Greek, Turkish studies concur on Epi-LASIK benefits

Results from two large long-term studies agree that Epi-LASIK is a safe and effective refractive surgery alternative for the treatment of low to moderate myopia with or without astigmatism. Vikentia J. Katsanevaki MD PhD, Vardinoyannion Eye Institute, University of Crete, Greece, presented results from 234 eyes followed for at least one year, at the X XIX Congress of the European Society of Cataract & Refractive Surgeons.

All procedures utilised the Centurion SES Epikeratome (Norwood Abbey) for epithelial flap separation and the Allegretto Wave 200 Hz excimer laser (Wavelight) for the ablations. "As we saw when Dr Pallikaris initiated this research, the big advantage of surface ablation with Epi-LASIK is that the mechanical separation of the epithelial flap preserves the basement membrane, and so it provides good viable tissue to protect the stroma during the first days after the surgical insult. Thus, Epi-LASIK affords improved control of postoperative corneal wound healing and represents an advancement in surface ablation," reported Dr Katsanevaki.

Using the first generation of the Norwood Abbey epikeratome to create epithelial sheets 9.5 to 10-mm in diameter in 403 eyes, Dr Katsanevaki reported that successful separation of the epithelium occurred in 368 (91%) cases. An incomplete flap was created in seven percent of eyes. The separation was uneven with penetration into the stroma in another two percent. Among the latter cases, the penetration occurred outside the visual axis in five eyes, and in those cases, the procedure was completed as planned at the same session.

LASIK was performed one to two months later in the remaining two eyes where the site of penetration was within the optical zone, "W ith 10 and 14 months of follow-up available for the latter two eyes, BCVA remained unchanged in one and improved by one line in the other. Only a faint scar could be seen within the visual axis but it was not associated with topographic changes. And so, while these situations are best avoided, excellent visual and refractive results are still possible if they occur," Dr Katsanevaki said.

Variable postoperative pain

She presented efficacy and safety results for the 234 eyes with one year of follow-up. Patients rated postoperative pain on a scale of 0 (none) to 4 (needing oral medication) every two hours until 24 hours. "This is not a pain-free procedure and there were high standard deviations for the postoperative mean pain ratings. However, the average peak score was below the threshold for a burning feeling. Only 12% of patients reported a pain score greater than one at its peak, representing something worse than discomfort, and the discomfort quickly dissipated. At 10 hours after surgery, only 1% of patients reported a pain worse than discomfort and none did at 24 hours," Dr Katsanevaki said.

The analyses of refractive outcomes and visual acuity data showed some early variability. Mean visual acuity during the first days was 0.50 with a slight worsening on day three, but by day six, when re-epithelialisation had occurred in the vast majority of eyes, mean UCVA improved to 0.64. By one month, mean UCVA was 0.85, reaching 1.01 at three months. It continued to improve slightly throughout the first year.

Mean spherical equivalent was reduced from -3.59 D preoperatively to -0.31 D at one month. This improved further to -0.20 D at three months and remained relatively stable thereafter.

"Between one and three months, only 15% of eyes showed a change in SE exceeding 0.5 D. By one year, mean SE was -0.20 D. Considering the small subgroup of 20 eyes with follow-up to 24 months, none had a change in SE greater than 0.5 D between months six and 24," Dr Katsanevaki reported.

BCVA improved during follow-up

Early epithelial healing also showed an impact on best-corrected acuity. At one month, 12% of eyes had a greater than one line BCVA loss while 16% had a greater than one line BCVA gain. At subsequent visits, the proportion of eyes with BCVA loss decreased while the proportion with improved BCVA increased. By one year, 53% of eyes showed a gain of a greater than one line and no eyes had a greater than one line loss. Looking at the 20 eyes with two years of follow-up, a similar percentage showed a gain in BCVA at their last visit.

"Improvement in BCVA is a true benefit of Epi-LASIK," Dr Katsanevaki said.

