ABSTRACT

PURPOSE: To evaluate results of two surface excimer laser refractive surgery techniques—photorefractive keratectomy (PRK) and butterfly laser epithelial keratomileusis (butterfly LASEK).

METHODS: A prospective, randomized, double-masked study of 51 patients (102 eyes) who underwent laser refractive surgery. One eye of each patient was randomized to be operated with PRK and the fellow eye with butterfly LASEK. Patients were followed for 1 year.

RESULTS: No significant difference between groups for distance uncorrected visual acuity (UCVA) \((P=0.559)\) was noted. At 1 year, 98\% (50 eyes) in the PRK group and 96.1\% (49 eyes) in the butterfly LASEK group reached UCVA of 20/20. Predictability, efficacy, safety, and stability were not statistically significant between groups. Safety index was 1.0 for PRK and 0.996 for butterfly LASEK. One eye in the butterfly LASEK group lost one line of best-spectacle corrected visual acuity. At 12 months, 94.1\% (48 eyes) and 86.3\% (44 eyes) in the PRK and butterfly LASEK groups \((P=0.188)\), respectively, had a spherical equivalent refraction of \(\pm 0.50\) diopters. Slight haze was observed in both groups. A statistical difference in haze between the groups was observed only in the first postoperative month, with higher intensity in the butterfly LASEK group \((0.18\pm0.39)\) compared to the PRK group \((0.08\pm0.21)\) \((P=0.04)\).

CONCLUSIONS: Butterfly LASEK had similar predictability, efficacy, safety, stability, and haze incidence to PRK for the treatment of low to moderate myopia. However, on the second postoperative day, PRK showed better UCVA than butterfly LASEK. [J Refract Surg. 2008;24:671-684.]

The corneal healing process with various refractive surgery techniques has been under investigation for many years. Proper postoperative corneal healing is fundamental in corneal health maintenance and visual recovery and is a determining factor in the efficacy and safety of the surgical procedures. In refractive surgery, an improper healing is primarily responsible for the development of hypercorrections, hypocorrections, and corneal haze.1,2 Laser epithelial keratomileusis (LASEK) was developed for the purpose of improving corneal healing and consequently accelerating the visual recovery while reducing postoperative discomfort and haze formation associated with photorefractive keratectomy (PRK).3 Laser epithelial keratomileusis has become a viable alternative to PRK and LASIK in select patients. However, some studies have not shown the expected benefits of LASEK compared to PRK.4-6 Vinciguerra and Camesasca7 reported a new technique—butterfly LASEK—in 2002 with the aim of improving LASEK results. Butterfly LASEK preserves the connections between flap epithelial cells and limbal cells, consequently reducing epithelial damage. In 2003, Vinciguerra et al8 reported results of a 1-year study of 542 eyes. The surgeries were performed in patients with myopia of \(\leq 22.50\) diopters (D) (preoperative mean spherical equivalent refraction was \(-5.30\pm3.70\) D). It showed butterfly LASEK to be a safe procedure with excellent results, comparable to or better than PRK and LASIK.

Until 2007, Vinciguerra et al8 was the only butterfly LASEK technique study published in the literature, but it was not prospective, controlled, nor comparative. Therefore the in-
individual differences, advantages, and disadvantages between PRK and butterfly LASEK are not known. The aim of our study was to evaluate and compare the results of PRK and butterfly LASEK techniques.

**PATIENTS AND METHODS**

This prospective, randomized, double-masked study involved 102 eyes of 51 patients undergoing excimer laser refractive surgery at the Sadalla Amin Ghanem Eye Hospital, performed by the same surgeon (V.C.G.) from August to October 2004. One eye of each patient was randomly selected to be operated with PRK and the fellow eye with butterfly LASEK. Randomization was carried out by using a box containing 26 pieces of paper (13 written PRK and 13 written butterfly LASEK) and another box with 26 pieces of paper (13 right eye and 13 left eye). When the patient arrived at the hospital the assistant picked a piece of paper from each box thus indicating the technique and the eye to be operated. Best spectacle-corrected visual acuity (BSCVA) was 20/20 in all eyes. All patients had stable refractions for ≥1 year.

The study included patients aged 21 to 36 years with 1.50 to 5.50 diopters (D) of myopia, negative astigmatism ≤1.50 D, spherical anisometropia ≤1.50 D, and follow-up ≥1 year. Patients with ocular illness, including strabismus, or previous ocular surgery were excluded. Patients suffering from systemic autoimmune illness, diabetes, or women who were pregnant or breastfeeding were also excluded.

Two (3.9%) of the 51 butterfly LASEK eyes had to be converted to PRK because the epithelial flap disintegrated. We were able to perform butterfly LASEK in the fellow eye.

