Effects of advanced surface ablations and intralase femtosecond LASIK on higher order aberrations and visual acuity outcome

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Received 4 April 2011; revised 15 April 2011; accepted 17 April 2011
Available online 30 April 2011

KEYWORDS
Advanced corneal surface ablation; iLASIK; Higher order aberrations; Visual acuity; Excimer laser; LASIK; Femtosecond

Abstract Background/aims: To study the changes in wavefront (ocular) and corneal higher order aberrations (HOAs) and visual acuity (VA) outcome following wavefront-guided advanced surface ablation (ASA) techniques and intralase femtosecond LASIK (iLASIK) in myopia treatment.

Methods: Ocular aberration and corneal topography of 240 eyes in the ASA techniques (this was equally divided into a flap-on group where the epithelial flap was preserved and reapplied to the photoablated stromal bed and a flap-off group when the epithelial flap was discarded during the procedure), and 138 eyes in the iLASIK group were obtained before and 3 months following treatment. The correlation of aberrations with best spectacle-corrected visual acuity was analyzed.

Results: At 3 months, there was statistically significant \( P < 0.001 \) surgically induced increase in spherical aberration (SA) in each of the techniques for both ocular and corneal analysis. iLASIK induced significantly less ocular and corneal HOAs \( P < 0.001 \). The mean manifest refractive spherical equivalent was closer to attempted correction compared to other groups \( P < 0.001 \).
Eighty-three eyes (70%) of flap-on, 80 (67%) flap-off and 94 eyes (68%) in the iLASIK group achieved 20/20 uncorrected VA. Fifteen eyes (11%) accomplished 20/12.5 or better in iLASIK compared to 4 (3%) for flap-on and 7 (6%) for flap-off ASA group. Only the flap-off treatment showed a consistent correlation between the corrected aberrations and visual performance.

Conclusion: At 3 months, all procedures resulted in a significant increase in HOAs and SA. All had comparable 20/20 VA and 11% of iLASIK patients achieved 20/12.5 or better level.
ophthalmic suspension 0.1% (FML, Allergan) four times a day for 2 months and then tapered over another 4 weeks and artificial tears as required. These patients also received ketorolac 0.5% (Acular LS, Allergan) four times daily for 24 h, and acetaminophen/codeine phosphate (TYLENOL® with Codeine) 1 tablet 4–6 times daily for pain control.

iLASIK patients were seen at 1 and 3 days; 1 week; and 1, 3, 6 and 12 months after surgery. Patients in the ASA group were seen daily for the first week, then 1, 2, 3, 6 and 12 months postoperatively. All eyes were assessed preoperative and postoperative for uncorrected distance visual acuity (UDVA), and best spectacle-corrected distance visual acuity (CDVA) using Snellen chart. A detailed and systematic recording of visual acuity was followed with documentation of up to a single loss or gain of a letter in a given line, for example, 20/12.5 +1 (i.e., all the letters on line 12.5 were seen plus one on next line) or 20/12.5 −1 (i.e., one letter was not seen on that line).

Datasets that passed the normality test (Shapiro-Wilk) are presented as mean ± standard deviation (SD). The data that failed the normality test are presented as median [25, 75 confidence intervals (CI)]. Root-mean-square (RMS) wavefront error was used as global optical quality metric. All values and group comparisons were performed using One Way Analysis of Variance (ANOVA) and within group comparisons using paired t-tests. Correlations were performed using Pearson Correlations. Visual acuity was compared by the logarithm of the minimum angle of resolution with expression unit of minutes of arc (min. arc). In addition, changes in the HOAs and it’s predictability of the visual and refractive outcome were evaluated. A P value of 0.05 or less was considered to be statistically significant for all analyses.

