· Clinical research ·

Postoperative visual outcomes and analysis of Q value guided non-linear aspheric monovision LASIK for myopic astigmatism and presbyopia

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Abstract

• AIM: To evaluate the monocular and binocular visual outcomes in myopic astigmatism and presbyopia patients, after laser *in situ* keratomileusis (LASIK) with a Q value guided non-linear aspheric monovision protocol.

• METHODS: A retrospective and non-comparative study was performed based upon 80 eyes of 40 consecutive patients with myopic astigmatism and presbyopia, who underwent Q value guided non-linear aspheric monovision LASIK by the Carl Zeiss Meditec CRS-Master software and MEL 80 excimer laser, from August 2006 to March 2009. At the 1 day, 1 week, 1 month, 3, 6 months, 1 year postoperative visits, the examinations were carried out in terms of distance and near, monocular and binocular visual acuity, manifest refraction, topography and keratometry, wavefront assessment, contrast sensitivity, and stereopsis. In addition, questionnaires of asthenopic symptoms due to near-distance work were also implemented for all the patients preoperatively and 6 months postoperatively.

• RESULTS: Six months postoperatively 92% and 99% of the differences between spherical equivalent (SE) and target SE were in the ranges of 0. 50D and 1. 00D, respectively. 3 months to 1 year postoperatively, the variation of SE was -0. 06 ± 0. 37D. 1 month postoperatively, achieved monocular uncorrected distance visual acuity of 20/20 was in 95% of distance eyes, and binocular uncorrected near visual acuity of J2 in 87. 5%, and J5 in 100% of patients. 1 week postoperatively, a slight decrease in contrast sensitivity and stereopsis ($P < 0.05$) was observed in binocular. 1 to 3 months later contrast sensitivity increased, but there was no change in stereopsis 1 month postoperatively. The average change in refraction between 3 months and 1 year was -0. 06 ± 0. 31D. Asthenopic symptoms due to near-distance work were improved.

• CONCLUSION: Q value guided non-linear aspheric monovision LASIK is a valid, well-tolerated, stable, and effective option for myopic patients with presbyopia in moderate to high myopic astigmatism. Good visual outcomes could be obtained with this procedure.

• KEYWORDS: monovision; LASIK; Q value; visual acuity; aberration; contrast sensitivity

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INTRODUCTION

Monovision (MV), defined as a method of presbyopic correction whereby 1 eye is corrected for distance vision and the fellow eye for near vision, has been widely used in contact lenses and refractive surgery correction of presbyopia for decades. Westsmith[1] proposed and recommended for the correction of presbyopia firstly in 1958, subsequently Beler[2] published the first article on MV correction for presbyopia in 1977. The principle of interocular blurry suppression is selective inhibition of the cerebral cortex to accept blurry as clear as the other eye, forming far and near vision and thereby a clearer image. The ideal range of MV eyes and clear vision is equal to the plus range of both clear monocular visions, which could be free from interference from the other eye blurry image. MV surgery was first reported in the RK[3,4]. MV excimer laser surgery, serving as an advanced treatment for myopia and astigmatism in recent years with presbyopic since 1999, was employed in PRK surgery initially by Wright *et al* [5]. In recent times, MV-LASIK has reached a high patient satisfaction above 90%[6-8].

Based upon the experience of the treatment of myopia by using MEL80 and CRS-Master (Carl Zeiss Meditec AG, Jena, Germany), together with the theory based upon a lower degree of anisometropia able to achieve satisfactory distance vision and near vision eyes, we carried out Q value guided non-linear aspheric monovision LASIK to analyze the information of patients from August 1, 2006 to March 31, 2009, in order to evaluate the safety and efficacy of LASIK with the MEL 80 and CRS-Master for treating myopic astigmatism with presbyopia using Q-value guided aspheric MV protocol.

MATERIALS AND METHODS

Patients The present study was a retrospective non-comparative one with 185 consecutive myopic astigmatism and presbyopic

patients underwent Q value guided non-linear aspheric monovision LASIK surgery with CRS-Master software and MEL80 excimer laser in our hospital, during the period of August 1, 2006 and March 31, 2009.

