INTRODUCTION

Advanced surface ablation has become the preferred corneal refractive surgery for many refractive surgeons. This is due to fewer complication rates compared to laser in situ keratomileusis (LASIK) specifically, no flap- and flap-related complications, and very minimal risk of ectasia. In Saudi Arabia and similar regions with a very high incidence of vernal keratoconjunctivitis and consequently, keratoconus and keratoconus suspects, surface refractive treatments may be more appropriate. Laser-assisted subepithelial keratomileusis (LASEK), and recently, epithelial laser in situ keratomileusis (Epi-LASIK) are surface ablation procedures, where an epithelial flap is created and preserved, which combines the advantages of both LASIK and photorefractive keratectomy (PRK), while mitigating the complications of both procedures. Although Epi-LASIK represents a recent development in refractive surgery technology, I personally prefer performing LASEK to avoid using the suction ring and the significant increase in intraocular pressure. In my opinion, performing LASEK means “stress free refractive surgery.” This study evaluated the efficacy, predictability, and safety of LASEK for the treatment of myopia and myopic astigmatism.
MATERIALS AND METHODS

Study design
Approval from the Institutional Review Board of Magrabi hospitals was obtained for the study, and a chart review was performed of 250 eyes that underwent LASEK. All surgeries were performed by the same surgeon (F.M.T.) between July 2008 and January 2010. The database was compiled by excluding all eyes that had a preoperative manifest sphere greater than 7.50 diopters (D), hyperopic sphere, cylinder of more than 3.00 D, preoperative best spectacle corrected visual acuity (BSCVA) of 20/40 or worse, and cases targeted for near or partial correction.

Patients
A total of 173 eyes were reviewed after excluding 77 eyes which did not meet the inclusion criteria. All patients were 18 years of age or older and had between 0.00 D and −7.50 D of myopia with up to −3.00 D of astigmatism. The preoperative evaluation included uncorrected visual acuity (UCVA; LogMAR notation), best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, ocular dominance, slit-lamp examination, keratometry, tonometry, pachymetry, placido disk-based computerized videokeratography, elevation-based computerized videokeratography (Pentacam, Oculus GmbH. Wetzlar, Germany), aberrometry (OPD-Scan, Nidek Co. Ltd., Gamagori, Japan), mesopic pupil size measurement using a pupillometer, and dilated fundus examination.

Surgical procedure
After topical anesthesia, a lid speculum was inserted, a semisharp circular well was used to administer 25% alcohol for 25-30 seconds on the corneal epithelial surface. Prior to alcohol exposure, positioning marks were used to mark the corneal surface. The margins of the delineated area were freed using vannas scissors and jeweler’s forceps and leaving 2-3 clock-hours of intact margins for the hinge. The loosened epithelium was then peeled back using a Merocel sponge. After standard laser ablation, the epithelial sheet was gently repositioned using intermittent irrigation. The epithelium was carefully realigned using the preplaced positioning marks and allowed to dry for 3-5 minutes. A combination of antibiotics and steroids eye drops was applied, followed by placing a bandage contact lens to reduce the mechanical friction by the eyelid and to reduce postoperative pain. The CXIII excimer laser (Nidek Co. Ltd., Gamagori, Japan) was used for laser ablation. The humidity in the Jazan area is very high reaching up to 90%; hence a dehumidifier was used in the room to reduce humidity to 40%.

Prophylactic mitomycin-C (MMC) 0.05% was applied for 15-60 seconds in eyes that had more than 70 µm of ablation, to reduce the risk of haze formation.

The postoperative regimen varied according to the depth of ablation. If the depth of ablation was more than 70 µm, topical antibiotics and prednisolone acetate 1% eye drops four times per day for 2 weeks, followed by fluorometholone for 2-3 months on a tapered dose was prescribed. If less than 70 µm of ablation, topical antibiotics and prednisolone acetate 1% eye drops four times per day for 1 week, followed by fluorometholone for 1 month on a tapered dose was provided. Lubrication was prescribed as required. Patients were reviewed every day or every other day until corneal epithelial healing was complete. After complete re-epithelialization, patients were followed up at 2 weeks, 1 and 3 months.