Preoperative ophthalmologic examination included monocular distance visual acuity, with and without correction; monocular near uncorrected visual acuity (UCVA) using the Jaeger chart at 40 cm; distance and near cover test; external ocular exam; slit-lamp microscopy; type 1 Schirmer test without anesthetic; computerized corneal topography; Orbscan (Bausch & Lomb, Rochester, NY); manifest and cycloplegic refractions, but only the cycloplegic refraction was used for analysis; central corneal ultrasound pachymetry; Goldmann applanation tonometry; and indirect ophthalmoscopy including a retinal periphery examination under mydriasis.

The results of these tests were recorded, along with the patient’s initials, age, gender, race, and profession.

**SURGICAL TECHNIQUES**

Three drops of proximetacaine cloridrate (Anestalcon; Alcon, São Paulo, Brazil) were administered 20 minutes before surgery (observing at 5-minute intervals), and one drop of tetracaine cloridrate with phenylephrine hydrochloride and boric acid (Anestesico; Allergan, Guarulhos, Brazil) administered 5 minutes before surgery. Asepsis of the hemiface of the operated eye was performed with povidone 10%, without direct contact on the ocular surface, followed by sterile physiologic saline solution for 10 seconds. A sterile drape and blepharostat with aspiration were used. Paracetamol 750 mg (Tylenol; Janssen-Cilag, São José dos Campos, Brazil) tablets were given to the patients 30 minutes before surgery.

One drop of each gatifloxacin 0.3% (Zymar; Allergan) and ketorolac tromethamine 0.5% (Acular; Allergan) were administered after the PRK and butterfly LASEK photoablation. A therapeutic contact lens (Acuvue 2; Johnson & Johnson, Limerick, Ireland) was fitted at the end of the surgery.

**PHOTOREFRACTIVE KERATECTOMY**

After marking the ocular axis with a Sinskey hook (Katena Products Inc, Denville, NJ), the corneal epithelium to be removed was delimited using an 8.5-mm ring, centered in the previous mark. The epithelium was removed with a blunt spatula and photoablation was performed.

**BUTTERFLY LASER EPITHELIAL KERATOMILEUSIS**

After the visual axis was marked, a linear abrasion was created in the corneal epithelium from 8 o’clock to 11 o’clock (paracentral to the visual axis) with a fine Sinskey hook. With the 8.5-mm ring centered in the mark, pressure was applied on the cornea and two drops of 20% diluted alcohol in balanced saline solution were administered, which remained in contact with the epithelium for 20 seconds until removal with a surgical sponge (Merocel; Medtronic Ophthalmics, Jacksonville, Fla). Two epithelial semi-disks were created using a blunt spatula, maintaining the broadest possible joint area between the semi-disks and peripheral epithelium, while leaving Bowman’s layer exposed in the 8-mm center. Following photoablation, the epithelial semi-disks were repositioned and the surface was left to dry for 3 minutes.

**POSTOPERATIVE FOLLOW-UP**

Postoperatively, manifest refraction was performed only on day 14, with cycloplegic refraction being performed at later postoperative evaluations. Gatifloxacin 0.3% and ketorolac tromethamine 0.5% eye drops were used every 6 hours, tobramycin 0.3% and dexamethasone 0.1% every 8 hours, and several drops of physiologic saline solution 0.9% every 2
hours (while awake) until the therapeutic contact lens was removed. The flasks of the physiologic saline solution were changed daily. After the contact lens was removed, hypromellose (Genteal; Ciba, Annonay, France) eye drops were administered 4 times daily until the flask was emptied, and flurometholone acetate 0.1% (Florate; Alcon) was administered 4 times daily for 1 month, then tapered to 3 times daily for 1 month and 2 times daily for 1 month. The hypromellose eye drops were continued according to patient discomfort after having finished the first flask. Patients were advised to maintain a minimum interval of 15 minutes between eye drops, and to keep the eyes closed for 1 minute, except in the case of the hypromellose. Ascorbic acid (vitamin C) 500 mg every 12 hours for 4 months was prescribed. Postoperative evaluations were performed at 2 and 4 days, 2 weeks, and 1, 3, 6, and 12 months. Just before surgery, each patient received a follow-up schedule, which included a detailed postoperative regimen. The patient was also re-oriented at each visit.

If any visible epithelial defect was present at the end of the 4th postoperative day, the therapeutic contact lens was maintained and daily evaluations were performed until reepithelization was complete. Before contact lens removal, several drops of physiologic saline solution were instilled. If epithelial defects were observed after contact lens removal, the lenses were replaced with new ones, which remained until reepithelization was complete. At postoperative day 14 and thereafter, visual quality was evaluated subjectively. Before visual acuity was evaluated, the patient was questioned which eye he/she believed to have the best visual quality or if it was the same. Then visual acuity measurement was performed. If the patient missed one or two letters of the 20/20 line, UCVA was considered 20/20− or 20/20−−, respectively. Corneal haze was defined according to the haze grade described by Fantas et al9: grade 0.5 indicates trace haze, seen with careful oblique illumination with slit-lamp microscopy; grade 1.0, more prominent haze that does not interfere with visibility of fine iris details; grade 2.0, mild obscuration of iris details; grade 3.0, moderate obscuration of the iris and lens; and grade 4.0, completely opaque stroma in the area of ablation.