Preoperative eligible patient selection criteria: (1) Older than 45 years, best-corrected visual acuity (BCVA) better than 20/20, uncorrected visual acuity (UCVA) less than 20/40; (2) Meeting the requirements of LASIK treatment, having a certain thickness of the cornea, and stable refraction; (3) Having less than 8.50D, withstand at least -0.75D of anisometropia; (4) Stopping wearing contact lenses for 2 weeks and rigid gas permeable (RGP) for 4 weeks; (5) Excluding keratoconus, diabetes, hyperthyroidism and other contraindications and pathological changes in the eye and systems; (6) Mental health, voluntary surgical requirements, data analysis and publication of their informed consent and permission. All the treatments were performed by the single surgeon.

Average follow-up time was 12.5 months. To sum up, 40 patients, 80 eyes were processed by statistical analyses. Age: 40-49 (mean 44.5) years. Spherical equivalent: mean: -4.75D ± 1.80D, range: -2.00--8.00D, cylinder: mean -0.86D ± 0.64D, maximum: -2.50D.

Methods

Preoperative assessment All study patients underwent the same full preoperative examination, including measurement of distance and near UCVA, BCVA, refraction, intraocular pressure, anterior segment, fundus, corneal topography, wavefront examination, ultrasonic corneal thickness measurements, contrast sensitivity, and stereoscopic vision. BCVA and UCVA were examined with international standards logarithmic visual acuity chart, particularly, near UCVA was checked with Jaeger near vision chart. Preoperative and postoperative distance vision correction and postoperative 1 week later were performed to measure stereoscopic and contrast sensitivity, using the United States Randot Stereotesis' three-dimensional graph (circle graph, depending on the sharp range 40'-800'), and US CSV-1000E contrast sensitivity function. The detailed information was presented as follows: Corneal thickness is 486-647μm with an average of 551.8 ± 29.0μm. Corneal diameter is 3.59-8.40mm with as average of 5.69 ± 0.84mm. Corneal curvature is 39.90-47.60D with an average of 44.00 ± 1.50D. Average contrast sensitivity: 3cpd frequency of 1.624, 6cpd frequency of 1.860, 12cpd frequency of 1.537, and 18cpd frequency is 112.9. Stereopsis has an average of 94.80 ± 64.72.

Dominant eye Regular dominant eye was measured four times. If the same result appeared for more than three times, the measured eye could be determined as the dominant eye. Otherwise the MV assessment was repeated on each eye in turn and then the dominance was decided according to the comfort of the patient.

Monovision treatment assessment In the case of full correction in dominant eye and the non-dominant eye corrected in the range -0.75D to -2.00D, patients had to be tested for their tolerance to anisometropia. The anticipated postoperative refraction was determined as below: After binocular fully correction, the examiner stood in front of the patient to block his/her view of the visual acuity chart while concurrently set a +1.50D lens into the non-dominant eye. The examiner then moved to the side of the patient allowing him/her to view the chart once again. If the patient considered that everything looked fine with nothing strange and no ghosting, the examiner asked the patient to read the smallest letters those able to see at a distance. Subsequently, the near chart was brought in front of the patient at 40cm and the patient was asked to read the smallest print that comfortable to read. At this point, the examiner covered the patient's dominant eye and asked him/her to read the smallest print that able to be seen and report the feeling. If the patient did not feel blur, it was considered that +1.50D add could be tolerated. Otherwise the add on non-dominant eye had to be reduced in -0.25D gradually until they reported minimal or no cross-blurring. Age of the patient was not a consideration when choosing the add that used for the non-dominant eye. To some extent, an add of 1.50D was used whenever possible and this was reduced only if necessary, according to the iteration of the add required for minimal to no cross-blurry. The add was increased to more than 1.50D only if the patient could not comfortably read J2. Glasses-wearing before the surgery was recommended to patients for a period of 2 to 3 months, and it was not recommended to wear contact lenses.

