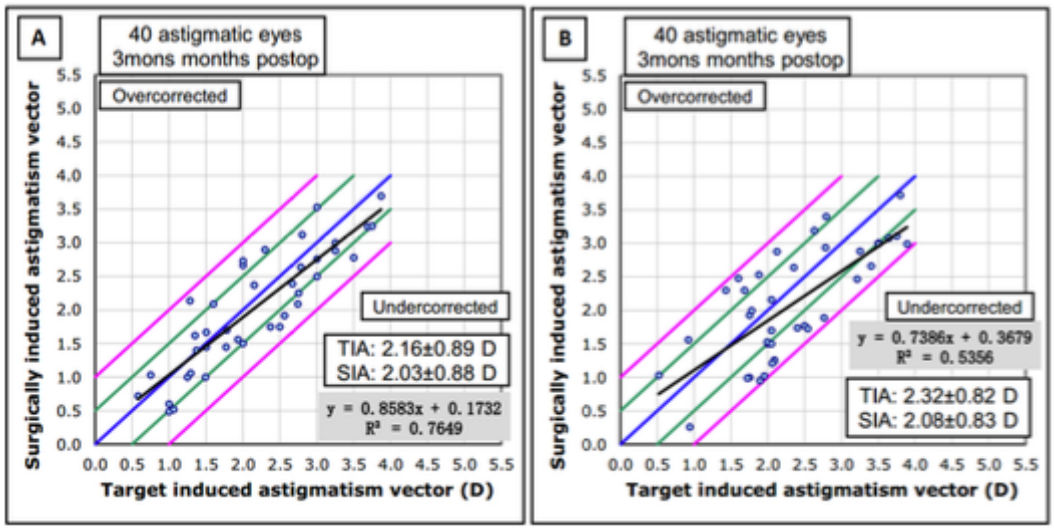

Figure 3

Postoperative changes in TIA and SIA (A: experimental group and B: control group)

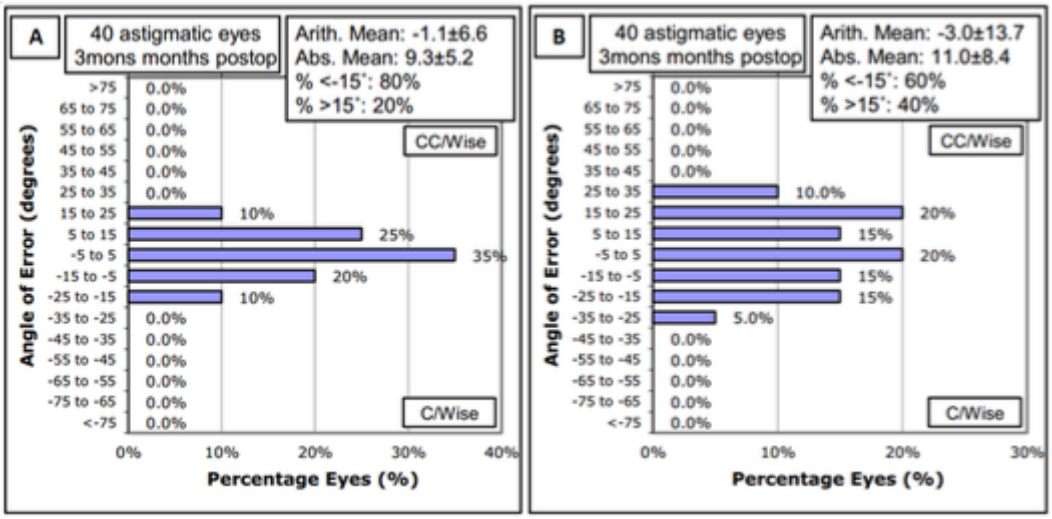

Figure 4

Axial direction changes of astigmatism in subjects 3 months after surgery (A: experimental group and B: control group)

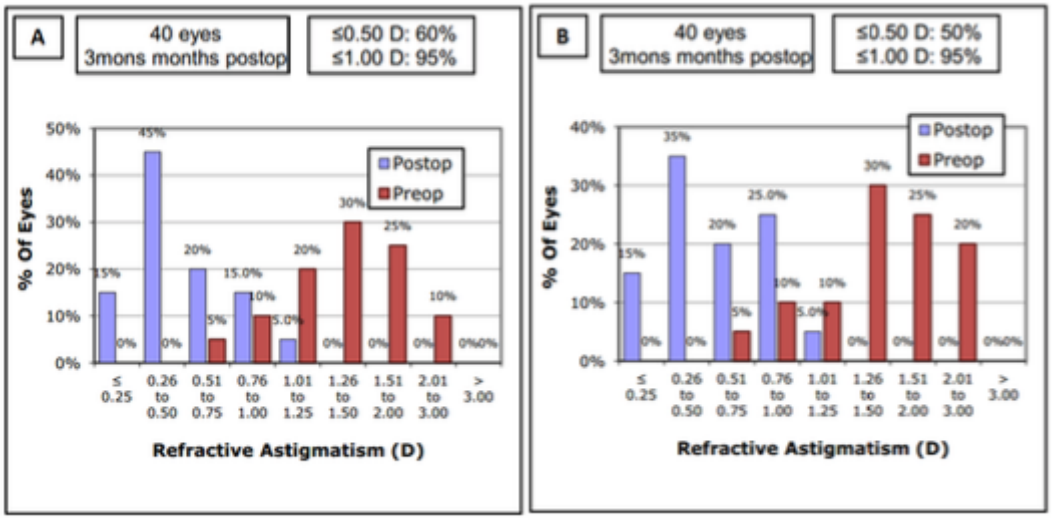

Figure 5

Changes in degree of astigmatism in subjects 3 months after surgery (A: experimental group and B: control group)