3. Results

There were no statistically significant differences between flap-on, flap-off ASA and iLASIK groups in the mean preoperative refractive spherical equivalent ± SD (−4.06 ± 1.93, −4.02 ± 1.98, and −3.79 ± 1.95 D, respectively), in the mean preoperative refractive cylinder power (0.50 ± 0.54, 0.61 ± 0.50, and 0.69 ± 0.66 D, respectively), nor in the mean age at the time of the treatment (34 ± 8.7, 34 ± 9, and 40 ± 9.0 years, respectively) (Table 1).

3.1. Snellen visual acuity

The mean preoperative UDVA was 20/320 for either flap-on or flap-off ASA and 20/250 +2 in the iLASIK (logmar 1.13 ± 0.52 vs. 1.20 ± 0.44), ranging from 20/30 to 20/320 +2, 20/30 +2 to 20/320 +2 and 20/30 +2 to 20/800, respectively. The mean preoperative CDVA was 20/16 in iLASIK (range, 20/25 +1 to 20/15) and 20/20 +1 in flap-on group (range, 20/16 to 20/30), flap-off 20/20 +1 (range, 20/16 to 20/30) (logmar −0.03 ± 0.05, −0.03 ± 0.06 vs. −0.03 ± 0.05).

At 3 months postoperatively, 70% of the flap-on eyes, 67% flap-off and 68% in the iLASIK group had UDVA of 20/20 or better. However, in iLASIK more eyes achieved UDVA of 20/12.5 or better (11%) compared to other groups (3% flap-on and 6% flap-off ASA) (Fig. 1). We found 98% of flap-on and iLASIK eyes obtained 20/40 UDVA, while all eyes from flap-off group achieved that. The mean CDVA was 20/20 +2 for flap-on and 20/16 −2 for flap-off as well as iLASIK group postoperatively. There was no significant difference between the groups UDVA or CDVA postoperatively.

Ten eyes (8%) in the flap-on and non in the flap-off group lost one line compared to two eyes (1.5%) in the iLASIK group and no eyes lost more than one line of CDVA (Fig. 2). On the other hand 18% (22/120) gained one line of CDVA in the flap-on, 23% (28/120) flap-off and 16% (22/136) in the iLASIK group (Fig. 2).

3.2. Mean manifest refraction spherical equivalent (MRSE)

One hundred and fourteen (95%) eyes in the flap-on group, 118 (98%) eyes in the flap-off and 114 (86%) in the iLASIK had a postoperative MRSE within ±0.50 D. Two hundred and forty (100%) in both flap-on or off and 126 eyes (95%) in the iLASIK were within ±1.00 D. All eyes were within ±2.00 D of attempted correction at 3 months postoperative. The iLASIK had postoperative MRSE closer to the emmetropia (P < 0.001) and tighter SD compared to flap-on or flap-off ASA groups (−0.14 ± 0.43, −0.62 ± 0.97 and −0.53 ± 0.81, respectively).

3.3. Wavefront (ocular) higher order aberrations

In both the flap-on and flap-off groups, there was a significant increase in ocular HOAs, SA and coma values at 3 months postoperatively (P < 0.001). However, the iLASIK group showed only statistically significant increase in SA (P < 0.001). Pairwise multiple comparison procedures (Dunn’s method) identified a difference between the groups with iLASIK inducing significantly lower HOAs and SA compared to flap-on or off group (P < 0.001). On the other hand, there was no statistical significant difference between the iLASIK and ASA group for the induced coma (P = 0.857) (Table 2).

3.4. Corneal higher order aberrations

Postoperatively in each of the groups (total ASA, flap-on, flap-off ASA and iLASIK) there was a statistically significant induction of corneal HOA, SA and coma from the preop value to 3 months postprocedure (ANOVA, P < 0.001). Pairwise multiple comparison procedures (Dunn’s method) identified a difference between the groups with HOAs being significantly lower in iLASIK compared to ASA flap-on or flap-off groups (P < 0.001). Also, there was statistically significant lower induction of SA in the iLASIK compared to the flap-off group (P = 0.50). Regarding coma, iLASIK induced significantly more compared to the flap-on group (P = 0.017) (Table 3).

