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LASEK for the correction of hyperopia with mitomycin C using SCHWIND AMARIS excimer laser：one-year follow-up

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SCHWIND AMARIS 准分子激光联合丝裂霉素 C 行 LASEK 术矫治远视的研究

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摘要

目的：评估 SCHWIND AMARIS 准分子激光在 LASEK 术中矫治远视手术中的有效性，安全性和可预测性。

方法：回顾性研究 LASEK 术联合使用丝裂霉素 C 矫治远视患者 33 例 66 眼，平均年龄 35. 42±1. 12 岁（范围 18 ~ 56a）。每位患者予 SCHWIND AMARIS 准分子激光行 LASEK 术。术后对其可预测性、安全性、有效性及主观验光情况进行评估，并分析客观验光、裸眼视力、最佳矫正视力及不良反应。

结果：平均屈光度为 3.2±1.6D(0 ~ 7D)，术前及术后平均等效球镜分别为 2. 34±1. 76D(-1. 25 ~ 7D)及 0. 30±0. 84D(-0.2 ~ 0.8D)(P=0. 001)。术后 6 ~ 12mo，平均远视为 0. 63±0.84D(-1. 75 ~ 2. 76D)。平均散光度为 0. 68±0.43D(0 ~ 2D)，61 眼(78. 2%)和 31 眼(39. 7%)散光度分别在±1D 和±0.50D 范围内。安全指数和有效性指数分别为 1. 08 和 1.6。

结论：应用 SCHWIND AMARIS 准分子激光联合丝裂霉素 C 行 LASEK 术矫治远视具有良好的视觉和屈光结果，而且无严重并发症。

关键词：LASEK；SCHWIND AMARIS；丝裂霉素 C；远视

Abstract

• AIM：To evaluate the efficacy，safety and predictability of laser-assisted sub-epithelial keratectomy（LASEK）for the correction of hyperopia using the SCHWIND AMARIS platform.

• METHODS：This retrospective single-surgeon study includes 66 eyes of 33 patients with hyperopia who underwent LASEK with mitomycin C（MMC）. The median age of patients was 35. 42±1. 12y（ranging 18 to 56y）. In each patient LASEK was performed using SCHWIND AMARIS excimer laser. Postoperatively clinical outcomes were evaluated in terms of predictability，safety，efficacy，subjective and objective refractions，uncorrected visual acuity（UCVA），best spectacle-corrected visual acuity（BSCVA）and adverse events.

• RESULTS：The mean baseline refraction was 3. 2±1. 6 diopters（D）（ranging 0 to 7 D）. The mean pre-operative and postoperative spherical equivalent（SE）were 2. 34±1. 76（ranging -1. 25 to 7 D）and 0. 30±0. 84（ranging -0. 2 to 0. 8 D）respectively（P=0. 001）. The mean hyperopia was 0. 63±0. 84 D（ranging -1. 75 to 2. 76 D）6 to 12mo postoperatively. Likewise，the mean astigmatism was 0. 68±0. 43 D（range 0 to 2 D）with 51（77. 3%）and 15（22. 7%）eyes within ±1 and ±0. 50 D respectively. The safety index and efficacy index were 1. 08 and 1. 6 respectively.

• CONCLUSION：LASEK using SCHWIND AMARIS with MMC yields good visual and refractive results for hyperopia. Moreover，there were no serious complications.

• KEYWORDS：LASEK；SCHWIND AMARIS；mitomycin C；hyperopia

INTRODUCTION

The development of excimer laser technology over the past 2 decades has portended a new phase in refractive surgery. Since 1983, when the modern period of refractive surgery began with the experimental introduction of the 193nm argon fluoride excimer laser by Trokel et al[1], refractive surgery has been widely used because of its precise predictability and safety in treating low to moderate myopia[2]. Photorefractive keratectomy (PRK) first used in human corneas in 1987 by McDonald et al[3]. In the early 1990s, The automated micro-keratome was modified and incorporated into laser in situ keratomileusis (LASIK)[4,5]. Since then, LASIK has become the most popular refractive procedure in the world and was considered by many experts to be the refractive procedure of choice. In 1999, laser-assisted sub-epithelial keratomileusis (LASEK) was introduced by Camellin[6]. This technique has become popular for correcting refractive errors (RE), particularly in cases with moderate degrees of myopia, suggesting that the refractive and visual outcomes in LASEK patients were better than conventional PRK[7,8].