Surgical procedure Design and operation of surgery were completed by the same doctor. According to the preoperative test results, Carl Zeiss Mel80 excimer laser was used to treat. The Laser spot diameter was 0.7mm, the frequency was 250Hz, optical zone diameter was 6.0mm, and the transition zone was 2.0mm. Produce lamellar corneal flaps with Amadus II microkeratome was made in Switzerland. The thickness of lamellar corneal flap was 140μm, and the hinge of the corneal flaps was on the nasal. It was planned to keep the corneal stromal bed with a thickness of more than 280μm. The protocol of Q value guided non-linear aspheric MV-LASIK could effectively reduce postoperative spherical aberration. Additional personalized iris recognition was based upon the limbus and the pupil to locate and track, in order to correct the pupil center deviation automatically, avoid the cutting the eccentric, and reduce astigmatism axis cutting error.

Postoperative medication and follow-up As a routine, 3g/L Ofloxacin eye drops, qid, for 1 week; 1g/L Fluorometholone eye drops, qid, for 1 week, reducing once per week until withdrawal; 1g/L Sodium hyaluronate eye drops, qid, for 12 weeks. Subsequent visiting were taken at the 1 week, 1 month, 3, 6, 12 months after the surgery. All the patients needed to have the routine examinations, involving binocular and monocular UCVA, corneal curvature, aberration inspection, contrast sensitivity and stereo vision inspection. Jaeger near vision chart (front 40cm) and international standard vision chart were used to assess patients' visual acuities. Questionnaire of asthenopic symptoms due to near-distance work were taken 1 year postoperatively. All the retreatments should be done 2 month after situation stable

(spherical degree changes within 0. 25D, cylinder changes within the 0. 50D).

Statistical Analysis Results of the study were analyzed by SPSS 13. 0 statistical analysis software. The comparison of two independent samples was performed with *t*-test. The difference was statistically significant when $P<0.05$.

RESULTS

General Conditions All the surgeries were done successfully, with perfect corneal flaps making, and no broken flap, free flap and other adverse conditions happened. All patients had no corneal flap edema after the surgery and no harmful vision complications. Moreover, intraocular pressure (IOP) and corneal topography were within the normal range.

The Difference between the Target Refraction One month after the surgery, 89% of eyes reference to the target diopter difference was within 0. 50D, and 79% within 1. 00D. 6 months after the surgery, 92% of eye reference to the target diopter difference was within 0. 50D, and 99% within 1. 00D.

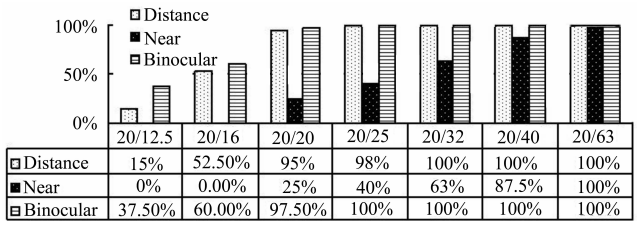
Postoperative Refraction Stability Refractive eye after 3 months to 1 year, only 6% eyes reference changes over 0. 50D, 99% eyes reference changes below 1. 00D. During the year, SE changes were in the range of -0. 06 ± 0. 37D.

Visual Acuity Mean spherical equivalent refraction of distance and near eyes before the treatment ($\bar{x}\pm s, n=40$) were -4. 95 ± 1. 79D and -4. 68 ± 1. 82D, respectively. However, those in 1 month after the treatment were -0. 49 ± 0. 42D and -0. 97 ± 0. 66D, -0. 35 ± 0. 34D and -0. 85 ± 0. 64D in 3 months, -0. 31 ± 0. 38D and -0. 82 ± 0. 51D in 6 months, and -0. 29 ± 0. 22D and -0. 81 ± 0. 53D in 12 months. Result of distance visual acuity, near visual acuity, and binocular visual acuity 1 month postoperatively were shown in the following figures (Figure 1-3). Using the measured datum, the bar chart were plotted with percentage of eyes as ordinate against visual acuity as abscissa.

Changes of Spherical Aberration Before the surgery, binocular higher order aberrations RMS value in 6. 0mm pupil diameter ($\bar{x}\pm s, n=40$) of distance and near eyes were -0. 251 ± 0. 026 and 0. 249 ± 0. 024, respectively. However, those in 1 month after the surgery were 0. 608 ± 0. 051 and 0. 941 ± 0. 066, 0. 476 ± 0. 034 and 0. 881 ± 0. 086 in 3 months, 0. 340 ± 0. 031 and 0. 606 ± 0. 052 in 6 months, and 0. 304 ± 0. 025 and 0. 579 ± 0. 048 in 1 year.