3.5. Correlation between changes in aberration and CDVA postoperatively

Surgically induced corneal aberrations were significantly correlated to the changes in CDVA following surgery in the flap-off ASA for HOA, SA and coma (−0.250, P = 0.006), (−0.247, P = 0.007) and (−0.180, P = 0.051), respectively. On the other hand, the flap-on subgroup did not show any significant correlation for previous parameters while iLASIK group identified significant correlation only for corneal SA (−0.194, P = 0.025).

Flap-off ASA also showed significant correlation between change in ocular aberrations and change in CDVA following
surgery for HOA, SA and coma (−0.371, \(P < 0.0001\)), (−0.309, \(P = 0.0007\)) and (−0.182, \(P = 0.049\)). No significant correlations were identified for the iLASIK and only a significant correlation for flap-on group for ocular HOA (0.079, \(P = 0.039\)).

4. Discussion
The results of this study as well as those reported by other investigators indicate that the WF ASA and LASIK have excellent efficacy, predictability and safety profile for correction of myopia (Kulkamthorn et al., 2008; Partal and Manche, 2006; Slade et al., 2009). Most of the studies comparing surface ablation with LASIK are conducted using mechanical microkeratomes rather than the Femtosecond laser for flap creation (Chung et al., 2006; Hersh et al., 1998; McAlinden and Moore, 2010) or compare the iLASIK to one of the ASA techniques rather than both flap-on and flap-off procedures (Slade et al., 2009). Slade et al. (2009) used the Alcon LADARVision 4000 CustomCornea excimer laser and found that 88% of iLASIK vs. 48% for AA-PRK had UDVA of 20/20 or better at 3 months, slightly different than those in our current study (68% in iLASIK and 57% for AA-PRK). In the same study they also found that 46% of iLASIK eyes had 20/16 or better compared with 16% for AA-PRK. We found 40% of eyes achieved 20/16 in iLASIK as well as AA-PRK group and 46% in the total ASA group (53% and 11% for flap-on and flap-off, respectively). These differences were found to persist at 1-year follow-up (Wallau and Campos, 2009).

The differences between our results and the ones obtained by Slade et al. may be caused by a small sample size or lower myopia treated by Slade et al. (50 eyes, max. SE treated −5.75 D). The other difference could be related to the excimer laser platform used. However, similar to Slade et al. (2009) we found an excellent safety profile for both ASA and iLASIK with no procedure having loss of two lines or more of CDVA.

Clinical experience and previously published research have indicated that non-optimal postoperative visual outcomes after refractive surgery are associated with an increase in ocular (Moreno-Barriuso et al., 2001) or corneal aberrations (Applegate et al., 2000). Nevertheless, the theoretical advantages of the epithelial flap repositioning on the photoablated stroma and degree of importance of viability of epithelial cells have not yet been studied well. While some had shown the advantage of retaining epithelial flaps in term of reduction of subepithelial stromal (Javier et al., 2006) and corneal wound healing response (Ma et al., 2003). There are others that demonstrated that there was no significant difference in HOAs between EpiLASIK and Epi-PRK eyes at any interval (Kalyvianaki et al.,...
corneal spherical-like aberrations are increased more in AA-PRK at 3 months follow-up. It also has been noted that ence for ocular HOAs, coma or SA between iLASIK and (Seiler et al., 2000). In the present study, only the flap-off treat-
correlation between ocular wavefront error and CDVA in PRK stabilized by 3 months.

healing response between procedures which may not have been suggest some differences in the postoperative corneal wound acuity at 20/16 or better (53% vs. 11%) were noticed. This may (70% vs. 67%) but dissimilar outcomes for uncorrected visual 20/20 were very close er increase in ocular and corneal aberrations compared with

2008). In our study, the flap-off group generally revealed greater increase in ocular and corneal aberrations compared with the flap-on, however the UDVA of 20/20 were very close (70% vs. 67%) but dissimilar outcomes for uncorrected visual acuity at 20/16 or better (53% vs. 11%) were noticed. This may suggest some differences in the postoperative corneal wound healing response between procedures which may not have been stabilized by 3 months.