**STATISTICAL ANALYSIS**

Parametric calculations were used for the numerical variables and non-parametric calculations were used for categorical or nominal variables and proportions. A P value of <.05 was considered statistically significant. Data were analyzed using Microsoft Excel 2000 (Microsoft; Redmond, Wash); Statistica for Windows (StatSoft Inc, Tulsa, Okla) release 5.0 A, 1995; Minitab (Minitab Inc) release 14.2, 2005; SPSS for Windows (SPSS Inc, Chicago, Ill) release 10.0.1, 1999; and NCSS release 2000.

**RESULTS**

One hundred two eyes of 51 patients (18 [35%] men, 33 [65%] women) were evaluated. Patient age ranged from 21 to 36 years (mean: 28.06±4.13 years). Patients were clinically followed for 12 months. Fifty-one eyes underwent PRK: 24 (47%) right eyes and 27 (53%) left eyes. Conversely, of the 51 eyes undergoing the butterfly LASEK technique, 27 (53%) were right and 24 (47%) were left. When these proportions were compared, no statistically significant differences were observed ($\chi^2=0.16$ and $P=.692$).
Patients were followed for 12 months. During the postoperative period, until the removal of the therapeutic contact lens, no patient missed any visit. Two patients missed follow-up on postoperative day 14, one patient at month 1, one at month 3, one at month 6, and none at month 12. No patient missed more than one required evaluation.

**DISTANCE UNCORRECTED VISUAL ACUITY**

Mean preoperative distance UCVA in both groups was similar \( (P=0.287) \) at approximately 20/250 (logMAR 1.1) (Table 1). On postoperative day 2, PRK showed better distance UCVA (mean: 20/60; logMAR 0.47) than butterfly LASEK (mean: 20/70; logMAR 0.56) \( (P=0.025) \). On postoperative day 4, a slight improvement was noted when compared to postoperative day 2. On postoperative day 14, both groups showed similar results with an approximate mean UCVA of 20/30 \( (P=0.108) \). On postoperative day 30, PRK again showed better distance UCVA (mean: 20/25+; logMAR 0.08) than butterfly LASEK (mean: 20/25−; logMAR 0.11) \( (P=0.034) \). From the 3rd through the 12th postoperative months, no significant difference between groups was noted.

**EFFICACY**

In postoperative month 1, 43% (44 eyes) had distance UCVA of 20/20 (including 20/20− and 20/20−−), whereas UCVA in months 3, 6, and 12 was 89% (91 eyes), 96% (98 eyes), and 94% (96 eyes), respectively (Fig 1). At postoperative month 12, 98% (50 eyes) in the PRK group and 96% (49 eyes) in the butterfly LASEK group achieved UCVA of 20/20. No statistically significant difference was noted between groups \( (P=0.559) \). Uncorrected visual acuity of 20/25 or better was achieved in 100% (102 eyes) in both groups.

**NEAR UNCORRECTED VISUAL ACUITY**

Table 2 and Figure 2 show gradual improvement in near UCVA that was more accentuated on the 14th postoperative day, but stabilized after month 3. During the preoperative period, PRK patients had significantly better near UCVA \( (2.2) \) than butterfly LASEK patients \( (2.41) \) \( (P=0.04) \). On postoperative day 2, the PRK patients continued to present with better near UCVA \( (3.61) \) compared to butterfly LASEK \( (4.41) \) \( (P=0.048) \). No difference between groups was observed on postoperative days 4 and 14, and 1, 3, 6, and 12 months.

On postoperative day 14, 72.5% (74 eyes) presented near UCVA of J1, 93.1% (95 eyes) in month 1, and 100% (102 eyes) in month 3.

**DISTANCE BEST SPECTACLE-CORRECTED VISUAL ACUITY**

A worsening of distance BSCVA was observed on postoperative day 14 compared to preoperative values, with recovery by month 3 (Table 3). This improvement occurred quickly in postoperative month 1 and gradually from months 1 through 3.

Distance BSCVA was similar between groups in the preoperative evaluation \( (P=0.451) \) and at all postoperative evaluations until month 12, except in postoperative month 1. A better BSCVA was observed in the PRK group \( (20/20−); \logMAR 0.04 \) compared to the butterfly LASEK group \( (20/20−−); \logMAR 0.06 \) \( (P=0.032) \).

