**Comparison of LASIK and Surface Ablation by Using Propensity Score Analysis: A Multicenter Study in Korea**

**Kyung-Sun Na,1,2 So-Hyang Chung,1 Jin Kook Kim,3 Eun Jin Jang,4 Na Rae Lee,4 and Choun-Ki Joo1,4**

**PURPOSE.** We compared the 3-year outcomes with regard to efficacy, stability, and safety of LASIK and surface ablation performed at multiple centers in Korea.

**METHODS.** The charts of 5109 eyes that underwent LASIK or surface ablation, including LASEK, epi-LASK, and photorefractive keratectomy (PRK), at multiple centers between 2002 and 2005 were reviewed. Of these, 577 LASIK-treated eyes and 577 propensity score-matched surface-ablated eyes were included in this cohort study. A standardized case report form (CRF) was completed based on a review of the 3-year follow-up chart. The CRF included the preoperative, surgical, and postoperative data for the refractive error, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), IOP, corneal thickness, keratometry, corneal topography, Schirmer test, and tear breakup time (TBUT).

**RESULTS.** The efficacy index calculated after 3 years and the postoperative spherical equivalents measured at 3 months or 5 years did not differ between the LASIK and surface ablation groups. Although myopic regression was observed in the surface ablation group through postoperative years 1 and 2, this difference did not affect the visual acuity significantly. Surface ablation did carry a higher cumulative incidence of corneal haze.

**CONCLUSIONS.** LASIK and surface ablation produced similar postoperative visual efficacy after corneal healing. The outcome predictability did not differ between the 2 groups, but myopic regression was observed more frequently in the surface ablation group. Corneal haze after surface ablation is much more common than reported previously. (Ophthalmology) 2012;53:7116–7121 DOI:10.1167/iovs.12-9826

Photorefractive keratectomy (PRK)1,2 was the most commonly performed surgical treatment for myopia in the mid-1990s before the introduction of LASIK, which avoids disadvantages of PRK, such as postoperative pain, corneal haze, and slow visual rehabilitation.3–6 However, LASIK has unique risks, including flap-related complications, such as free cap, incomplete flap, buttonholes, epithelial ingrowth, lost flaps, and deep lamellar keratitis.7–10 Surgical procedures have continued to evolve, and laser epithelial keratomileusis (LASEK) may combine the advantages of PRK and LASIK while avoiding the disadvantages of both.11,12 Furthermore, epi-LASK, which was developed in 2001 by Pallikaris et al.,13 was introduced as posing less risk of flap-related complications.1,14

Surface ablation can be performed by mechanical or laser removal of the epithelium or, after epithelial flap formation, by the use of alcohol (LASEK) or a microkeratome (epi-LASK). Although LASIK now is the most common surgical treatment for myopia, many ophthalmologists consider surface ablation, including PRK, LASEK, and epi-LASK, to be a safer modality. Many reports have compared visual outcomes and complications after stromal versus surface ablation,16–18 but the lack of data from randomized controlled trial (RCT) data has precluded any conclusion regarding which procedure is safer or more efficacious.

The propensity score, first proposed by Rosenbaum and Rubin in 1983, has been used increasingly as an alternative to RCTs.20,21 Although RCTs are accepted as the gold standard for assessing the efficacy of surgical procedures, they are used rarely in medical fields because of ethical issues. A patient’s propensity score is his or her own conditional probability of undergoing one particular treatment versus another based on the observed confounders.20–24 The use of this method allows for unbiased estimation of the treatment effect. In our study, we matched patients who underwent LASIK or surface ablation at multiple university hospitals in Korea based on propensity scores calculated from several preoperative conditions, and then performed a nonrandomized retrospective review of data collected using a uniform case report form (CRF) to compare the efficacy, safety, and stability of the 2 procedures.