Some had documented that there is a statistically significant correlation between ocular wavefront error and CDVA in PRK (Seiler et al., 2000). In the present study, only the flap-off treatment showed a consistent correlation between the corrected aberrations and visual performance. This finding suggests that postoperative changes in aberration contribute to the final VA outcome of light into the eye (Marcos, 2001). It also appears that in iLASIK the corneal changes are minimal so that the compen-

Slade et al. (2009) showed no statistical significant difference for ocular HOAs, coma or SA between iLASIK and AA-PRK at 3 months follow-up. It also has been noted that corneal spherical-like aberrations are increased more in LASEK than after iLASIK even with the same laser platform (Buzzonetti et al., 2004). On the other hand, Wallau and Campos documented that total HOA and spherical aberration were statistically significantly higher in LASIK eyes than in the MMC-PRK group during the 1-year follow-up (Wallau and Campos, 2009). In our cohort, iLASIK induced lower corneal and ocular HOA compared to either flap-on or off groups. Despite that all procedure types induced significant corneal aberrations; this was not directly proportional with increase in the ocular aberrations, where we found that the induced ocular aberrations were smaller than the corneal. This finding suggests that postoperative ocular aberrations are compensated by changes to the posterior cornea and/or to the internal pathway of light into the eye (Marcos, 2001). It also appears that in iLASIK the corneal changes are minimal so that the compensation mechanism is sufficient to minimize the global ocular effect from the introduced changes on anterior corneal surface. So, it is proposed that these differences are primarily due to the method of flap creation (McAlinden and Moore, 2010; Tran et al., 2005); hence, the creation of stromal flap by itself may modify HOAs in a different manner than ASA which

### Table 2 Ocular aberration with 5.00 mm pupil.

<table>
<thead>
<tr>
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<th>HOA (µm)</th>
<th>SA (µm)</th>
<th>Coma (µm)</th>
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</thead>
<tbody>
<tr>
<td><strong>Flap-on (Epi-LASIK + LASEK), mean ± SD or median (50% CI) (N = 120)</strong></td>
<td></td>
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</tr>
<tr>
<td>Preop</td>
<td>0.372 (0.292; 0.472)</td>
<td>0.195 (0.140; 0.252)</td>
<td>0.202 (0.117; 0.312)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.538 (0.455; 0.670)</td>
<td>0.326 (0.223; 0.424)</td>
<td>0.230 (0.135; 0.349)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.161 (0.046; 0.306) [&lt; 0.001]</td>
<td>0.134 (0.033; 0.218) [&lt; 0.001]</td>
<td>0.019 (−0.042; 0.093) [0.178]</td>
</tr>
<tr>
<td><strong>Flap-off (Epi-PRK + AA-PRK), mean ± SD or median (50% CI) (N = 120)</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preop</td>
<td>0.342 (0.302; 0.404)</td>
<td>0.162 (0.118; 0.209)</td>
<td>0.201 (0.137; 0.276)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.541 (0.430; 0.660)</td>
<td>0.315 (0.222; 0.428)</td>
<td>0.265 (0.162; 0.364)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.198 (0.075; 0.323) [&lt; 0.001]</td>
<td>0.150 (0.069; 0.274) [&lt; 0.001]</td>
<td>0.046 (−0.032; 0.158) [&lt; 0.001]</td>
</tr>
<tr>
<td><strong>iLASIK, mean ± SD or median (50% CI) (N = 137)</strong></td>
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<tr>
<td>Preop</td>
<td>0.214 (0.164; 0.275)</td>
<td>0.223 (0.170; 0.270)</td>
<td>0.140 (0.083; 0.212)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.316 (0.244; 0.393)</td>
<td>0.328 (0.242; 0.441)</td>
<td>0.200 (0.139; 0.281)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.102 (0.015; 0.192) [&lt; 0.001]</td>
<td>0.118 (0.032; 0.209) [&lt; 0.001]</td>
<td>0.065 (−0.032; 0.159) [&lt; 0.001]</td>
</tr>
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</table>

* N = number of eyes in that group.

