Visual quality improvement in refractive surgery
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LASIK AND LASEK AFTER REFRACTIVE LENS EXCHANGE WITH DIFFRACTIVE MULTIFOCAL IOL IMPLANTATION
ABSTRACT

PURPOSE: To evaluate the efficiency and safety of excimer laser procedures for residual refractive errors after refractive lens exchange (RLE) with a diffractive multifocal IOL (Restor™) at 3 and 6 months.

SETTING: Private refractive Surgery Clinic, Retina, Driebergen, the Netherlands.

METHODS: Forty seven eyes (25 patients) had either LASIK or LASEK for residual ametropia after RLE. LASEK was performed with 30 sec 20% alcohol, LASIK with the XP microkeratome. The Technolas excimer laser was used in all eyes. Outcome measures were the post-operative spherical equivalent (SE), sphere and cylindrical refraction for distance, uncorrected distance acuity (UDVA), corrected distance acuity (CVA), uncorrected near visual acuity (UNVA), patient satisfaction based on questionnaires, complication rate, and retreatment percentage.

RESULTS: In LASIK mean pre-operative SE refraction was +0.50D + 0.72 D (range -1.88 to +1.25). Mean post-operative SE was +0.29 +0.34 D (range -0.25 to +1.00). Visual acuity improved from a mean UDVA of 0.63 to 1.08 and 1.13 at 3 and 6 months, respectively. UNVA improved from 0.96 to 0.99. In LASEK mean pre-operative SE was +0.34 D + 0.73 D (range -0.75 to +1.5D). Postoperatively mean SE was +0.21 D + 0.13D. UDVA improved from 0.58 to 0.99 and 1.13 at 3 and 6 months, respectively. UNVA improved from 0.96 to 0.99. The change in UDVA and CVA was statistically significant (p<0.001 paired t-test). Patient satisfaction was graded 8.6 on a scale of 10.

CONCLUSIONS: LASIK and LASEK for small residual errors is efficacious and safe. It provides the patients the uncorrected far and near vision that was intended with the multifocal IOL implantation.

KEYWORDS: LASIK, LASEK, excimer laser, bioptics, multifocal IOL

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Submitted for publication
INTRODUCTION

Refractive lens exchange (RLE) is a procedure in which the crystalline lens is removed and exchanged for an intra-ocular lens. The indications for these procedures are still developing. The main finding in the patients seeking this procedure is the fact that they are presbyopic and need different spectacle correction for far and near vision, and are motivated to do a procedure which may enhance their spectacle freedom. A residual refractive error is a reason for reduced patient satisfaction. Postoperative halos and visual disturbances are other reasons for dissatisfaction.

Excimer laser has been a safe and efficient way to treat myopia and some forms of hyperopia and astigmatism with success.

The combination of the use of RLE and a corneal laser procedure is known as bioptics. The indication for bioptics is the existence of a refractive error after an intra-ocular lens procedure. There are 2 reasons for residual ametropia. Preexisting corneal astigmatism that cannot be corrected by this specific spherical intra-ocular lens, and a residual refractive error as a result of surgically induced astigmatism or IOL decentration during surgery or wound healing.

Safety and efficiency of corneal laser refractive surgery after pseudophakia have been described. PRK on multifocal pseudophakic eyes has been described by Lescicotti in 2004. Zaldivar treated a mean refractive error of -2.61 D. The range of residual refractive errors in other studies ranged from -2.19 D to -3.76 D with astigmatism up to 6 D treated. The post-operative LASIK and PRK spherical equivalent refraction ranged between -0.88 D to +0.09D. The range of indications for corneal laser refractive procedures in (multifocal) pseudophakia has not yet been described in guidelines. One of the questions is – at what refractive error, and what level of uncorrected distance acuity should such a procedure be performed?

METHODS

In a prospective consecutive case-series, 26 patients (45 eyes) with a residual refractive error after refractive lens exchange with the Restor +4, were studied. The Tenets of the Declaration of Helsinki were adhered to.