**METHODS**

**Data Source**

The data used in our retrospective cohort study were collected from multiple ophthalmology centers in Korea at the following institutions: The Catholic University of Korea, Yonsei University College of Medicine, University of Ulsan College of Medicine, Seoul National University College of Medicine, Inje University College of Medicine, and B & VIIT Eye Center. The Institutional Review Board of each university approved the study, which was conducted in accordance with the 1990 Declaration of Helsinki and subsequent amendments. The charts of all patients who underwent LASIK or surface ablation, including LASEK, epi-LASK, and PRK, between January 1, 2002 and December 31, 2005 were reviewed, and data
Table 1. Baseline Characteristics of Eyes that Underwent LASIK and Surface Ablation for Myopia in Overall Cohort and Propensity-Matched Cohort

<table>
<thead>
<tr>
<th>Overall Cohort Propensity-Matched Cohort*</th>
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<tbody>
<tr>
<td>LASIK, Surface Ablation,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>3401</td>
<td>1708</td>
<td>577</td>
<td>577</td>
<td></td>
</tr>
<tr>
<td>Sex, M:F</td>
<td>883:2518</td>
<td>393:1315</td>
<td>0.021†</td>
<td>161:416</td>
<td>0.692</td>
</tr>
<tr>
<td>Age, y</td>
<td>59±13.5</td>
<td>50±14.6</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>UCVA, logMAR</td>
<td>1.02</td>
<td>1.10</td>
<td>&lt;0.001†</td>
<td>1.06</td>
<td>0.926</td>
</tr>
<tr>
<td>SE, D (range)</td>
<td>4.96 (6.00, 8.00)</td>
<td>4.89 (6.27, 9.73)</td>
<td>0.356</td>
<td>5.05 (6.31, 9.65)</td>
<td>0.959</td>
</tr>
<tr>
<td>Keratometry, D</td>
<td>43.32 (41.25, 45.42)</td>
<td>43.30 (41.25, 45.42)</td>
<td>0.28</td>
<td>43.30 (41.25, 45.42)</td>
<td>0.28</td>
</tr>
<tr>
<td>Corneal size, mm</td>
<td>11.48 ± 0.37</td>
<td>11.50 ± 0.39</td>
<td>0.141</td>
<td>11.50 ± 0.39</td>
<td>0.141</td>
</tr>
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</table>

* Matching variables: age, UCVA, BSCVA, IOP, manifest refraction spherical equivalent, and corneal thickness, as well as all interaction terms of the matching variables. This logistic model had good discrimination between the 2 groups (c-statistic = 0.72).

† Significantly different by independent t-test or Fisher’s exact test for categorical variables.

Study Patients and Design

Of the patients whose records were reviewed, 5109 eyes remained after the exclusion of 286 eyes with a history of eye disease or diabetes, 50 eyes with hyperopia, and 76 eyes for which the surgical procedure was unknown. The 3401 LASIK-treated eyes and 1708 surface ablated eyes identified were matched one-to-one using propensity scores to reduce the effect of treatment-selection bias. The preoperative characteristics considered for estimation of the propensity score are listed in Table 1.

Statistical Analysis

The outcomes of LASIK and surface ablation were compared between patients matched by propensity scores that were estimated using a multivariable logistic regression model based on the following preoperative criteria: age, UCVA, BSCVA, IOP, manifest refraction spherical equivalent (MRSE), and corneal thickness, as well as all interaction terms of the matching variables. This logistic model had good discrimination between the 2 groups (c-statistic = 0.72).

One-to-one matching was performed by the Greedy matching method using a macro (available online in the public domain at http://www2.sas.com/proceedings/sugi26/p214–26.pdf). After propensity score matching, the balance of the 2 surgical procedure groups was evaluated using the independent t-test for continuous variables and the χ² test or Fisher’s exact test for categorical variables. A P value of less than 0.05 was considered statistically significant.

The postoperative UCVA, efficacy index, safety index, and refractive error of the propensity-matched data were analyzed using independent t-tests. The χ² test or Fisher’s exact test was performed to evaluate the complications. The accuracy of the 3-month and 3-year postoperative results was verified by comparing the proportions of the 2 groups using the Mantel-Haenszel χ² test.
Cox proportional hazard regression models were used to compare the incidence rates of corneal haze following LASIK and surface ablation after adjustment for age, preoperative UCVA, SE, central corneal thickness, keratometry, and corneal size in the overall cohort. After propensity score matching, the Cox proportional regression model was adjusted for covariates, such as keratometry and corneal size. The hazard ratio and 95% confidence interval (95% CI) were calculated. The cumulative incidence was compared between the groups using the log-rank test. All statistical analyses were performed using SAS 9.1.3 (SAS Institute, Cary, NC).