Data acquisition and analysis
All visual acuity measurements were reported as minus logarithm of minimum angle of resolution (LogMAR). Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, 15.0) software. Descriptive data and frequency graphs were plotted and the data are presented based on Holladay’s recommendations.

RESULTS

The study cohort comprised 173 eyes of 91 patients who underwent LASEK. There were 29 males and 62 females. The mean age was 26.72 ± 5.1 years (range, 18 years to 40 years). Table 1 demonstrates that the mean preoperative spherical equivalent refraction was −3.71 diopters (D) ± 1.63 D (range, −0.88 D to −8.25 D). The mean preoperative LogMAR BSCVA was −0.0374 ± 0.0767 (range −0.47 to 0.00) and the mean follow-up was 32 weeks.

Epithelial separation and postoperative re-epithelialization
As healing progressed, the migrating new epithelium gradually replaced the epithelial sheet over 2-10 days. Complete epithelialization occurred in 4.70 ± 2.09 days [Figure 1]. Complete epithelial healing occurred by the fifth postoperative day in 75% of the eyes.

Efficacy
The mean UCVA at the final visit was 0.04674 ± 0.07710

Table 1: Preoperative information of the study population

<table>
<thead>
<tr>
<th></th>
<th>Range</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
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</thead>
<tbody>
<tr>
<td>LOGBSCVA</td>
<td>0.47</td>
<td>-0.47</td>
<td>0.00</td>
<td>-0.0374</td>
<td>0.07670</td>
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<tr>
<td>MRxsph</td>
<td>7.5</td>
<td>-7.50</td>
<td>0.00</td>
<td>-3.4021</td>
<td>1.64603</td>
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<tr>
<td>MRxcyl</td>
<td>3.00</td>
<td>-3.00</td>
<td>0.00</td>
<td>-0.6185</td>
<td>0.6980</td>
</tr>
<tr>
<td>SE</td>
<td>7.38</td>
<td>8.25</td>
<td>-0.875</td>
<td>-3.711</td>
<td>1.6338</td>
</tr>
<tr>
<td>Pupil diameter</td>
<td>5.00</td>
<td>2.00</td>
<td>7.00</td>
<td>5.3324</td>
<td>0.6082</td>
</tr>
<tr>
<td>Follow-up (in days)</td>
<td>767</td>
<td>5</td>
<td>772</td>
<td>225.56</td>
<td>230.333</td>
</tr>
</tbody>
</table>
Predictability
The mean postoperative spherical equivalent was $-0.05 \pm 0.335 \text{D}$ (range $-1.63 \text{ to } 1.00 \text{D}$) [Table 2]. One sixty-four (94.94%) and all the eyes (100%) were within $\pm 0.50 \text{ D}$ and $\pm 1.00 \text{ D}$ of the attempted correction respectively [Figure 3].

Safety
The mean postoperative BSCVA was $-0.0164 \pm 0.0497$ (range, $-0.3010 \text{ LogMAR to } 0.124 \text{ LogMAR}$). Figure 4 depicts that at the final follow-up visit, two eyes (1.32%) lost two lines [Figure 4]. More than two-thirds of eyes (68.9%) had no loss of postoperative BSCVA and no eye lost more than two lines, 22.4% of eyes gained one line to four lines. Overall, the safety index which is the ratio of mean postoperative BSCVA to mean preoperative BSCVA at the final visit was 1.05.

Corneal Haze and Postoperative Complications
At final visit, 79.7% of the operated eyes had a clear cornea. More than one-sixth (17.34%) of the eyes developed grade 1 haze while only 2.89% eyes developed grade 2 haze. No eyes developed grade 3 or 4 haze [Figure 5].

Postoperative Pain
The only postoperative complications observed was pain with 90.7% of the patients experiencing mild pain. Only two patients (1.2%) had moderate pain and 14 patients (8.1%) had severe pain [Figure 6].

**DISCUSSION**

LASEK has become a viable alternative to previous procedures as it avoids flap related complications in LASIK and the slow visual recovery of PRK. Furthermore, LASEK has been found to have similar predictability, efficacy, safety, and patient satisfaction to PRK and LASIK for the treatment of mild to moderate myopia. LASEK has similar effectiveness to epi-LASIK for the correction of myopia. Conversely, Reilly and colleagues have established that Epi-LASIK has a slight advantage over PRK and LASEK in the early postoperative course with regard to pain and haze.