Both the RLE and the corneal laser procedures were done by a single surgeon (RLG). All RLE procedures were done between November 2007 and April 2009. RLE was done after oral and written informed consent of the patient. The IOL choice was based on the IOLmaster 5.0 (Zeiss, Germany) with emmetropia as the target. RLE was performed with the Ozil, Infiniti (Alcon, Forth Worth, USA), with a 2.75 near clear 12 o’clock incision. Curvilinear capsulorrhexis was done in all cases, with the optic of the intra-ocular lens (IOL) being covered by the rhexis edge. A Restor +4D (Alcon, Fort Worth, USA) was implanted in all these cases. Vigorous anterior and posterior capsular polishing was performed.
Indication for LASIK and LASEK after the RLE was dissatisfaction of the patient with the uncorrected distance vision, which could be corrected with a spherocylindrical spectacle correction. The secondary indications were either a pre-operative cylinder that could not be corrected with the incision, a residual ametropia that improved with corrective lenses (a planned enhancement), or a residual refractive error that improved with refraction (an enhancement because of a surprise in refractive outcome after RLE).

The patients had to have improved visual acuity after manifest refraction. Other causes of visual loss were considered to be exclusion criteria for laser enhancement after RLE.

Informed consent for the study was obtained from all the participants.

Pre-operatively patients underwent a complete ophthalmic examination, including uncorrected and corrected distance visual acuity (UCDA, BCDA), near visual acuity (NVA), autorefraction and manifest refraction, slitlamp examination, tearfilm assessment by fluorescein staining, tear breakup time measurement, and Schirmer’s testing with anesthetic eyedrops, tonometry, orbscan topography, orbscan pachymetry and on indication sonogage pachymetry, dilated fundoscopy and biomicroscopy, assessment of IOL position, and posterior capsular clarity. Baseline retreatment refraction was done at least 12 weeks post RLE. Refraction had to be stable, and without contact lenses to prevent treating warpage effects.

LASIK was performed with the Technolas Z217 and the 120 XP microkeratome (Technolas, Munich, Germany). LASEK was done with 20% alcohol for 30 seconds, and rinse with BSS. Standard ablations were done with the Planoscan Nomogram (Technolas, Munich, Germany) Manifest refraction was used for the treatment planning.

LASIK or LASEK was performed according to the Guidelines of the Netherlands Society of Refractive Surgeons (2006 edition), and according to patients’ preference. There was no minimal stated refraction to be eligible for the procedure.

Outcome measurements are distance and near visual acuity, uncorrected and corrected, efficacy and safety indices, complications, patient satisfaction, retreatment rates, mean SE refraction, mean sphere and cylinder refraction, pre and post laser enhancement procedure, and the patient satisfaction as recorded (scale 1 bad 10 best) on the questionnaire we routinely use in our clinic.

RESULTS

Demographic data
We describe the results of 45 eyes of 26 patients which had consecutive enhancement procedures done for residual refractive errors after RLE.

The mean age was 58.89 years, with a range of 51.5 to 66.17 years. Of the patients 80.7% were males.

In 27 eyes LASEK was done, and in 18 eyes LASIK was performed.

The initial refraction before RLE was hyperopic in 22 eyes, and myopic in 23 eyes. In the LASIK group a planned bioptics procedure was done in 6 of the 18 eyes. In the
other 12 eyes the indication was an unplanned residual error. In LASEK 19 of 27 eyes a planned bioptics procedure was done.