**SAFETY**

In the first postoperative month, 67 (66%) eyes had BSCVA of 20/20 (including 20/20− and 20/20−−); of these, 37 (55%) eyes were in the PRK group and 30 (45%) eyes were in the butterfly LASEK group. Ninety-nine percent, 100%, and 99% of eyes had BSCVA of 20/20 in postoperative months 3, 6, and 12, respectively. Mean preoperative decimal BSCVA was 1.0 in both groups, whereas BSCVA was 1.0 in the PRK group and 0.996 in the butterfly LASEK group at 12 months. Safety index was 1.0 and 0.996 in the PRK and butterfly LASEK groups, respectively. One eye in the butterfly LASEK group lost one line of BSCVA at 12 months.
(20/25), without a detectable cause. No other patient from either group had a loss of one or more lines.

**Spherical Cycloplegic Refraction**

Table 4 shows a slight hypercorrection of 0.50 D in both groups occurring in postoperative month 1, but gradual regression of 0.25 D up to month 3. From the 6th to 12th postoperative month, a tendency for regression is observed.

From the 3rd to 6th month, the PRK group presented lower spherical refraction than the butterfly LASEK group, but no difference was observed in the 12th postoperative month (Table 4).

**Cylindrical Cycloplegic Refraction**

The cylindrical refraction (refractive astigmatism) did not show a statistically significant difference between groups at any evaluation. During the preoperative period, mean cylindrical refraction was $-0.71\pm0.37$ D in the PRK group and $-0.70\pm0.33$ D in the butterfly LASEK group ($P=.955$). Mean cylindrical refraction at last follow-up was $-0.19\pm0.23$ D (range: 0 to $-0.75$ D) in the PRK group and $-0.15\pm0.22$ D (range: 0 to $-0.75$ D) in the butterfly LASEK group ($P=.536$). In the 1st postoperative month, 87% of patients (89 eyes) presented cylindrical refraction $\leq0.50$ D, and 100% (102 eyes), 99% (101 eyes), and 97% (99 eyes) in months 3, 6, and 12, respectively. In the 12th postoperative month, three eyes had cylindrical refraction $>0.50$ D, with two eyes from the PRK group ($-0.75$ D in both cases) and one from the butterfly LASEK group ($-0.75$ D).

**Defocus Equivalent**

The defocus equivalent showed no statistically

**Table 2**

<table>
<thead>
<tr>
<th>Postoperative Day</th>
<th>No. of Eyes</th>
<th>PRK</th>
<th>Butterfly LASEK</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
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<td>.039</td>
</tr>
<tr>
<td>2</td>
<td>51</td>
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<td>4.41±1.93</td>
<td>.048</td>
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<td>4</td>
<td>51</td>
<td>4.04±1.84</td>
<td>4.10±1.91</td>
<td>NS</td>
</tr>
<tr>
<td>14</td>
<td>49</td>
<td>1.43±1.02</td>
<td>1.75±1.39</td>
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</tr>
<tr>
<td>30</td>
<td>50</td>
<td>1.10±0.50</td>
<td>1.12±0.59</td>
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</tr>
<tr>
<td>90</td>
<td>50</td>
<td>1.00±0.00</td>
<td>1.00±0.00</td>
<td>NS</td>
</tr>
<tr>
<td>180</td>
<td>50</td>
<td>1.00±0.00</td>
<td>1.00±0.00</td>
<td>NS</td>
</tr>
<tr>
<td>360</td>
<td>51</td>
<td>1.00±0.00</td>
<td>1.00±0.00</td>
<td>NS</td>
</tr>
</tbody>
</table>

PRK = photorefractive keratectomy, LASEK = laser epithelial keratomileusis, UCVA = uncorrected visual acuity, NS = not significant
*Calculated by paired t test.

Figure 2. Near uncorrected visual acuity (UCVA) over time after photorefractive keratectomy (PRK) and butterfly LASEK (BLASEK). On the 2nd postoperative day, PRK presented better near UCVA than butterfly LASEK. Gradual improvement was observed (more accentuated on the 14th postoperative day) with stabilization after the 3rd postoperative month.
significant difference between groups at any evaluation. Preoperatively, mean defocus equivalent was 3.38±1.35 D in the PRK group and 3.53±1.41 D in the butterfly LASEK group (P=.6). At last follow-up, the mean was 0.32±0.29 D (range: 0 to 1.00 D) in the PRK group and 0.38±0.32 D (range: 0 to 1.25 D) in the butterfly LASEK group (P=.33) (Fig 3).

**SPHERICAL EQUIVALENT REFRACTION**

Spherical equivalent refraction showed no statistically significant difference between the two groups at any evaluation, except in the 3rd postoperative month when the mean of the PRK group (0.13±0.36 D) was lower than in the butterfly LASEK group (0.31±0.39 D) (P=.017) (Table 5, Fig 4). Mean spherical equivalent refraction was −3.17±1.26 D in the PRK group and −3.31±1.34 D in the butterfly LASEK group (P=.601). At last follow-up, the mean was 0.12±0.33 D (range: +0.75 to −0.88 D) in the PRK group and 0.16±0.41 D (range: +1.25 to −0.88 D) in the butterfly LASEK group (P=.614).