**RESULTS**

**Subject Characteristics**

The overall cohort before matching comprised 3401 eyes in the LASIK-treated group and 1708 eyes in the surface ablation-treated group. Preoperative characteristics, such as the corneal thickness, inevitably bias the surgeon’s choice of surgical intervention. To eliminate this bias, we selected propensity score-matched groups from the cohort. One-to-one matching according to the propensity score resulted in LASIK and surface ablation groups containing 577 eyes each. The preoperative characteristics before and after the matching are listed in Table 1. In the propensity-matched cohort, the LASIK and surface ablation groups did not differ significantly in age, sex, preoperative UCVA, BSCVA, IOP, spherical and cylindrical error, corneal thickness, corneal curvature, anterior chamber depth, or corneal size.

**Efficacy**

Table 2 shows the preoperative BSCVA and postoperative UCVA of both groups. The mean logMAR UCVA 1 month after surgery differed significantly between the groups (0.015 ± 0.13 for the LASIK group and 0.043 ± 0.13 for the surface ablation group). The mean postoperative UCVA no longer differed between the groups after visual rehabilitation was achieved in the surface ablation group; however, the UCVA values of both groups declined over 3 years, being 0.017 ± 0.12 vs. 0.054 ± 0.15 after 1 year and 0.054 ± 0.15 vs. 0.075 ± 0.14 after 3 years in the LASIK and surface ablation groups, respectively. After 3 years, the efficacy index (postoperative UCVA/preoperative BCVA) was 0.91 for the LASIK group and 0.86 for the surface ablation group; these results did not differ significantly.

**Predictability**

The spherical equivalent did not differ significantly between the treatment groups either 3 months or 3 years after surgery (P values of 0.345 and 0.943, respectively, by the Mantel-Haenszel $\chi^2$ test). Emmetropia $\pm 1.0$ diopter (D) was achieved in 79% of the LASIK group and 76.5% of the surface ablation group 3 months after surgery, and in 64.9% of the LASIK group and 66.7% of the surface ablation group 3 years after surgery (Figs. 1, 2).

**Stability**

The mean preoperative MRSE value was $-5.05$ D in the LASIK group and $-4.99$ D in the surface ablation group. One to 6 months after surgery, the MRSE value did not differ significantly between the 2 groups ($-0.32$ vs. $-0.35$ D 1 month after surgery, $-0.45$ vs. $-0.51$ D 3 months after surgery, and $-0.54$ vs. $-0.61$ D 6 months after surgery). After 1 year, the mean MRSE of the LASIK group was $-0.59$ vs. $-0.84$ D for the surface ablation group, which was a significant difference. The 2-year result also differed significantly between the groups ($-0.69$ vs. $-1.10$ D for the LASIK and surface ablation groups, respective-

![Figure 1](image1.png)

**Figure 1.** Predictability 3 months after surgery of the postoperative refractive errors of propensity-matched eyes that underwent LASIK or surface ablation for treatment of myopia.

![Figure 2](image2.png)

**Figure 2.** Predictability 3 years after surgery of the postoperative refractive errors of propensity-matched eyes that underwent LASIK or surface ablation for treatment of myopia.
ly). However, the MRSE were no longer significantly different after 3 years (−0.71 D for the LASIK group and −0.80 D for the surface ablation group, Fig. 3).

**Safety**

The mean postoperative logMAR BSCVA was −0.002 ± 0.06 for LASIK and 0.002 ± 0.04 for surface ablation. The safety index (postoperative BCVA/preoperative BCVA) values were 0.99 ± 0.09 and 0.99 ± 0.13 after 1 month, 0.99 ± 0.09 and 1.01 ± 0.05 after 1 year, and 1.01 ± 0.05 and 1.02 ± 0.07 after 3 years for the LASIK and surface ablation groups, respectively (Fig. 4). The 2 groups did not differ significantly at any point over the 3 years.

**Complications**

The complications seen after LASIK and surface ablation over the 3-year follow-up period are shown in Table 3. Corneal haze occurred in 0.9% of the LASIK group and 6.6% of the surface ablation group (P < 0.001).