Pre-operative data
In the LASIK group there were 18 eyes. The mean age was 57.1 years (range 51.5-63 years). The pre-operative spherical equivalent refraction was 0.50D + 0.72 D (range 0

### Table 1: pre-operative and post-operative refractive and visual acuity results in LASIK.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-operative</th>
<th>Post-operative at 3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refraction (D)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.50 ± 0.72</td>
<td>0.29 ± 0.34</td>
<td>0.10 ± 0.23</td>
</tr>
<tr>
<td></td>
<td>(0 to +1.25)</td>
<td>(-0.25 to +1.0)</td>
<td>(-0.25 to +0.62)</td>
</tr>
<tr>
<td>Sphere</td>
<td>1.21 ± 0.62</td>
<td>0.43 ± 0.33</td>
<td>0.23 ± 0.75</td>
</tr>
<tr>
<td></td>
<td>(-0.75 to 1.5)</td>
<td>( plano to 1.25)</td>
<td>( plano to +0.75)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-1.01 ± 0.62</td>
<td>-0.30 ± 0.39</td>
<td>-0.25 ± 0.39</td>
</tr>
<tr>
<td></td>
<td>( plano to -2.25)</td>
<td>( plano to -1.00)</td>
<td>( plano to -1.00)</td>
</tr>
<tr>
<td><strong>Visual acuity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDVA</td>
<td>0.63 ± 0.2</td>
<td>1.08 ± 0.18</td>
<td>1.13 ± 0.16</td>
</tr>
<tr>
<td></td>
<td>(0.32-0.9)</td>
<td>(0.8-1.25)</td>
<td>(0.8-1.25)</td>
</tr>
<tr>
<td>CDVA</td>
<td>1.1 ± 0.16</td>
<td>1.175 ± 0.22</td>
<td>1.21 ± 0.20</td>
</tr>
<tr>
<td></td>
<td>(0.9-1.5)</td>
<td>(0.8-1.6)</td>
<td>(0.9-1.6)</td>
</tr>
<tr>
<td>UNVA</td>
<td>0.96 ± 0.09</td>
<td>0.99 ± 0.05</td>
<td>0.99 ± 0.05</td>
</tr>
<tr>
<td></td>
<td>(0.8-1.0)</td>
<td>(0.8-1.0)</td>
<td>(0.8-1.0)</td>
</tr>
</tbody>
</table>

All values are written as the mean with standard deviation, with the range between parenthesis.

### Table 2: pre-operative and post-operative refractive an visual acuity results in LASEK.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-operative</th>
<th>3m post-operative</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refraction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.34 D ± 0.73 D</td>
<td>plano ± 0.5D</td>
<td>-0.06 ± 0.22</td>
</tr>
<tr>
<td></td>
<td>(-0.75 to +1.5)</td>
<td>(-0.625 to +0.625D)</td>
<td>(-0.62 to +0.62)</td>
</tr>
<tr>
<td>Sphere</td>
<td>1.09 ± 0.2</td>
<td>+0.17D ± 0.50 D</td>
<td>0.04 ± 0.23</td>
</tr>
<tr>
<td></td>
<td>(-0.25 to 2.5)</td>
<td>(-0.25 to +1.25 D)</td>
<td>(-0.25 to +0.75)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-1.44 ± 0.59</td>
<td>-0.32 D ± 0.42 D</td>
<td>-0.20 ± 0.28</td>
</tr>
<tr>
<td></td>
<td>(-0.5 to -2.75 D)</td>
<td>( plano to -1.25 D)</td>
<td>( plano to -0.75)</td>
</tr>
<tr>
<td><strong>Visual acuity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDVA</td>
<td>0.58 ± 0.19</td>
<td>0.99 ± 0.26</td>
<td>1.13 ±0.21</td>
</tr>
<tr>
<td></td>
<td>(0.32-0.8)</td>
<td>(0.32-1.35)</td>
<td>(0.8-1.6)</td>
</tr>
<tr>
<td>CDVA</td>
<td>1.05 ± 0.17</td>
<td>1.11 ± 0.16</td>
<td>1.18 ±0.20</td>
</tr>
<tr>
<td></td>
<td>(0.7-1.25)</td>
<td>(0.63-1.35)</td>
<td>(0.8-1.6)</td>
</tr>
<tr>
<td>UNVA</td>
<td>0.96 ± 0.09</td>
<td>0.99 ± 0.05</td>
<td>0.97 ± 0.08</td>
</tr>
<tr>
<td></td>
<td>(0.8-1.0)</td>
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<td>(0.8-1.0)</td>
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</table>

