Long-term Results of Laser in Situ Keratomileusis for High Myopia

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The objective of this study was to evaluate the results of laser in situ keratomileusis (LASIK) for high myopia after a follow-up of two years. A total of 42 eyes from 33 patients with high myopia (range: -9.00 D to -25.50 D) were studied. LASIK was performed using an automated microkeratome (Steinway, USA) and OmniMed II excimer laser with the standard MKM program (Summit Technology, Inc., Waltham, MA) in all patients. The patients were followed up at one, three, six, 12 and 24 months. During follow-up manifest refraction and best corrected and uncorrected visual acuity were measured. Any complications were also analyzed. The two-year follow-up results were as follows. The mean postoperative manifest spherical equivalents (MSE) were -0.51 D at one month, -1.09 D at three months, -1.78 D at six months, -2.17 D at 12 months and -2.61 D at 24 months. Myopic regression continued during the two-year follow-up (p<0.05). The accuracy of the intended postoperative correction within ±2.00 D was 73.8% at one month, 69.1% at three months, 52.4% at six months, 52.4% at 12 months, and 45.2% at 24 months. The best corrected visual acuity (BCVA) was unchanged or increased in 35 eyes (83.3%). Only three eyes (7.2%) lost two or more lines of BCVA. This was due to irregular astigmatism in one eye, macular degeneration in one eye, and rhegmatogenous retinal detachment in one eye. In this study, LASIK was effective and safe in the correction of high myopia, however continuous myopic regression was seen over the two-year follow-up. Refining the nomogram to adjust for progressive myopic regression will be necessary in order to obtain better results.

Key words: best corrected visual acuity, high myopia, laser in situ keratomileusis, long-term results

INTRODUCTION

Laser in situ keratomileusis (LASIK) has emerged over the past nine years as a promising procedure for the correction of myopia.1 It has been suggested in many reports that LASIK is superior to photorefractive keratectomy (PRK), especially in cases with high myopia.2-9 Quick visual rehabilitation, minimal postoperative discomfort, and the ability to correct a high degree of myopia with little postoperative corneal haze are some of the reasons...
for the popularity of LASIK over other surgical options for visual correction. Fewer postoperative visits and the short-term use of topical eye drops are additional advantages. However, these advantages make it difficult to follow patients for a long period after the procedure. Recently, Knorz et al. \(^{10}\) reported two-year results after LASIK, but there have been few other reports of the long-term results of LASIK. We evaluated the results of LASIK in high myopes who had been followed for two or more years.

**PATIENTS AND METHODS**

LASIK for the correction of myopia has been performed at Korea University Hospital since July 1994. Thirty-three patients (42 eyes) with myopia of at least 9.00 D, who had undergone LASIK and had been followed for at least two years were selected for inclusion in this study. Manifest refraction, cycloplegic refraction, central corneal thickness and computerized corneal topography had all been evaluated prior to surgery. The inclusion criteria for surgery were: (1) patient age of at least 18 years or older, (2) a stable preoperative corneal topography without evidence of keratoconus, and (3) corneal thickness allowing for a minimum residual untreated posterior corneal thickness of 250 μm. LASIK was not performed in the following cases: (1) eyes with macular disease reducing the best-corrected visual acuity to below 20/40, (2) eyes with advanced or uncontrolled glaucoma, (3) eyes with active inflammatory or infectious ocular disease, (4) eyes with media opacities, and (5) eyes with current or recent retinal detachment.

All of the surgeries were performed using the following technique by one surgeon (H-M. K.). In brief, an 8.5 to 9.0 mm diameter anterior corneal flap, measuring between 130 and 160 μm in thickness, was created using an automated micokeratome (Steinway, USA). This was followed by a spherical mid-stromal ablation using the Summit Omnimed II excimer laser with the standard MKM program (Waltham, MA). This one-pass multizone software program consisted of a 4.5 mm inner zone and an outer zone varying between 5.5 and 6.0 mm, depending on the amount of the desired correction. After stromal ablation, the flap was repositioned to its original location and the interface was irrigated with a balanced salt solution. After a three-minute wait to promote flap-stromal bed adherence, 0.3% ofloxacin drops were instilled, lid taping was done and a shield was placed over the eye. On the first postoperative day, the lid tape was removed. Ofloxacin (0.3%) and fluorometholone (0.1%) were administered four times daily for one week and then discontinued. Postoperative visits were at one week, and one, three, six, 12, and 24 months. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), manifest refraction, slit lamp examination, topography and fundus examination were performed at each visit.

The mean values for UCVA, BCVA and manifest refraction were calculated, and the paired t-test (repeated measure method) was used to evaluate the significance of the postoperative changes in manifest refraction over time for up to two years. P-values of less than 0.05 were considered to be statistically significant.