Epithelial flap in Camellin's LASEK technique is detached after application of an alcohol solution and repositioned as in the LASIK procedure following laser ablation. The epithelium regenerates in a few days; during this time the flap protects the ablated stromal surface. Mitomycin C (MMC) is an alkylating agent with cytotoxic and anti-proliferative effects. It is used as prophylactic to keep away from haze after primary surface ablation and for modulation of corneal wound healing[9].

Although results for hyperopic corrections have been encouraging, the surgical correction of hyperopia remains a challenge in spite of the development of numerous technologies. Surface ablation for the correction of hyperopia is documented with poor predictability, slower visual recovery and refractive stability compared to myopic treatments[10-13]. To our knowledge there are few investigations related to hyperopic LASEK using MMC[13]. To address this issue and evaluate the safety and efficacy of LASEK for hyperopia using MMC, we conducted this retrospective study.

SUBJECTS AND METHODS

Patients' Number and Assessment　This retrospective study comprised 66 eyes of 33 patients who had LASEK for hyperopia, performed with the AMARIS excimer laser (SCHWIND eye-tech-solutions, Kleinostheim, Germany). The Institutional Review Board of the Eye Research Center, Bina Eye Hospital approved this study and followed the tenets of the Declaration of Helsinki. Exclusion criteria were: corneal or retinal disease, previous eye surgery, collagen vascular disease, keratoconus, glaucoma, cataract, pregnancy and current systematic corticosteroid therapy. Hard contact lenses were discontinued 3wk and soft contact lenses 2wk before the final measurement and surgery. The preoperative examination included measurement of uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions; slit-lamp bio-microscopy; fundus evaluation; and corneal topography. The goal of all surgeries was emmetropia. Patients were followed for 6 to 12mo postoperatively. The nature of the procedures and its related benefits and risks were explained precisely to all patients.

Operative Procedure　The procedures were performed by the same surgeon (Jadidi K) under sterile conditions and topical anesthesia (proparacain hydrochloride 0.5%). Twenty percent alcohol was applied to the center of the cornea for 15s using a corneal well. It was then thoroughly rinsed with a balanced salt solution. A 9 mm epithelial trephine (Shahinian LASEK trephine; Katena Products Inc., Denville, NJ, USA) was used to create a 270° epithelial hinge. The epithelial flap was reflected back from the cornea with an epithelial peeler (hack knife and vok cell Sloane LASEK Micro Hoe; Katena Products Inc.). Excimer laser treatment was performed using the nomogram. The optical zone varied between 6 mm and 7 mm, and transition zone was calculated based on the patient's age, RE, and K readings by means of the nomogram. Following ablation, with regard to the refraction number of each patient, a cellulose surgical spear soaked in 0.02% MMC was applied to the ablated area. The duration of MMC application was 30s. The epithelial flap was rinsed with a balanced salt solution before being repositioned with the edges overlapping the original intact epithelium. A new bandage contact lens (BCL) was placed after laser ablation on the cornea and one drop each of a topical antibiotic agent and steroidal agent was given. Postoperatively patients were given bethamethasone drops 4 times a day, chloramphenicole drops 4 times a day, and preservative-free artificial tears every 2h. Chloramphenicol drops was discontinued 1wk postoperatively but betamethasone drops tapered off during 4-6wk. Moreover, there were no serious complications except low grade corneal haze.

Safety, Efficacy and Predictability　The safety of the procedure was defined as the percentage of eyes losing more than 2 lines of Snellen BSCVA. Safety index is equal to the ratio (mean postoperative BSCVA/mean preoperative BSCVA). The efficacy was defined as the percentage of the eyes, achieving a UCVA of 0.5 (20/40) or better postoperatively. The efficacy index is equal to the ratio (mean postoperative UCVA/mean preoperative BSCVA)[14,15]. The predictability of refractive SE was the percentage of eyes with ±1 D and ±0.50 D of emmetropia at 6 to 12mo postoperatively[16].

Statistical Analysis　All visual acuity measurements were converted from Snellen to logarithm of the minimum angel of resolution (logMAR). All continuous variables were expressed as mean (SD), correspondingly for non-normal data were expressed as median (IQ). Paired student t-test and colmogrov-smirnov test were used to compare ophthalmologic changes pre and post operatively for normal and non-normal continuous variables, respectively. $P < 0.05$ were considered statistically significant. All analyzes were

Table 1　Mean preoperative and postoperative visual and refractive outcomes during 6-12mo follow-up period

Parameters	Before surgery	6 to 12mo after surgery	P
BCVA（logMAR）	0.06±0.13	0.05±0.10	0.804
Refractiveerror（D）	3.2±1.6	0.6±0.8	<0.001
Astigmatism（D）	−1.8±1.7	−0.7±0.4	<0.001
SE	2.3±1.8	0.3±0.8	<0.001