Haze ratings showed that at one month 88% of eyes were clear or had only trace haze and the rest were considered to have mild haze. Moderate haze was seen in only one percent of eyes at three and six months, and no eyes developed marked haze. At one year, 89% of eyes were clear and the rest had trace haze. The results were similar among the 20 eyes seen after two years.

The researchers evaluated contrast sensitivity at four spatial frequencies (3, 6, 12, and 18 cycles per degree), and the results showed no loss throughout follow-up.

"Those findings are consistent with the excellent quality of vision we expect after surface treatment," Dr Katsanevaki said.

Turkish research concurs

Efekan Coskunseven MD, Dunya Eye Hospital, Istanbul, Turkey, reported outcomes for 118 eyes of 62 patients with one year of follow-up. Mean preoperative MRSE for that series of eyes was -3.77 D. He used the same technique as Dr Katsanevaki.
“Reports of an increasing incidence of iatrogenic ectasia and suggestions that the LASIK flap could be associated with unpredictable biomechanical corneal changes have led to a resurgence of interest in surface ablation. The advantage of Epi-LASIK compared with LASEK is that it does not require alcohol for epithelial loosening and it results in creation of a viable epithelial flap that can act as a natural contact lens to decrease postoperative pain and haze formation,” Dr Coskunsever said.

Postoperatively patients had up to -6.0 D of myopia and up to 2 D of cylinder. Mean UCVA was 0.12 and mean BCVA was 0.93.

Patients were followed daily after surgery until epithelialisation occurred and then at one, three, six, and 12 months. As in the C rete study, patients graded postoperative pain every two hours for the first 10 hours after surgery using a 0 to 4 scale. Postoperative pain peaked in intensity at eight hours, when the mean rating was 1, but again the standard deviation was high. By 10 hours, the mean score had decreased to 0.46, and the average daily scores showed a steady decline after surgery to reach a very low level of 0.15 by day four.

“The discomfort level never exceeded grade 3 for any patient and no one required any oral medications for pain relief,” Dr Coskunsever observed.

One day after surgery, the corneas were clear and UCVA was excellent with a range from 0.5 to 0.8 and an average of 0.63. UCVA was slightly reduced on day two and fell slightly further on day three, only to improve thereafter. At day seven, mean UCVA was 0.72 and it remained at about that level at one month. By three months, mean UCVA had improved to 0.80, and it showed a further slight improvement at six and 12 months. Mean MRSE was 0.6 D at one month, improved to -0.54 D at three months, and settled at -0.40 D at months six and 12.

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Clear corneas at one year

At one month after surgery, 36% of eyes showed trace haze, six percent had mild haze, and two percent had haze that was moderate or marked. By three months, haze was absent in 78% of eyes, trace in 18% and mild or moderate in four percent. No eyes had moderate or worse haze by six months. At 12 months, 99% of eyes were clear with the remaining one percent having only trace haze present. Compared with the preoperative value, mean BCVA was slightly worsened at one month when it was 0.87. However, it returned to the baseline level at three months and remained stable thereafter.

At one month after surgery, 12% of eyes had lost two or more lines of best-corrected acuity, while BSCVA remained unchanged in 70% and improved in almost eight percent. By three months, only 2.4% of eyes had lost two lines of BSCVA and none had a greater than two lines loss. Twenty-five percent showed gains of one to three lines. A one-line loss affected 4.9% of eyes at six months and 2.4% at 12 months while the proportion with a one to three line gain improved to 31%.

Both investigators concluded that visual rehabilitation is slower after Epi-LASIK compared with LASIK. However, in contrast to PRK, discomfort was minimal following Epi-LASIK, there were no problems with significant haze, and the refractive and visual results were excellent overall and generally stable beginning at three months.

Silent SILENT epithelial basement membrane dystrophy (EBMD) appears to be a common cause of massive corneal epithelial sloughing during LASIK, according to the findings of a new Spanish study.