**PREDICTIBILITY**

The refraction predictability presented no statistically significant difference between groups (Figs 5 and 6). At 12 months, 94% (48 eyes) and 86% (44 eyes) in the PRK and butterfly LASEK groups, respectively, had spherical equivalent refraction of ±0.50 D (P=.188). One hundred percent (51 eyes) and 98% (50 eyes) in the PRK and butterfly LASEK groups, respectively, were within ±1.00 D (P=.312). Only one eye from the butterfly LASEK group had a spherical equivalent refraction >1.00 D (+1.25 D) from the 3rd to the 12th postoperative month.

**RETREATMENT**

No retreatments were performed during the follow-up period.
STABILITY

No eye presented spherical equivalent refraction variation >1.00 D during follow-up (Fig 7).

SURGICAL TIME

Mean surgical time for the 51 eyes undergoing PRK was 304.9\pm 58.77 seconds (approximately 5 minutes), and 608.4\pm 76.88 seconds (approximately 10 minutes) for the 51 eyes undergoing butterfly LASEK, taking approximately twice as long as the former technique ($t=21.22; P<.001$).

VISUAL QUALITY—PATIENT PREFERENCE FOR PRK OR BUTTERFLY LASEK

No statistically significant difference in postoperative subjective visual quality was observed between groups, despite a slight preference for the PRK technique (Table 6, Fig 8). On the 14th postoperative day, 10 (20.4%) patients preferred the eye operated with the PRK technique and 11 (22.5%) patients preferred butterfly LASEK ($P=.806$). In postoperative month 1, a tendency towards PRK was noted, but was of no statistical significance, and was preferred in 11 (22%) patients, while only 4 (8%) patients showed a preference for butterfly LASEK ($P=.053$). No significant difference was noted for the remaining postoperative period.

The percentage of patients with equal visual quality between both eyes increased with increasing postoperative time and was 57% (29 patients), 70% (36 patients), 90% (46 patients), 92% (47 patients), and 94% (48 patients) on postoperative day 14, and 1, 6, and 12 months, respectively.

INTRAOCULAR PRESSURE

Intraocular pressure (IOP) did not present statistically significant differences between groups in any evaluation. Mean preoperative IOP in the PRK group was 12.86\pm 2.4 mmHg and 12.73\pm 2.5 mmHg in the butterfly LASEK group ($P=.301$). At postoperative month 12, IOP was 11\pm 2.2 mmHg in the PRK group.
Comparison of PRK and Butterfly LASEK/Ghanem et al

Figure 4. Spherical equivalent refractive outcome after photorefractive keratectomy (PRK) and butterfly LASEK (BLASEK). No statistically significant difference between the two groups was noted at any follow-up, except in the 3rd postoperative month when the mean of the PRK group was lower than the BLASEK group.

Figure 5. Attempted versus achieved correction after photorefractive keratectomy (PRK) at 12 months. The interrupted lines represent ±0.50 diopters (D) and the solid lines ±1.00 D of the intended correction. The percentage of eyes presenting spherical equivalent refraction at 12 months in the ±0.50 D range was 94% and 100% in the ±1.00 D range for the PRK group.

Figure 6. Attempted versus achieved correction after butterfly LASEK (BLASEK) at 12 months. The interrupted lines represent ±0.50 diopters (D) and the solid lines ±1.00 D of the intended correction. The percentage of eyes presenting spherical equivalent refraction at 12 months in the ±0.50 D range was 86% and 98% in the ±1.00 D range for the BLASEK group.

and 10.92±2.2 mmHg in the butterfly LASEK group (P=.772).

An average increase in the preoperative IOP of 1.2 mmHg was seen up to the 1st month, with gradual decrease thereafter, reaching preoperative levels around the 3rd postoperative month. The values in month 12 were approximately 2 mmHg lower than preoperative.

On the 14th postoperative day, three eyes from the butterfly LASEK group and one from the PRK group presented IOP higher than 20 mmHg. Three eyes had IOP of 22 mmHg and did not need treatment, while one eye from the butterfly LASEK group reached 31 mmHg, which was medicated with timolol maleate 0.5% twice a day and the topical corticoid (fluorometholone; Florate, Alcon) reduced to twice daily. At 1 month, IOP still presented at 28 mmHg. Prednisolone acetate 0.12% (Predmild; Allergan) once a day for 30 days was used to replace the fluorometholone acetate 0.1%
Fifteen days after beginning prednisolone, the IOP was 16 mmHg, which persisted even without the timolol regimen.

CORNEAL HAZE

The incidence of haze was low for both groups. Only in postoperative month 1 was a statistical difference observed between groups, with higher haze intensity in the butterfly LASEK group (0.18±0.388) compared to the PRK group (0.08±0.21) (P=.034) (Table 7). The highest intensity was observed in month 3, with a gradual reduction up to month 12 (Figs 9 and 10).