The relative risk for corneal haze after adjustment for keratometry and corneal size was 8.67 (95% CI, 3.37–22.30) for the surface ablation group relative to the propensity-matched LASIK group (Table 4). The cumulative incidence of corneal haze was higher in the surface ablation group relative to the propensity-matched LASIK group (Table 4). The cumulative incidence of corneal haze was higher in the surface ablation group relative to the propensity-matched LASIK group (Table 4). The mean postoperative logMAR BSCVA was −0.002 ± 0.06 for LASIK and 0.002 ± 0.04 for surface ablation. The safety index (postoperative BCVA/preoperative BCVA) values were 0.99 ± 0.09 and 0.99 ± 0.13 after 1 month, 0.99 ± 0.09 and 1.01 ± 0.05 after 1 year, and 1.01 ± 0.05 and 1.02 ± 0.07 after 3 years for the LASIK and surface ablation groups, respectively (Fig. 5). In the total cohort before matching, a higher preoperative spherical equivalent was a risk factor for corneal haze after surface ablation (see Supplementary Material and Supplementary Table S1, available at http://www.iovs.orglookup/suppl/doi:10.1167/iovs.12-9826/-/DCSupplemental).

**DISCUSSION**

In our study, we compared the 3-year efficacy, safety, predictability, and stability of the LASIK and surface ablation procedures. Many investigators have reported the long-term results of LASIK and surface ablation surgeries. Ghadhfan et al. concluded that PRK provided slightly better visual outcomes than LASIK or LASEK in eyes with low-to-moderate myopia.16 For eyes with high myopia, transepithelial PRK produced better visual outcomes than LASIK, LASEK, and other methods of PRK. Shortt et al. performed a meta-analysis of randomized controlled subjects and discovered that the efficacy and safety of LASIK are superior to those of PRK.20 Mohamad et al. reviewed retrospectively 10-year follow-up charts, and concluded that LASIK and PRK have similar long-term efficacy for treatment of high myopia ranging from −10.00 to −18.00 D, with LASIK producing superior visual acuity within the first 2 years.27 Tolbaigy et al. conducted a control-matched comparison of LASIK and LASEK for treatment of low-to-moderate myopia and suggested that, although the visual acuity and refractive results favored LASEK, the differences were not clinically significant.17 Scerrati et al. compared the results of 60 myopic eyes that had undergone LASIK surgery to those of 60 that had undergone LASEK surgery and found that the visual efficacy was better in the LASEK group than in the LASIK group.18 Kim et al. concluded, after reviewing results from 470 highly myopic eyes, that LASIK surgery was superior to LASEK.19 The results of the previous studies are not consistent and have issues associated with their retrospective nature, such as inter-observer bias. Our study aimed to overcome these problems by using propensity score matching and CRF preparation.

Although myopic regression was observed in the surface ablation group through postoperative years 1 and 2, this difference did not affect visual acuity significantly. Our study revealed that the most common complication of laser refractive surgery is the induction of dry eye disease (DED). However, limited data were available for the Schirmer test, TBUT, subjective symptom score, and objective signs, precluding further investigation of DED after surgery. The most common
significant complication that adversely affected BSCVA was corneal haze, which occurred 8 times more frequently after surface ablation. The incidence and severity of corneal haze are correlated positively with the preoperative refractive error, and our study revealed that myopia worse than −6.0 D and central corneal thickness <500 μm are risk factors for corneal haze. PRK no longer is recommended for patients with high myopia, and the phakic IOL is preferred over LASIK for these patients, especially when the corneas are relatively thin. In both groups, most of the cases of corneal haze occurred during the first 6 months; therefore, late occurrence may not be a concern. The cohort group before matching was analyzed to determine the details of the risk for corneal haze following surface ablation. The incidence rates of corneal haze at the final follow-up visit were 4.6% for eyes with myopia less severe than −6 D, 16.0% for those with high myopia between −6 and −10 D, and 16.1% for those with extremely high myopia worse than −10 D. The hazard ratio increased to 3.33 for eyes with high myopia and 2.47 for those with extremely high myopia relative to those with myopia less severe than −6 D. Kim et al. examined the 3-year results of PRK on 35 consecutive eyes with myopia ranging from −2 to −6 D and reported a 34.3% frequency of trace corneal haze. In our study, the incidence of corneal haze was much lower in patients with myopia less severe than −6 D. Long-term studies have shown varied rates of corneal haze: O’Connor et al. reported 17.2% after 12 years, Rajan et al. 4% after 12 years, and Shojaei et al. 3.09% of patients with trace haze 8 years after PRK. The results of our study agreed with all except O’Connor et al. This difference may be due to factors, such as the use of mitomycin-C (MMC) soaking, chilled balanced salt solution (BSS) immediately after ablation, postoperative therapeutic contact lenses, and topical anti-inflammatory drugs. Another consideration is the degree of corneal haze. We reviewed the corneal status in the patient records for significant haze, so trace corneal haze would have been lost during data collection.