**RESULTS**

Forty-two eyes from 33 patients (17 female, 16 male) were studied. The mean age at the time of the surgery was 30.9 ± 7.9 years. Preoperative patient data are shown in Table 1.

Postoperative mean spherical equivalent (MSE) values over time are shown in Figure 1. MSE was \(-0.51\) D (±2.09) at one month and regression continued for the entire 24 month follow-up. At the 24 months visit, MSE was \(-2.61\) D (±2.07). The serial regression was statistically significant for up to 24 months on analysis by the repeated measure test (p<0.05). The total amount of regression from the one month visit to the 24 month visit was 2.10 D.

The percentage of eyes that approached the intended correction over time decreased up to the six month visit, maintained that level up to the 12 month visit, and then decreased again at the 24 month visit (Fig. 2). At the 24 month visit, 28.6% of the eyes were within ±1.00 D, and 45.2% were within ±2.00 D.

Uncorrected visual acuity data is presented in Figure 3. Postoperatively, the percentage of eyes with 20/40 or better UCVA reached a peak at the three month visit, declined steadily up to the 12 month visit, and then maintained the same level at
Table 1. Preoperative patient data

<table>
<thead>
<tr>
<th>Age (year)</th>
<th>range</th>
<th>20–44</th>
</tr>
</thead>
<tbody>
<tr>
<td>range</td>
<td>20–44</td>
<td>30.9 ± 7.9</td>
</tr>
<tr>
<td>Sex</td>
<td>mean ± SD</td>
<td>16</td>
</tr>
<tr>
<td>male</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>female</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td>mean ± SD</td>
<td>-15.94 ± 4.08</td>
</tr>
<tr>
<td>range</td>
<td>-9.00–25.50</td>
<td></td>
</tr>
<tr>
<td>Visual acuity, number(%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>uncorrected</td>
<td>20/400 or less</td>
<td>42(100)</td>
</tr>
<tr>
<td>best corrected</td>
<td>20/20 or better</td>
<td>2(4.7)</td>
</tr>
<tr>
<td></td>
<td>20/40 or better</td>
<td>33(78.6)</td>
</tr>
<tr>
<td></td>
<td>20/80 or better</td>
<td>41(97.6)</td>
</tr>
</tbody>
</table>

Fig. 1. Change in mean manifest spherical equivalent (diopters[D]) over a two year period after laser in situ keratomileusis (LASIK). Regression continued, and the changes were statistically significant for up to two years after surgery (p<0.05).

Fig. 2. Percent of eyes within 1 and 2 diopters of intended correction from one month to 24 months after laser in situ keratomileusis (LASIK). Base line refraction (D); -9.00 to -25.50.

Fig. 3. Uncorrected visual acuity from one month to 24 months after laser in situ keratomileusis (LASIK). Base line refraction (D); -9.00 to -25.50.

Fig. 4. Changes in best corrected visual acuity (BCVA) between preoperative and postoperative evaluation at the final 24 month follow-up visit (minus sign means loss of vision, zero means no change in vision, plus sign means gain of vision). Base line refraction (D); -9.00 to -25.50.

the 24 month visit. The percentage of eyes with 20/30 visual acuity showed a similar pattern.

Figure 4 shows the change in BCVA from the preoperative examination to the last follow-up visit. Fourteen eyes (33.3%) gained one line of BCVA,
and ten eyes (23.8%) gained two or more lines of BCVA. Eleven eyes (26.2%) showed no change. Four eyes (9.5%) lost one line of BCVA, and three eyes (7.1%) lost two or more lines of BCVA. Of the three eyes that lost two or more lines, one eye had irregular astigmatism and over-correction at one month postoperatively, which did not disappear. Another eye had macular degeneration that developed 12 months postoperatively, and the third eye had a rheumatogenous retinal detachment involving the macula at 36 months after LASIK.

During the last follow-up, loss of BCVA of more than two lines occurred in nine eyes, including the aforementioned three eyes. However, six of these eyes lost two or more lines only temporarily, and then were restored to preoperative BCVA or better. Of these, one eye lost two lines at one month and regained them at 12 months, and the others lost two lines at one month and regained them at three months. Irregular astigmatism was shown on the topography of all of these eyes.

There were no intraoperative flap complications such as button-hole flap, free flap or incomplete flap. However, one eye had a foreign body at the interface of the corneal flap, which was irrigated with BSS after lifting the flap one day after LASIK. In addition, one eye that had a retinal hole without macular involvement 22 months after surgery underwent laser treatment, but did not lose BCVA.