All values are written as the mean with standard deviation, with the range between parenthesis.
to +1.25). The mean pre-operative sphere was +1.21 D ± 0.62 D (range from +0.75 to +1.50). The pre-operative cylinder was -1.01 D ± 0.62 D (range 0 to -2.25 D). The mean pre-operative uncorrected distance visual acuity (UDVA) was 0.63 ± 0.2 (range 0.32 to 0.9). The pre-operative corrected distance visual acuity (CDVA) was 1.1 ± 0.16 (range 0.9 to 1.5). The pre-operative uncorrected near visual acuity (UNVA) was 0.96 ± 0.09 (0.8-1.0). The mean time between the RLE and the LASIK was 191 days ± 62 (range 125 days to 362 days).

In the LASEK group there were 27 eyes. The mean age was 60.1 years (range 54.5-66.2 years). The mean pre-operative spherical equivalent refraction was +0.34 D ± 0.73 D (range -0.75 to +1.5). The pre-operative mean sphere was 1.09 ± 0.2 (-0.25 to 2.5). The pre-operative cylinder was -1.44 ± 0.59 (range -0.5 to -2.75 D). The pre-operative UDVA was 0.58 ± 0.19 (range 0.32-0.8), and the mean CDVA was 1.05

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**Figure 1:** Attempted versus achieved sphere correction in LASIK and LASEK bioptics. The diagonal lines represent ± 0.5 D of the y=x.

**Figure 2:** Attempted versus achieved cylinder correction in LASIK and LASEK bioptics. The diagonal lines represent ± 0.5D from the y=x.

**Figure 3:** Lines lost and gained in LASIK and LASEK bioptics at 3 and 6 months. Most losses of lines were due to refractive error.

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**Table 1:** pre-operative and post-operative refractive and visual acuity results in LASIK. All values are written as the mean with standard deviation, with the range between parenthesis.

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<th>Post-operative at 6 months</th>
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<tbody>
<tr>
<td>Refraction (D)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>+0.50 ± 0.72 (0 to +1.25)</td>
<td>+0.29 ± 0.34 (-0.25 to +1.0)</td>
<td>+0.10 ± 0.23 (-0.25 to +0.62)</td>
</tr>
<tr>
<td>Sphere</td>
<td>1.21 ± 0.62 (-0.75 to +1.5)</td>
<td>0.43 ± 0.33 (plano to +1.0)</td>
<td>0.23 ± 0.75 (plano to +0.75)</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-1.01 ± 0.62 (plano to -2.25)</td>
<td>-0.30 ± 0.39 (plano to -1.0)</td>
<td>-0.25 ± 0.39 (plano to -1.0)</td>
</tr>
<tr>
<td>Visual Acuity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDVA</td>
<td>0.63 ± 0.2 (0.32-0.9)</td>
<td>1.08 ± 0.18 (0.8-1.25)</td>
<td>1.13 ± 0.16 (0.8-1.25)</td>
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<tr>
<td>CDVA</td>
<td>1.1 ± 0.16 (0.9-1.5)</td>
<td>1.175 ± 0.22 (0.8-1.6)</td>
<td>1.21 ± 0.20 (0.9-1.6)</td>
</tr>
<tr>
<td>UNVA</td>
<td>0.96 ± 0.09 (0.8-1.0)</td>
<td>0.99 ± 0.05 (0.8-1.0)</td>
<td>0.99 ± 0.05 (0.8-1.0)</td>
</tr>
</tbody>
</table>

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LASIK and LASEK after RLE with MFIOL implantation bioptics. The blue hues are pre-operative visual acuity, while the red hues are the post-operative visual acuities. We see an improvement in both corrected and uncorrected visual acuities for distance and near vision.

Figure 4: Predictability of the LASIK and LASEK bioptics treatments.