The percentage of eyes from the PRK group that did not present haze on postoperative day 14, and 1, 3, 6, and 12 months was 92% (47 eyes), 86% (44 eyes), 84% (43 eyes), 92% (47 eyes), and 92% (47 eyes), respectively, whereas in the butterfly LASEK group it was 86% (44 eyes), 76% (39 eyes), 74% (38 eyes), 86% (44 eyes), and 92% (47 eyes), respectively.

PREOPERATIVE CORNEAL THICKNESS

The arithmetic mean and standard deviation of the preoperative corneal thickness was 539.10±30.73 µm for the PRK group and 541.63±32.52 µm for the butterfly LASEK group. The paired t test showed a statistically significant difference between the two means (t=2.34 and P=.023).

DISCUSSION

Slow postoperative visual recovery and ocular discomfort are limiting factors for both PRK and LASEK. Many people seeking refractive surgery are professionals who cannot be away from work for many days; therefore, they are attracted to procedures such as LASIK, which allows for quick visual recovery despite
Comparison of PRK and Butterfly LASEK/Ghanem et al

the higher risk of intraoperative and long-term complications. With the improvement of lasers, ocular tracing systems, and ablation profiles, it is possible to have a more homogeneous stromal bed, thereby offering a faster visual recovery. However, the visual recovery of surface ablations (PRK or LASEK) depends also on the speed of reepithelization, corneal epithelium reorganization, and the desired correction. Myopia ≤5.00 D presents faster visual recovery with less loss of lines than higher myopias. In our study, the mean distance UCVA on postoperative days 2, 4, and 14 and month 1 was 20/60, 20/50, 20/30, and 20/25, respectively, in the PRK group and 20/70, 20/60, 20/30 and 20/25, respectively, in the butterfly LASEK group. At 2 weeks postoperative, 96% (49 eyes) in the PRK group and 92% (47 eyes) in the butterfly LASEK group were around 20/40 or better. At 4 weeks, 100% (102 eyes) achieved 20/40 or better. Zadok et al reported that 2 and 4 weeks after bilateral PRK, UCVA was 20/40 in at least one of the eyes in 86% and 100% of patients, respectively. It was concluded that most of the patients could resume their daily activities in 2 weeks. Walker and Wilson compared the postoperative visual recovery between PRK and LASIK in patients with ≤5.00 D of myopia. Mean UCVA after 1 week was 20/25 in the PRK group and 20/20 in the LASIK group. The difference was statistically significant (P<.001) in the 1st week, but not in the 1st and 6th postoperative month. Our study appears to show a slower visual recovery. This difference is expected, considering that we used an ablation zone of 8.5 mm and Walker et al used 6 mm. The smaller the deepithelized area for ablation, the faster the reepithelization and visual recovery will be, especially if the surgical technique, excimer laser, desired correction, and postoperative medications are similar. Scerrati showed that good BSCVA was achieved in a shorter time after LASIK than after LASEK, but BSCVA was better in LASEK at the final follow-up. However, Scerrati did not present any statistical analysis, and only 70% of eyes achieved BSCVA of

### TABLE 7

<table>
<thead>
<tr>
<th>Postoperative Day</th>
<th>No. of Eyes</th>
<th>PRK</th>
<th>Butterfly LASEK</th>
<th>P Value*</th>
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<tr>
<td>14</td>
<td>49</td>
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<td>51</td>
<td>0.04±0.14</td>
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<td>NS</td>
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</tbody>
</table>

PRK = photorefractive keratectomy, LASEK = laser epithelial keratomileusis
*Calculated by paired t test.
20/20 6 months after LASIK. These results were worse than expected, with a significant number of eyes losing lines of vision.

Several other studies on visual recovery in LASEK and/or PRK showed similar results to those obtained in our study. However, contrary to the former results, Autrata and Rehurek and Leccisotti showed a significantly faster visual recovery with LASEK compared to PRK at the end of postoperative week 1, but visual recovery was similar after month 1.

A loss of only one line of BSCVA in the butterfly LASEK group for no apparent reason (transparent optical media and regular topography) was seen. The main factor responsible for the loss in visual acuity is haze. The higher the degree of refractive error to be corrected, the higher the haze incidence, which lowers the safety level of the surgery. Both PRK and butterfly LASEK showed excellent safety levels. Some studies did not show loss of BSCVA. In the study by Vinciguerra et al of 542 eyes operated with the butterfly LASEK technique, only 0.3% of eyes lost one line of BSCVA. These were exciting results, considering that patients were operated with up to 22.50 D of myopia. However, until now no other results regarding this technique have been published that would allow comparison and safety assurance. In the study by Shah et al, one line was lost in 14% of eyes operated with LASEK, but none lost two lines. Feit et al showed loss of one line in 8% and two lines in 0.6% of eyes. Research by Autrata and Rehurek did not present statistically significant differences in the safety level between the PRK and LASEK techniques. There was loss of one line in the PRK group and no loss in the LASEK group.