Our study has some limitations. First, the rate of missing follow-up data was substantial: the 577 matched subjects in each group at the time of surgery decreased to 571 and 558 after 1 month, 400 and 447 after 3 months, 272 and 284 after 6 months, 181 and 179 after 1 year, 95 and 60 after 2 years, and 58 and 21 after 3 years in the LASIK and surface ablation groups, respectively. As the surgeries were performed in authorized university hospitals, which are tertiary eye-care centers, the loss of patients may reflect no experience of complications or discomfort rather than recruitment to other clinics. Second, as this was a multicenter study, there was no control over the number or uniformity of surgeons or technicians performing the preoperative examinations. The equipment used for preoperative measurements, such as the auto refractometer (RK-F1; Canon, Tokyo, Japan) and ORB II (Bausch & Lomb), and the surgical instruments, including those used for flap creation (LSK2 Carriazo-Barraquer manual microkeratome; Moria, SA), were used uniformly across the institutions. However, those used for laser ablation (VISX S2 or S4 [VISX, Inc.], Technolas 217z [Bausch & Lomb], and MEL80 [Carl Zeiss]), the detailed skills, preferred operations, or nomograms might have differed among surgeons. Our study focused on the overall surgical outcomes in Korea, and we therefore ignored the limitations inherent to the multicenter nature of the study. To overcome some of the weaknesses of the multicenter study design stemming from the variable preoperative, operative, and postoperative factors, a CRF was completed after consultation with investigators from each center. Third, refractive surgery continues to evolve rapidly, and all studies investigating the efficacy and safety of refractive surgery have essential limitations; for example, laser ablation

### Table 4. Hazard Ratios for Corneal Haze in Eye that Underwent LASIK and Surface Ablation for Myopia

<table>
<thead>
<tr>
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<th>Hazard Ratio</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Unadjusted survival model</td>
<td>10.80</td>
<td>7.09, 16.24</td>
</tr>
<tr>
<td>Adjusted survival model**</td>
<td>9.28</td>
<td>5.56, 16.06</td>
</tr>
<tr>
<td>Unadjusted survival model using propensity-matched cohort†</td>
<td>8.04</td>
<td>3.16, 20.42</td>
</tr>
<tr>
<td>Adjusted survival model using propensity-matched cohort‡</td>
<td>8.67</td>
<td>3.37, 22.30</td>
</tr>
</tbody>
</table>

** Age, preoperative UCVA, SE, CCK, keratometry, and corneal size.
† Matching variables: age, UCVA, BSCVA, IOP, MRSE, corneal thickness, and all interaction terms of matching variables.
‡ Keratometry and corneal size.

![Figure 5](image-url)  
**Figure 5.** The cumulative incidence of corneal haze in propensity-matched eyes that underwent LASIK or surface ablation for treatment of myopia.
Multicenter Study of LASIK and Surface Ablation 7121

no longer is used routinely for eyes with high myopia, as it has been replaced by a newer generation of phakic IOLs. In addition, the use of femtosecond lasers for flap creation for LASIK also has become popular owing to its safety and consistency. Lastly, confounding factors not included in the propensity score potentially could introduce bias. Yang et al. reported that untreated allergic conjunctivitis is a significant risk factor for haze and myopic progression after PRK. However, this study enrolled subjects who were followed for 5 years, and it is highly unlikely that ocular surface disease would go untreated in such patients. Tabbara et al. showed that the incidence of corneal haze after PRK was significantly higher among patients with brown irides. Until very recently, Korea was considered largely to be a racially homogeneous, intolerant country with little or no experience with large-scale immigration. Therefore, another advantage of this study is that the subjects were racially homogeneous.

In conclusion, the results of our propensity score-matched study suggested that LASIK and surface ablation provided similar visual efficacy once postoperative corneal healing was achieved. The procedures offered similar predictability, although myopic regression was observed more frequently in the surface ablation group. Corneal haze after surface ablation is much more common than reported previously. However, despite our use of statistical techniques intended to control for different sources of bias, it is difficult to draw a definite conclusion from our study.

Acknowledgments
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References