**DISCUSSION**

At present, LASIK is widely accepted as a surgical procedure for the correction of high myopia. Several previous studies have found that LASIK offers good results in cases of moderate and high myopia in terms of efficacy, predictability, stability, and safety.\(^2\)\(^-\)\(^9\) To fully prove the stability and safety of LASIK, more studies of its long-term results are necessary. However they are not available as of yet. Uncorrected visual acuity (UCVA) is the main criterion to assess the effectiveness of a refractive surgery.\(^11\) Some studies\(^2\)\(^-\)\(^5\) on LASIK for the correction of high myopia have reported a UCVA of 20/40 or better after surgery in 45.0% to 71.0% of the cases. Our data also showed improved UCVA after LASIK; 64.3% of our patients had a UCVA of 20/40 or better at three months, 54.0% at six months, 45.2% at 12 months and 45.2% at 24 months.

Concerning predictability, Pallikaris and Siganos\(^5\) reported that, in eyes with a preoperative myopia between \(-10.00\) and \(-26.00\) D, 66.0% had a refraction within 1.00 D of emmetropia 12 months after surgery. Kornz and Jendritz\(^\)\(^10\) found a final refraction within 1.00 D of emmetropia in 33% of eyes with a preoperative myopia between \(-15.00\) and \(-29.00\) D, 24 months after surgery. In our study, 28.6% were within 1.00 D of emmetropia 24 months after surgery.

In terms of stability, Chayet et al\(^12\) found early postoperative regression of effect that stabilized between three and six months after LASIK for the correction of high myopia (preoperative mean MSE, \(-14.02\) D). Güell and Muller\(^2\) reported more regression after LASIK for high myopia than after LASIK for moderate myopia, with stable results after six months. Pallikaris and Siganos\(^5\) observed a mean regression of less than 1.50 D between one and 12 months after LASIK. However, very few long-term results concerning the stability of LASIK have been reported as of yet. Our results showed that regression was continuous over the two year follow-up, and that these changes were statistically significant.

Chayet et al\(^12\) reported that early regression of the refractive effect after LASIK appears to be a consequence of an increase in corneal thickness associated with central corneal steepening. Compensatory epithelial hyperplasia (CHP) could be the key mechanism for this increase in corneal thickness. Besides CHP, potential mechanisms for this regression of the refractive effect may include nuclear sclerosis of the crystalline lens, corneal ectasia, corneal hydration, stromal synthesis and an increase in axial length. We believe that one or more of these mechanisms may cause this regression to continue after six months, and for up to two years, postoperatively. Further investigations will be required in order to confirm whether this regression continues after two years following LASIK for high myopia.

In a study by Pallikaris and Siganos,\(^2\) BCVA increased by one line in 40% of the eyes. Güell and Muller\(^2\) found this improvement in 18.6%. In our study, the percent of eyes gaining one or more lines was 57.1% (24 out of 42 eyes). This was greater
than the 16.7% (seven out of 42 eyes) losing one or more lines. In addition, of the seven eyes that lost one or more lines of BCVA, only three of them (7.2%) lost two or more lines.

BCVA is a general indicator of a variety of changes in the optics of the cornea and in visual functions after refractive surgical procedures. Because BCVA would actually be expected to increase slightly after refractive surgery due to the image magnification inherent in correcting myopia at the corneal rather than the spectacle plane,11 loss of visual acuity of two or more lines might be expected to have a clinical impact. The loss of BCVA in this study may have arisen from two different causes: (1) retinal lesions such as macular degeneration or rhegmatogenous retinal detachment which may develop in high myopia, or (2) corneal topography irregularities resulting in unfocused noise light degrading the focused image. The yearly incidence of retinal detachment has been estimated to be 0.015% in eyes with up to 4.75 D of myopia, 0.07% in eyes with 5.00 to 9.75 D of myopia, and 0.075% in eyes with myopia greater than 10.00 D.14 Therefore, further observation will be necessary in order to determine whether the risk of retinal detachment is indeed increased by LASIK during the lifetime of the patient. Surgeons should discuss possible retinal complications with patients before surgery and informed consents should be taken. In addition, more attention should be paid to the fundus examination in potential LASIK patients with high myopia.

Irregular astigmatism is a rare complication of LASIK with a reported incidence from 0 to 12%.2,4,15-18 In our study, one eye (2.4%) lost two lines of BCVA because of irregular astigmatism. During follow-up, we experienced seven cases of irregular astigmatism with two line loss of BCVA, but six of these eyes regained preoperative BCVA over time. One eye lost two lines at one month, which returned at 12 months. The others lost two lines at one month, which returned at three months. Hersh et al19 reported that the loss of BCVA and irregular topographic patterns, which they observed in the early postoperative period, recovered spontaneously over time.

In conclusion, the long-term results of LASIK for high myopia have revealed that LASIK may be a promising and safe procedure. However, refining the nomogram to adjust for the progressive myopic regression, which continued over two years or more after the surgery, will be required in order to obtain better results. The loss of BCVA due to irregular astigmatism returned to preoperative levels spontaneously in most cases. Therefore, observation without re-treatment should be sufficient. In addition, longer follow-up may be needed in order to evaluate the possible incidence of vision-threatening complications.

REFERENCES