Speaking at the X X III Congress of the European Society of Refractive and Cataract Surgery, Ahmed Galal MD PhD reported that among 5,670 eyes with normal appearing corneas that underwent LASIK over a 10-year period, 18 (0.32%) developed severe epithelial defects intraoperatively. A defect was defined as an epithelial irregularity measuring more than 9.0 mm² or involving at least 20% of the flap surface. The epithelial defects were microkeratome-related in one-third of the eyes. They resulted from poor irrigation during flap creation in another five percent of cases. However, the remaining 61% of eyes all developed signs of EBMD (i.e. intraepithelial microcysts, or “dots”) during post-LASIK follow-up, said Dr Galal, Vissum Institute of Ophthalmology, Alicante, Spain.

The 11 eyes with delayed EBMD had a mean preoperative uncorrected visual acuity of 20/400. At one month post-operatively, mean uncorrected visual acuity was about 20/35. It was slightly improved at three months and reached 20/30 at one year. The efficacy index (post-op UCVA/preop BSCVA) was 0.82.

Mean best-corrected acuity was 20/25 preoperatively. That dropped slightly at one month post-operatively, but improved thereafter and had returned to just slightly above the preoperative level by one year. The refractive results were favourable. Mean sphere for the 11 eyes was -0.66 D preoperatively, decreased to -0.66 D at one month, and reached -0.51 D at one year. At one month, 82% of the eyes were within 1.0 D of emmetropia and 55% were within 0.5 D. Those percentages improved at one year to 91% and 64%, respectively.

Those 11 eyes represented 0.2% of the entire cohort. None had any preoperative history of recurrent corneal erosions or any other signs of EBMD detected in a thorough preoperative examination.

Slower visual rehabilitation, flap complications

At one year after surgery the safety index for the group was 1.04. The refractive results were acceptable overall. None of the 11 eyes had lost two or more lines of best-corrected acuity. However, the eyes with silent EBMD had a delayed visual recovery and developed multiple complications. These complications included DLK and microfolds within the first month after surgery and, later, epithelial ingrowth and flap melting that persisted to one year.

When there are multiple causes for severe epithelial sloughing during LASIK, our study indicates this intraoperative complication is often a sign of silent EBMD. LASIK surgeons need to be aware of this hidden cause of severe sloughing. They should anticipate similar behaviour in the fellow eye, and postpone the visit of the patient while evaluating the aetiology. In eyes with EBMD, PRK is the refractive and therapeutic procedure of choice,” said Dr Galal.

All of the ablations were performed with the Technolas C-217 excimer laser (Bausch & Lomb). Three different microkeratomes were used during the same period. Surgery was performed using a two-week waiting period between eyes. The sixth patient underwent LASIK in the first eye and PRK in the fellow eye.

“When sloughing occurred during the procedure in the first eye of the first five patients, we thought it might be a microkeratome-related problem or related to flap irrigation. Therefore, we went on to operate on the other eye with greater caution. By the sixth patient, we recognised the potential for the same complication to occur in the second eye,” said Dr Galal.

Epithelial ingrowth developed in eight eyes between months one and three after surgery. Three eyes developed flap melts during the same period. Surgery performed in two eyes for epithelial ingrowth included lifting the flap, cleaning the interface of the cells, and applying 4.0% cocaine onto the stroma. Epithelial ingrowth persisted at one year in all three eyes. Four eyes had flap melts.

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Epithelial healing followed by DLK and microfolds

The intraoperative sloughing was complete in seven eyes and partial in four eyes. All of the epithelial defects healed within two to five days when managed with the usual postoperative regimen, which consists of topical antibiotic, corticosteroids, artificial tears, and placement of therapeutic contact lenses.

However, within the first month after surgery, DLK (grades I or II) developed in six eyes, and two eyes developed clinically significant flap microfolds. The DLK was treated with intensive corticosteroids. The surgeons handled the microfolds by flap lifting and interface hydration using distilled water to facilitate flap stretching.

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