In our study the results of LASIK and LASEK were clinically and statistically similar. Treatment of the residual refractive error resulted in a decrease in the refractive error, and an increase in the UCDA. Review of the literature shows the residual refractive error being higher than the refractive error that we resulted in a decrease in the refractive error, and an increase in the UCDA. In some patients (3 eyes) more than 1 procedure was needed to reach emmetropia. No severe adverse events were seen in the study group.

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Figure 3: Lines lost and gained in LASIK and LASEK bioptics at 3 and 6 months. Most losses of lines were due to refractive error.

Figure 5: Visual acuity in Snellen lines pre-operatively versus post-operatively in LASIK. The blue hues are pre-operative visual acuity, while the red hues are the post-operative visual acuities. We see an improvement in both corrected and uncorrected visual acuities for distance and near vision.

Figure 6: Visual acuity in Snellen lines pre-operatively versus post-operatively in LASEK bioptics. The blue hues are pre-operative visual acuity, while the red hues are the post-operative visual acuities. We see an improvement in both corrected and uncorrected visual acuities for distance and near vision.
BIOPTICS WITH MULTIFOCAL IOL’s

+ 0.17 (0.7-1.25). The pre-operative UNVA was 0.96 ± 0.23 (0.8-1). The mean time elapsed between RLE and the LASEK was 175 days ± 70 days (range 84 days to 364 days).

Postoperative results in the LASIK group at 3 months (18 eyes)
The mean UDVA was 1.08, while the mean UNVA was 0.99. The post-operative spherical equivalent was +0.29 D ± 0.34 D (range -0.25 to +1.0D). The mean post-operative sphere was +0.43 ± 0.33 (range plano to +1.25). The mean post-operative cylinder was -0.30 D ± 0.39 D (range 0 to -1.00D). Distance efficacy was 0.98, near efficacy was 1.01. Safety was 1.07.

Postoperative results in the LASIK group at 6 month (14 eyes)
The mean UDVA was 1.13 and the UNVA was 0.99. The mean postoperative spherical equivalent was +0.10 ± 0.0.23 (range -0.25 to +0.62). The mean post-operative sphere was +0.23 ± 0.3 (range plano to +0.75), and the mean post-operative cylinder was -0.25 ± 0.39 (range plano to -1.00). Four eyes of 3 patients were lost to follow up.

Postoperative results in the LASEK group at 3 months (27 eyes)
The mean UDVA was 0.99, and the mean UNVA was 0.99. The mean post-operative SE was plano + 0.5D (range -0.625 to +0.625D). The mean post-operative sphere was +0.17D ± 0.50 D (range -0.25 to +1.25 D). The mean post-operative cylinder was -0.32 D ± 0.42 D (range plano to -1.25 D). Efficacy for distance was 0.94 and for near 1.01. Safety was 1.06. In 3 eyes (2 patients) a second lasik procedure was needed. One of these patients had a map dot fingerprint dystrophy, and the other had no complicating factor. In all 3 eyes, VA was satisfactory after the second LASEK procedure. (UDVA 1.25, 1.0, 1.0). The LASEK enhancement rate was 11.1%.

Postoperative results in the LASEK group at 6 months (24 eyes)
The mean UDVA was 1.13 and the mean UNVA was 0.97. The post-operative SE was -0.06 ± 0.22 D (range -0.62 to +0.62D). The mean post-operative sphere was +0.04 ± 0.23 D (range -0.25 to +0.75 D), and the mean post-operative cylinder was -0.20 D ± 0.28 D (range plano to -0.75).

Three eyes of 2 patients were lost to follow up.

Complications and patient satisfaction
All patients completed a questionnaire following their RLE treatment and after the bioptics enhancement. One patient in each group (3 eyes) said they regretted their decision to have the procedure done, even though their Snellen acuity for far and near was equal to or exceeded the 1.0 (20/20). The mean grade the patients gave their satisfaction with the treatment and outcome on a scale of 1 (extremely bad) to 10 (excellent) was 8.6.