BSCVA：Best spectacle-corrected visual acuity；SE：Spherical equivalent. $P<0.05$ demonstrate significancy.

performed using SPSS version 18 software （SPSS Inc.，Chicago，IL，USA）

RESULTS

In this study of 33 patients，15（45.5%）were males and 18（54.5）% were females. The mean age at the time of the surgical intervention was $35.9±10.7$y（from 18 to 56）. Preoperative mean RE was $3.2±1.6$ diopters（D）（range：0 to +7.00 D），whereas 6 to 12mo postoperatively the mean RE was $0.6±0.8$ D（range：−1.75 to 2.76 D）. A significant reduction was reported between the preoperative and 1-year postoperative mean RE（$P<0.001$）（Table 1）. The mean preoperative and postoperative spherical equivalent（SE）were $2.34±1.76$（range−1.25 to 7 D）and $0.30±0.84$（range −0.2 to 0.8 D）respectively（$P=0.001$）. At 6 to 12mo，43（65.2%）eyes were within ±1.00 D of the intended correction RE and 23（34.8%）eyes were within ±0.50 D. Preoperative and 6 to 12mo postoperative mean astigmatism were $−1.8±1.7$（range：0 to 5.50）and $−0.7±0.4$（range：0 to 2），respectively. These results indicated a significant reduction（$P<0.001$）. At 6 to 12mo，51（77.3%）eyes were within ±1.00 D of the intended correction astigmatism and 15（22.7%）eyes were within ±0.50 D. Mean preoperative BSCVA was $0.06±0.13$ logMAR（range：0 to 0.70 logMAR）and mean 6 to 12mo postoperative BSCVA was $0.05±0.1$ logMAR（range：0 to 0.39 logMAR）. There was no significant difference between mean pre-operative and 6 to 12mo postoperative BSCVA（$P<0.804$）. The safety index and efficacy index were 1.08 and 1.6 respectively.

Additionally，at the six-month follow-up and thereafter，two eyes gained four lines of BSCVA，13 gained one line and 44 eyes showed no change. Three eyes lost one line of Snellen decimal equivalent BSCVA and four eyes lost more than one line（Figure 1）. Corneal haze was detected in just about 5% of our study cases that was not so serious to affect visual acuity（data not shown）.

DISCUSSION

LASIK for correcting hyperopia proved to be more challenging than correcting myopia primarily because the excimer lasers have to be capable of delivering peripheral laser pulses to flatten the peripheral cornea for steepening the central cornea. Secondarily，larger diameter flaps should be produced by a new generation of microkeratomes. Moreover，studies of hyperopic PRK and hyperopic LASIK have demonstrated acceptable efficacy for corrections up to 4.00 D，but with
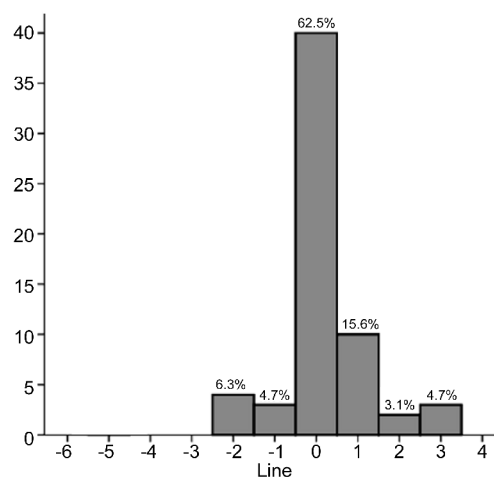

Figure 1　Percentages of eyes with BSCVA gain and loss 6-12mo after surgery.

limited predictability for higher-order corrections[10-12].

Alternatively，nowadays there are several laser systems capable of hyperopic ablations and various microkeratomes competent of creating large-diameter flaps. The AMARIS excimer laser technology is based on a new ablation patterns incorporating a six-dimensional eye-tracking subsystem which tracks not only pupil movements，but also rolling movements of the eye，as well as torsional movements and movements along the propagation axis of the laser. This pattern minimizes the induction of aberrations that will allow us to perform LASEK more predictably and safely[17,18]. Additionally，recent studies proposed LASEK to be superior refractive procedure compared with PRK and LASIK due to the possibility of larger diameter optical zone，a reduction in pain，faster visual rehabilitation，better visual acuity，decreased corneal haze，ability to treat thinner corneas and absence of stromal flap problems in LASEK-treated patients[19-27].