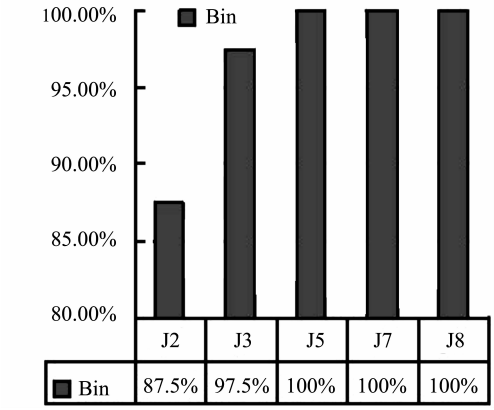
Changes in Contrast Sensitivity One week postoperatively, contrast sensitivity in all frequency decreased compared to that before the operation ($P<0.05$). 1-3 months postoperatively, contrast sensitivity in all frequency recovered gradually, reached or exceeded the preoperative level. The data were shown in Table 1.

Changes in Stereopsis One week postoperatively, stereoscopic vision decreased compared to that preoperatively. 1-3 months postoperatively, stereoscopic vision recovered gradually, and there were not any statistically significant differences between those before and after the operation. Before the surgery, change in stereopsis was 94. 80 ± 64. 72. However, that in 1 week postoperatively was 128. 26 ± 62. 05, 121. 67 ± 63. 89 in 1 month, and 112. 44 ± 62. 27 in 3 months.



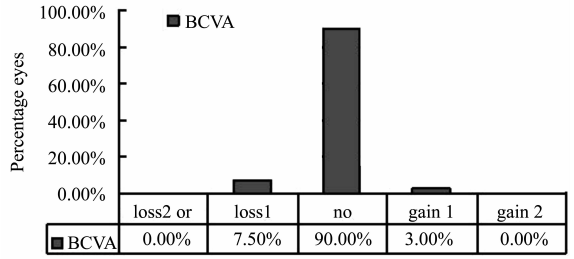
	20/12.5	20/16	20/20	20/25	20/32	20/40	20/63
Distance	15%	52.50%	95%	98%	100%	100%	100%
Near	0%	0.00%	25%	40%	63%	87.5%	100%
Binocular	37.50%	60.00%	97.50%	100%	100%	100%	100%

Figure 1 Distance visual acuity 1 month postoperatively.



	J2	J3	J5	J7	J8
Bin	87.5%	97.5%	100%	100%	100%

Figure 2 Near visual acuity 1 month postoperatively.



	loss2 or	loss1	no	gain 1	gain 2
BCVA	0.00%	7.50%	90.00%	3.00%	0.00%

Figure 3 BCVA 1 month postoperatively.

Table 1 Before and after surgery binocular changes in contrast sensitivity

	3.0 cpd	6.0 cpd	12.0 cpd	18.0 cpd
Pre-op	1. 624 ± 0. 163	1. 860 ± 0. 160	1. 531 ± 0. 138	1. 129 ± 0. 174
1wk post-op	1. 516 ± 0. 135	1. 767 ± 0. 140	1. 428 ± 0. 127	0. 988 ± 0. 179
1 mo post-op	1. 609 ± 0. 151	1. 800 ± 0. 154	1. 457 ± 0. 151	1. 035 ± 0. 171
3 mo post-op	1. 662 ± 0. 131	1. 839 ± 0. 138	1. 517 ± 0. 129	1. 082 ± 0. 176

Fatigue due to Near-distance Work Preoperation and 6 months postoperation, questionnaires of asthenopic symptoms due to near-distance work were assigned to patients.

Grading standard: according to the frequency of situations happening (often, occasionally, few, without), scoring for the following seven items (3-0 point): near sight blerring occasionally, reading blurring, near sight trouble of long time, long sight blurring, headache or nausea, fatigue, tearing after near-distance work. The mean preoperative score was 7. 61 ± 2. 17, 6 months postoperative one was 3. 02 ± 2. 02, and fatigue symptoms thus significantly improved.