A common complaint among patients operated with PRK or LASEK is the low near UCVA in the first postoperative days. Difficulties for reading or computer work are significant, preventing the patient from resuming work. Despite this, near UCVA evaluations are not performed in PRK or LASEK studies. The near UCVA was similar in both groups in our study, except it was worse in the butterfly LASEK group on postoperative day 2. It was noted that up to the 4th postoperative day, mean
near UCVA was J4, with an improvement to J1 in 73% (37 patients) on day 14. It must be considered that the time needed for this test is minimal, compared to the visual effort required for a work day. Therefore, during the preoperative evaluation for both PRK and LASEK, it is crucial to emphasize early postoperative difficulty with near vision, so the patient can organize his/her professional life.

When comparing two refractive surgery techniques, it is important to evaluate the refractive predictability and the rate of retreatments performed. The lower the procedure’s refractive predictability, the higher the number of retreatments and cost, which is usually associated with lower patient satisfaction. Predictability depends mainly on the preoperative degree of refractive error, surgical technique used, excimer laser technology, and proposed treatment profile. In the predictability of surface ablations, haze and regression are important factors and are proportional to the ablation depth and preoperative degree of refractive error.\(^{10,23,24}\)

In our study, the PRK and butterfly LASEK techniques presented similar refractional predictability at the end of the 12th month, although a higher percentage of patients were closer to emmetropia in the PRK group. The results found in both groups are similar to the ones found in literature. The study by Vinciguerra et al,\(^8\) which described the butterfly LASEK technique, reported that 83% of eyes were between ±0.50 D of spherical equivalent refraction on final postoperative evaluation at 12 months. Other investigations of LASEK noted that in the 6th postoperative month, 83% of eyes were within ±0.50 D\(^{14,17,25}\) and 98% were within ±1.00 D.\(^{17,25}\) Hashemi et al\(^18\) compared PRK with LASEK and reported that 72% and 81%, respectively, of eyes were within spherical equivalent refraction of ±0.50 D, and 94% and 91%, respectively, of eyes were between ±1.00 D at last follow-up. In a study by Autrata and Rehurek,\(^26\) the predictability between PRK and LASEK was also similar, although the percentage of patients between ±0.50 D was slightly lower than in our study. After 2-year follow-up, 62% of eyes operated with PRK and 57% of eyes operated with LASEK were within ±0.50 D of the expected refraction, whereas 92% and 91%, respectively, were within ±1.00 D. No technical variations to justify such results were identified. Refractive predictability for PRK, LASEK, and butterfly LASEK for myopia < −6.00 D is good; therefore, the retreatment rate is low, usually <5%.\(^{8,14,17}\)

According to Feit et al,\(^22\) the retreatment rate with LASEK was 6.7% after 4-year follow-up. In our study, only 1 of the 102 operated eyes remained with a spherical equivalent refraction >1.00 D (+1.25 D). No retreatment was performed as the patient was satisfied with his vision. We report the only study in the researched literature that compared the surgical time of both PRK and butterfly LASEK. Photorefractive keratectomy was performed in approximately half the time. This is due to some surgical steps required only with the butterfly LASEK technique: 1) paracentral linear abrasion; 2) 20-second time for the alcohol application; 3) creation of the epithelial disks; 4) epithelial disk repositioning; and 5) time of 3 minutes to improve adherence of the epithelium. Furthermore, with butterfly LASEK, the separation of the epithelial basal membrane of the corneal stroma must be performed more carefully so as not to impair epithelial disk integrity, which also increases surgical time.

A subjective evaluation was used to determine whether the PRK or butterfly LASEK technique showed better visual quality. Patients were asked to report which eye had better vision at the beginning of the postoperative evaluations, before visual acuity measurements were done. The percentage of patients who noted similar visual quality between eyes increased with longer postoperative follow-up time, reaching 94% (48 patients) in month 12. No statistically significant difference between the techniques was noted. This evaluation method may be challenged, because it is totally subjective. The ideal would be to also objectively evaluate contrast sensitivity and total ocular wavefront, to determine which technique provides a better visual quality. However, we believe the subjective opinion of the patient can be even more important than the numbers obtained from examinations. Patient subjective vision preference on the first postoperative days was not evaluated, as the surgeries were performed within a 2-day interval, but we conjecture there would be preference for the eye that was operated first. Pirouzian et al,\(^8\) when comparing LASEK with PRK in simultaneous bilateral surgeries, observed that all patients chose better vision in the eye operated with PRK. On the 30th postoperative day, preference was similar between the groups (50% for each technique). According to Litwak et al,\(^4\) on the 1st and 3rd postoperative days, most patients selected better vision in the eye operated with PRK in simultaneous bilateral surgeries. No evaluations were done on the subsequent postoperative days. Hashemi et al\(^19\) reported that patient satisfaction with vision was similar between PRK and LASEK in the 1st and 3rd postoperative month.