In this retrospective study，we assessed efficacy，safety and stability of hyperopic LASEK with MMC. The safety of the procedure was defined as the percentage of eyes losing more than 2 lines of Snellen BSCVA. We found that 6% of eyes lost 2 or more lines of BSCVA，indicating a reasonable level of safety. In addition，the efficacy and safety index were more than 1.00 at 6 to 12mo postoperatively that showed the visual outcomes were satisfactory.

In a prospective pilot study by O'Brart *et al*[28]（2007）comprised 45 patients（68 eyes），treated with LASEK，

preoperative mean SE was +2. 19 D, ranging from 0 to +4. 25 D, while mean pre − operative cylinder was − 0. 79 D, ranging from 0 to − 5. 0 D. Patients underwent LASEK with a SCHWIND ESIRIS excimer laser with a large optical zone of 7. 0 mm and a 1. 0 mm transition zone in every case. At the 6 to 12mo follow − up visits, 98% of eyes were within one dioptre of the intended correction, while 88% were within 0. 5D. At the six−month follow−up and thereafter, two eyes gained two lines of BSCVA, 11 gained one line and 28 eyes showed no change. Two eyes lost one line of Snellen decimal equivalent BSCVA. No eyes lost more than one line. Analysis of complications showed no axial corneal haze in any eyes, with a peripheral ring of faint haze 7. 0 mm in diameter in seven percent of eyes after between six and 12mo follow−up.

In our study, patients underwent LASEK with a SCHWIND AMARIS excimer laser. The optical zone and transition zone were 6. 6 mm and 1. 6 mm respectively. When comparing our results with those of O'Brart et al[28] (2007), they were similar regarding the mean reduction of the K average value. However, when we further analyzed this amount of reduction in relation to the initial preoperative values, we observed a positive significant correlation; that is, the higher the optical zone, the better outcome achieved after surgery. Moreover, in our study that were categorized based on ages and transition zone on outcome (data not shown), we revealed statistically significant difference between two groups in term of transition zone ($P = 0.004$), but no significant difference in term of ages was found ($P = 0.576$). Interestingly in O'Brart et al[28] study, transitional zone was lower than our study (1mm versus 1. 6 mm). We speculate that transitional zone may have a prominent role in outcome that should not be overlooked in future studies.

O'Brart et al[29] theorized that improved outcomes with the SCHWIND ESIRIS laser might be due to the large diameter optical zone and the smoother ablation profile achievable with scanning spot technology. He showed that hyperopic LASEK with the ESIRIS laser results appear to be very favorable compared to published outcomes with LASIK and PRK. LASEK with large diameter optical zone treatments (7. 0 mm or greater) achieves very favorable outcomes for the correction of hyperopia up to +4. 5 D hyperopia[30].

In this study, we demonstrated the reason of rather discouraging excimer laser hyperopic treatments in the past were due to too small optical zones; the optical zone was 6. 6 mm and it was slightly smaller than O'Brart et al[28] study, whereas the transitional zone was larger (1. 6 mm). Actually, the use of small optical zones will have a greater propensity to the induction of higher−order aberrations, especially as many hyperopes have a large angle kappa often requiring the treatment to be de−centered from the entrance pupil centre, which can result in a significant loss of postoperative visual performance, especially as (unlike myopic treatments) there are no benefits from postoperative retinal magnification. In addition, in myopic treatments we know that the large optical zone corrections (6. 0 mm or greater) are more predictable,

safer and more stable than smaller diameter (5. 0 mm or less) treatments. Therefore, knowing the facts mentioned above, to some extend may explain our results.

Also, de Ortueta et al[31] found a good predictability after H−LASIK with the ESIRIS system, with 92 % of the eyes having a postoperative refraction within ± 0. 50 D of the attempted correction. We demonstrated a refractive outcome within ±1.00 D of emmetropia in 78. 2% of eyes in the present study with AMARIS system. Thus in comparison to previous studies[28−31], there is slightly difference in terms of intended correction which could be explained by differences in optical zone and transitional zone. Likewise, we agree with O'Brart et al[28] theory, better outcomes in terms of predictability and visual performances are closely related to larger optical zone. Furthermore, we found that regression of initial effect was more stable than previous studies and no re−treatments were performed in the 6 to 12mo of follow − up due to under − correction or hyperopic regression, possibly because there was less stimulation of sub − epithelial connective tissue with LASEK.

In conclusion, we have shown − LASEK using SCHWIND AMARIS yields very satisfactory visual outcomes for hyperopia and hyperopic astigmatism. In addition, there were no sight−threatening complications. Further studies with a longer follow − up period and a larger number of patients are recommended to draw final conclusions about the efficiency and safety of LASEK using SCHWIND AMARIS. Ths study is underway, and the results will be reported soon.

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