DISCUSSION

Presbyopia, defined as accommodative power age-related decrease, has received much attention in recent years. Regardless of the refractive state, this physiological phenomenon occurs in various age groups. Some researchers [9,10] considered that MV-LASIK would increasingly become optimal refractive surgery options for presbyopic and pre-presbyopic

patients. Levinger *et al* [11] and Jain *et al* [12] reported that 80% and 88% of their patients satisfied with the quality of postoperative vision, respectively. Enough experience has accumulated in simple myopic astigmatism correction by using Q value guided non-linear aspheric LASIK by our group. Therefore, this treatment has been applied to the correction of presbyopia.

For patients with myopia combined with presbyopia, the most concerned was postoperative UCVA, in order to fulfil the basic requirement for stopping wearing the glasses. Our previous research showed that 1 month after the surgery, 95.00% of eyes gained the uncorrected distance visual acuity of 20/20 or better, and 100% of eyes gained 20/32 or better. 87.5% of the near eyes gained distance visual acuity of 20/40 or better, and 100% gained 20/63 or better. 87.5% of patients near vision reached J2, and 100% of the patients could see J5 clearly. Binocular distance visual acuity achieved 20/20, in 97.50% of patients, and 100% achieved 20/25. The requirement for retreatment was that uncorrected distance visual acuity was worse than 20/32. Since no patient required retreatment, the effect of the surgery could be excellent.

Previous studies on traditional contact lens monovision showed that the binocular distance vision was often slightly reduced (neural subtraction) after treatment, particularly for near addition of ≥2.00D [13-16]. However, opposite results were showed in the present study. Compared to the UCVA of distance eyes, the increase of binocular UCVA was statistically significant. Although the vision of non-dominant eyes were blurred, near eyes played a role of increasing binocular visual acuity.

During 3 months to 1 year after the surgery, slight refractive variation occurred in the treated eyes. FDA definite stable refractive surgery as that, the variation in spherical equivalent is <1.00D in 95% eyes for more than three months. In the present study, during 3 months to 1 year, 99% of patients' diopter variations were <1.00D, proving the stability and safety of the treatment.

The total high-order aberrations for both the dominant eye and non-dominant eye were statistically significantly increased compared to those preoperatively. It is well known that, positive spherical aberration was induced in this myopic population, compared with negative spherical aberration in the hyperopic population. Marcos *et al* [17] reported that both positive and negative spherical aberrations could increase the depth of field at large pupils. Artola *et al* [18] found that the increase in magnitude of spherical aberration after myopic photorefractive keratectomy resulted in an increase in the range of measured accommodation and near acuity in presbyopic patients. In the study of intraocular lens implantation, it was also shown that patients those implanted with a spherical intraocular lens (IOL) had greater depth of field than did patients implanted with an aspheric IOL [19]. Dan *et al* [20] reported that an average increase of 0.20μm of spherical aberration in 6mm analysis zone could cause a corresponding variation in the depth of field. The ultimate goal of MV-LASIK is that both eyes can see near and distance clearly through increasing the depth of field. However, larger spherical aberration might cause retinal image quality and contrast sensitivity decreased. Therefore, we can prove that, Q value guided non-linear aspheric MV-LASIK is able to be carried out within a level that could increase the depth of field, without affecting vision and contrast sensitivity. In this study, after 3 months postoperatively, both contrast sensitivity and spatial frequency recovered to preoperative levels, which could also prove the above viewpoint.

The success rate of MV-CL has been reported as 59%-67% in the previous studies, since considerable proportion of patients could not tolerate the additional degree of anisometropia [21]. Miranda and Krueger [22] have reported that the tolerance of elder MV-LASIK people was 93.9%, while that of younger patients was 88.2%, demonstrating a high success rate. The present study found that the treatment achieved a certain degree of binocular functional near and distance visual acuity through increasing the depth of field, which could decrease patients' discomfort resulting from anisometropia and improve the tolerance of surgery.