Pirouzian and colleagues concluded from their clinical trial comparing LASEK and PRK that patient satisfaction with postoperative visual acuity was equal between PRK and LASEK at 30 days postoperatively. However, they received contrasting perceptions from patients regarding the duration of the procedure and usage of an epithelial scrubber. About half of their patients preferred PRK over LASEK because of the faster surgical time. Alternately, the other half of patients preferred LASEK because they did not prefer the use an epithelial scrubber during the PRK procedure.

In the present study, epithelial separation was successfully performed with alcohol in all eyes without complications. The epithelium was easily repositioned over the corneal surface and edges were aligned to the initial margin but often the epithelial flap extended beyond the margin. Postoperatively the epithelium remained attached without significant dislodging or breakdown. The epithelial border migrated from the corneal periphery towards the center of the corneal surface during the healing phase.

Seventy-five percent of the eyes showed complete epithelial healing by the fifth day while Feit et al., have observed that 78% of 101 eyes had undergone healing by the third day. The difference between studies could be due to the retrospective design of the past study. However, there was agreement in the mean LogMAR UCVA between the studies which was 0.03 in Feit et al.’s study and 0.04 in our study.

Several reports in the literature have documented the safety, efficacy, and predictability of LASEK. Shahinian and Azar found that all the patients demonstrated an UCVA of 20/40 or better. In the present study, 63.0% of the study cohort presented with UCVA of 20/20 or better and all the subjects had 20/40 or better which is similar to Vandorselaer et al. who observed 96% eyes with UCVA of 20/40.

We used the CXIII excimer laser (Nidek Co. Ltd.) for laser ablation in the present study and we found that all the eyes were within $\pm 1.00 \text{ D}$ of the attempted correction. Although the procedure was performed in a hot and very humid region, we did not get significant under corrections. This is likely due to two factors—the nomogram and the use of the dehumidifier. Our personalized nomogram targets an over correct of 0.25 D to two factors—the nomogram and the use of the dehumidifier. Our personalized nomogram targets an over correct of 0.25 D especially for younger patients. The dehumidifier reduces the humidity at the operating room; hence moisture does not affect the ablation of the cornea. The mean postoperative spherical equivalent ($-0.05 \pm 0.335 \text{ D}$) was similar to the findings from the previous reports.

**Table 2: Refractive outcome of the study**

<table>
<thead>
<tr>
<th></th>
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<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRRx sphere post-op</td>
<td>2.5</td>
<td>−1.25</td>
<td>1.25</td>
<td>0.079</td>
<td>0.319</td>
</tr>
<tr>
<td>MRRx cylinder post-op</td>
<td>1.25</td>
<td>−1.25</td>
<td>0</td>
<td>−0.315</td>
<td>0.343</td>
</tr>
<tr>
<td>MRx SE</td>
<td>2.63</td>
<td>−1.63</td>
<td>1.00</td>
<td>−0.050</td>
<td>0.335</td>
</tr>
</tbody>
</table>
Some of the results of the present study differ from previous reports.\textsuperscript{19,21,22} For example, in the present study, 68.9% of the cohort did not lose postoperative BSCVA and 2.89% eyes had corneal haze grade 2. These outcomes differ from previous studies\textsuperscript{19,21,22} which reported that none of the eyes lost any line or had haze worse than grade 1. This dissimilarity could be
attributed to the longer postoperative follow-up of more than one year\textsuperscript{21,22} or smaller sample size\textsuperscript{25} compared to the present study. However there is ample evidence that postoperative haze after LASEK is a safety concern.\textsuperscript{20,22-27}

Though Lee et al.,\textsuperscript{7} Azar et al.,\textsuperscript{17} and Kornilovsky\textsuperscript{25} reported pain in only 66.6\%, 53\% and 63\% of patients respectively, it was interesting to note that all the patients in the present study reported some grade of pain while only 16 patients complained of moderate to severe pain.

In conclusion, LASEK was effective, predictable, and safe for the treatment of low myopia and myopic astigmatism. No sight threatening complications were observed other than pain and haze. However, long-term prospective studies of effectiveness and safety of LASEK are warranted.

REFERENCES