*Paired t-test or Signed Rank test.

* No significant change following surgery.

### Table 3 Corneal aberration with 5.00 mm pupil.

<table>
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<tr>
<td>Preop</td>
<td>0.154 (0.119; 0.186)</td>
<td>0.041 (0.007; 0.082)</td>
<td>0.083 (0.052; 0.117)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.248 (0.180; 0.297)</td>
<td>0.157 (0.089; 0.225)</td>
<td>0.092 (0.067; 0.151)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.078 (0.032; 0.143) [&lt; 0.001]</td>
<td>0.117 (0.050; 0.170) [&lt; 0.001]</td>
<td>0.013 (−0.032; 0.063) [0.029]</td>
</tr>
<tr>
<td><strong>Flap-off (Epi-PRK + AA-PRK), mean ± SD or median (50% CI) (N = 120)</strong></td>
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<td></td>
</tr>
<tr>
<td>Preop</td>
<td>0.159 (0.128; 0.197)</td>
<td>0.038 (0.000; 0.069)</td>
<td>0.091 (0.056; 0.138)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.205 (0.153; 0.294)</td>
<td>0.150 (0.083; 0.199)</td>
<td>0.107 (0.061; 0.142)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.066 (−0.010; 0.100) [&lt; 0.001]</td>
<td>0.123 (0.047; 0.171) [&lt; 0.001]</td>
<td>0.005 (−0.040; 0.065) [0.160]</td>
</tr>
<tr>
<td><strong>iLASIK, mean ± SD or median (50% CI) (N = 137)</strong></td>
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<td>0.039 (0.009; 0.082)</td>
<td>0.092 (0.057; 0.159)</td>
</tr>
<tr>
<td>3 M postop</td>
<td>0.148 (0.103; 0.222)</td>
<td>0.154 (0.087; 0.209)</td>
<td>0.113 (0.067; 0.162)</td>
</tr>
<tr>
<td>Change [P value]*</td>
<td>0.017 (−0.040; 0.066) [0.227]</td>
<td>0.048 (0.004; 0.085) [&lt; 0.001]</td>
<td>0.020 (−0.035; 0.065) [0.052]</td>
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</table>

* N = total number of eyes in that group.

* Paired t-test or Signed Rank test.

* No significant change following surgery.
provoke greater wound remodeling response. These may also indicate that placing the ablation under a thin planar iLASIK flap may account for less induced aberrations, specially that corneal wound healing response after PRK has been found to be greater and longer than after LASIK (Ma et al., 2003). In addition, wound healing may not have stabilized at 3 months for ASA resulting in higher aberrations than might be present with a longer follow-up. Also as seen in other published comparisons, by the third postoperative month, the difference between the two groups begin to equalize and by 6 month there is no statistical difference between the groups (Slade et al., 2009). Further investigations with longer follow-up periods are warranted.

5. Conclusion

ASA techniques and iLASIK are safe and effective in treating myopia. All procedures resulted in a significant increase in HOAs and SA and all had comparable 20/20 VA, while iLASIK was more effective at 20/12.5 or better level. The flap-off treatment showed a significant negative correlation between the corrected aberrations and visual performance (as aberration decreased, CDVA increases) postoperatively, indicating that modifying the existing ablation pattern for this technique to compensate for induced HOAs may have the potential to improve the visual outcomes.

Competing interest

None to declare. Authors did not receive any funding or support for the work presented in the manuscript.

Dr. Jackson is a consultant and research investigator for AMO, however, has no financial interest in VISX or AMO.

References