Three preoperative patients' non-dominant eyes could not tolerate an additional degree of near -0.50D, but the planned extra degree after the operation would be -1.00D. Because good postoperative visual quality was obtained, there would be no requirement for a retreatment. As a result, we can explain the treatment has a higher tolerance success rate than the MV-CL. In some cases, patients had to give up due to unsuitability to contact lenses. Therefore, we did not use contact lenses for patients for adaptation before surgery.

The study found that contrast sensitivity decreased 1 week after the surgery, and recovered gradually within 1 to 3 months postoperatively, thereby reaching or exceeding the preoperative level. It could be explained as follows: (1) intraoperative laser cutting changed characteristics of the physical structure of the cornea, generated complex optical problems, and reduced imaging contrast, subsequently leading to the decrease of contrast sensitivity. Over time, layer residuals were gradually absorbed, and the reaction layer gradually reduced. As a result, impact of the operation on the contrast sensitivity was transient; (2) the application of intraoperative mechanical microkeratome increased higher-order aberrations; (3) dry eye was a common short-term phenomenon after the LASIK surgery. Dry eye could affect the recovery of the corneal epithelium followed by the visual clarity. These factors led to early postoperative contrast sensitivity reduced, and decline in the visual quality. As time went by, corneal epithelial healing and stabilization of the tear film function could improve the visual qualities of most patients compared to those in the early postoperative period.

Goldberg *et al* [23] considered that monovision surgery had no significant effect on the binocular peripheral vision and binocular field of vision, but made the depth perception declined slightly and lead to the subsequent adaptation. This study showed that, stereopsis was decreased initially and then

increased. The main consideration could be attributable to the MV-LASIK, which could pose monocular blurry effect on stereopsis. Therefore, for professional career patients requiring a sharp stereoscopic visual function, the surgical monovision should be considered carefully.

The main concerns of patients related to the weakened regulate ability of presbyopia and the improvement of inconvenience from near-work activity. This study focused on near-distance work and also quantified and scored the fatigue, the outcomes could thus serve as an important evidence for the visual quality improvement.

In conclusion, Q value guided non-linear aspheric MV-LASIK is a stable, well tolerated, safe and effective treatment for moderate to high myopia or myopic astigmatism and presbyopia patients.

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Q 值优化非球面切削单眼视 LASIK 术后视觉效果分析

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摘要

目的:评价利用 Q 值优化的非球面切削单眼视 LASIK 手术方式矫正近视散光联合老视的单眼及双眼视觉效果。

方法:选择 2006-08-01/2009-03-31 之间在我院利用 Carl Zeiss Meditec CRS-Master 软件及 MEL80 准分子激光进行 Q 值优化的非球面切削单眼视 LASIK 手术的近视或者近视散光联合老视的 40 名连续随访患者(80 眼),术后 1d;1wk;1,3,6mo 及 1a 进行验光、单眼及双眼视近及视远裸眼视力、角膜曲率、像差检查,术后 1wk;1,3,6mo 及 1a 进行对比敏感度及立体视觉检查进行视觉质量评估,并在术后 6mo 进行患者近距离工作视觉疲劳问卷调查。

结果:Q 值优化的非球面切削单眼视 LASIK 术后视觉质量研究结果如下:术后 6mo 等效球镜屈光度与目标屈光度相比 92% 在 ±0.50D 以内,99% 在 ±1.00D,术后 3mo ~ 1a 的屈光值的变化为-0.06 ±0.37D。术后 1mo 主视眼的裸眼远视力 95% 达到 20/20;双眼裸眼近视力 87.5% 达到 J2,100% 达到 J5。术后 1wk,双眼对比敏感度与术前矫正后相比有下降趋势,术后 1 ~ 3mo 逐渐恢复。术后 1wk 时,近立体视锐度有所降低($P<0.05$),其他立体视锐度均无明显改变(均为 $P>0.05$)。术后患者近距离工作视疲劳症状明显改善。

结论:Q 值优化的非球面切削单眼视 LASIK 手术方式,对于中度近视至高度近视及散光联合老视患者,是一种耐受性好,稳定安全有效的治疗方法。

关键词:单眼视;LASIK;Q 值;视力;像差;对比敏感度