Haze is one of the more feared complications with surface excimer laser refractive surgery, with an incidence ranging from 0% to almost 20% in the correction of higher diopters,\(^27-29\) increasing to 82% with retreatments.\(^30\) In our study, similar results were observed, with an absence of haze in 92% (94 eyes), grade 0.5 in 7% (7 eyes), and grade 1.0 in 1% (1 eye) in postoperative evaluations of the eye that was operated first. Pirouzian et al,\(^6\) when comparing LASEK with PRK in simultaneous bilateral surgeries, observed that all patients chose better vision in the eye operated with PRK. On the 30th postoperative day, preference was similar between the groups (50% for each technique). According to Litwak et al,\(^4\) on the 1st and 3rd postoperative days, most patients selected better vision in the eye operated with PRK in simultaneous bilateral surgeries. No evaluations were done on the subsequent postoperative days. Hashemi et al\(^19\) reported that patient satisfaction with vision was similar between PRK and LASEK in the 1st and 3rd postoperative month.

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tive month 12. There were no significant differences between the PRK and butterfly LASEK groups, except in the 1st postoperative month where the butterfly LASEK group showed higher haze incidence.

When presenting results of his first patients operated with the LASEK technique, Camellin described haze incidence with grade 0.5 in 20% of eyes and grade 1.0 or higher in 5% of eyes. This can be considered a low incidence, as the refractional error of the patients was high (−8.00 to −22.50 D). Studies are still questionable in relation to the haze incidence when comparing PRK and LASEK, whereby PRK showed equal or higher incidence. Vinciguerra and Camesasca, when presenting their first results with the butterfly LASEK technique in patients with refractional errors between −1.75 and −9.00 D, showed no haze in 96% of eyes and grade 0.5 in just 4% of eyes. Lee et al also showed haze higher in the first month after PRK (0.86 ± 0.45) when compared to LASEK (0.46 ± 0.24) (P = .02). In the 3rd postoperative month, there was a reduction in haze intensity with no statistically significant difference between groups (0.45 ± 0.27 for PRK and 0.29 ± 0.26 for LASEK). However, in our study we observed a lower haze intensity in the 1st and 3rd month when compared to the study by Lee et al, both for PRK (0.08 ± 0.21 and 0.13 ± 0.36, respectively) and for butterfly LASEK (0.18 ± 0.39 and 0.19 ± 0.35, respectively). In this study, haze achieved the highest intensity in the 3rd postoperative month of PRK and LASEK, followed by gradual reduction. We found haze in month 3 in 21% (21 eyes) (12% [12 eyes] grade 0.5; 8% [8 eyes] grade 1; 1% [1 eye] grade 2). Most of the haze cases observed in the cited studies were slight and without significant clinical importance, but some reached incidence of almost 50% in 3 months. The specific cellular events that reduce haze in LASEK surgery are unknown, but it is believed the epithelial disk protects the ablated stroma from contact with tear inflammatory cells and mediators, thereby decreasing apoptosis and necrosis of the keratocytes of the anterior stroma, activation of the keratocytes, and consequently haze formation. Although most of the comparative studies between PRK and LASEK presented more haze incidence in PRK, Litwak et al and Hashemi et al observed no difference. Furthermore, and in accordance with our investigation, Hashemi et al showed a greater tendency for haze formation with LASEK.

Our study included intra-patient comparison of two surface refractive surgery techniques with excimer laser, using the same laser, same surgeon (V.C.G.), same postoperative medication, and similar diopters among eyes. In addition, the study presents high relevance as it was prospective, paired, comparative, masked, and randomized. The following limitations were observed: 1) the bilateral eyes were not operated on the same day, as we believed simultaneous surgery can expose patients to unnecessary risk, especially bilateral infection (but in our opinion, a 2-day difference does not significantly alter the results); and 2) the surgeon performed the postoperative evaluation of all patients. Although the study was masked for the patient and the ophthalmologist performing the postoperative evaluations (V.C.G.), it was possible to identify the technique used in the first postoperative days. Nevertheless, such identification is possible for any ophthalmologist performing the postoperative evaluation. Furthermore, the 102 surgeries were performed in a short period of time (3 months), making it almost impossible to correlate the technique performed with the operated eye after the first postoperative days. Although PRK and LASEK have proven their efficacy, predictability, and safety, the search continues for new techniques with even better results.

From this study we can conclude that butterfly LASEK had similar predictability, efficacy, safety, stability, and haze incidence to PRK in the treatment of low to moderate myopia. However, on the 2nd postoperative day, PRK showed better distance and near UCVA than butterfly LASEK, which may jeopardize patient and surgeon satisfaction when compared to PRK and LASIK.

REFERENCES

Comparison of PRK and Butterfly LASEK/Ghanem et al