No serious adverse events were seen. In 3 eyes, 1 in the LASIK group and 2 eyes in the LASEK group, the laser treatment had to be repeated before the target refraction and visual acuity could be achieved.
DISCUSSION

In our study we show that both LASIK and LASEK are effective in treating small residual refractive errors after refractive lens exchange. The difference between both the UCDA and BCDA pre-operatively versus the post-operative UCDA was clinically as well as statistically significant. In some patients (3 eyes) more than 1 procedure was needed to reach emmetropia. No severe adverse events were seen in the study group.

A review of the literature shows that multifocal lenses are effective in restoring far and near vision in patients with cataract and also in clear lens extraction. Patient satisfaction depends on how well maximal uncorrected visual acuity was achieved. With the current IOL technology small residual errors are the leading cause of dissatisfaction, whereas only a few years ago the main limitation was the photic phenomena caused by the older generation multifocal IOL’s. Motivation is an important factor in satisfaction after multifocal IOL implantation and acceptance of visually disturbing phenomena. The only factor that can be improved after implantation is treatment of the residual refractive error.

LASIK and LASEK have been shown to be predictable and safe after cataract surgery with monofocal lens implantations. There are few reports of LASIK and LASEK for residual errors after multifocal IOL implantation and overall the results are good.

Predictability is another issue that plays a role in the decision to treat small residual refractive errors after a multifocal IOL implantation.

In our study the results of LASIK and LASEK were clinically and statistically similar. Treatment resulted in a decrease in the refractive error, and an increase in the UCDA. Review of the literature shows the residual refractive error being higher than the refractive error that we decided to treat. In contrast to the study done by Piñero et al, we did not divide the treatments into hyperopic and myopic treatments, because of the small refractive error to be treated. In the mentioned study the predictability of the hyperopic treatments was lower than of the myopic treatments, however there was a mix of several multifocal lenses with different technologies of multifocality and also no mention of which laser treatment nomogram was used. In our study the number of eyes was not large enough to come to such conclusions, and the overall results were very good, with a high patient satisfaction. Some of these studies used wavefront treatments to reduce the residual refractive error. Wavefront measurements are in our experience problematic with the Hartmann-Shack technology, this is in accordance with the literature. A wavefront measurement with a dilated pupil will also measure aberrations that are beyond the 6 mm optic of the IOL, and these aberrations when corrected on the central cornea can in our opinion not lead to good visual and refractive results. In our study the results of standard laser treatments are acceptable, and lead to an improved UCDA, UCNA, and patient satisfaction.

Time between the IOL procedure and the bioptics procedure is different between the different studies. Macsai in her excellent review states that most authors consider 6-12 weeks to be the minimum time span to have the cornea wounds stabilize before
proceeding with LASIK.\textsuperscript{25} We prefer to defer treatment until we have stability in complaints. The stability of the operative wounds of the RLE is one argument, but in our experience early post-operative tear-film disturbances as caused by lens surgery and prolonged eye-drop therapy causes fluctuating vision in the first few months. The mean time to surgery was nearly 6 months while in a few patients, in whom the bioptics procedure was planned before RLE, we went ahead as early as 13 weeks. At 3-6 months most complaints relating to dysphotopsias and halos have usually abated, and neuroadaptation has had time to take place.

In our patients none of the patients had a posterior capsulotomy done before the laser procedure. Usually the motivation for early posterior capsulotomy is to enhance stability of the refraction, which can possibly be upset by IOL movement following posterior capsulotomy. In our opinion posterior capsulotomies should only be done for clinically significant visual complaints. These complaints may be contrast related (patients often describe this as seeing through a plastic sandwich bag). Often near visual acuity decreases first and faster than far acuity, and can be tested by refracting them with the near SE refraction put in for far. If there is a discrepancy, near vision worse than far, this supports the diagnosis that the PCO is visually significant.

In conclusion: Standard laser ablation following RLE, by way of LASIK or LASEK results in better UCDA and better UVNA in a predictable and safe manner. More study is needed to enhance effectiveness and predictability of this procedure.

REFERENCES