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# Epi-LASIK yields high satisfaction in patients with moderate to high myopia

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in London

EPI-LASIK with the Amadeus II epikeratome (AMO) may be able to correct a broader range of refractive errors than LASIK and produce a slightly better refractive outcome than LASEK, according to a series of presentations at the XXIV Congress of the ESCRS.

In the first of the presentations Dariel Mathur MBBS, MS, New Delhi, India told the congress that epi-LASIK with the Amadeus II epikeratome produced very satisfactory outcomes in terms of visual acuity, pain and haze in a study involving patients with moderate to high myopia.

The study included 110 eyes of 67 patients who underwent Epi-LASIK to correct -3.0 D to -11.0 D of myopia (mean: -7.21 D). The patients had a mean age of 25.75 years, ranging from 20 to 46 years. None had previous ocular diseases or systemic diseases that could affect epithelial healing. All had a stable refraction for at least one year prior to surgery.

Dr Mathur and her associates performed epithelial separations in all eyes with the Amadeus II Epikeratome (AMO) and wavefront-guided ablations with the VISX Star S4 excimer laser, using the CustomVue algorithms.

The epikeratome used in the study is a modification of the ACCMI/Amadeus microkeratome. A redesign of the blade and blade holder provides surgeons with the option of performing either LASIK or epi-LASIK. In the surface ablation procedure a plastic block takes the place of a blade and cleaves the epithelium just beneath the basement membrane, Dr Mathur noted.

"This viable flap, only 60 microns thick, gives us a precious 100 extra microns of stroma to work with. This is very important in Asian populations, where we do tend to have thinner corneas," she said.

The mean time to complete epithelial healing in the study was 3.61 days (range: three to five days), Dr Mathur noted. On average, patients were pain free after one and a half days, she added.

## UCVA and BCVA improved during follow-up

The mean uncorrected visual acuity on the day when the epithelium was completely healed and the bandage contact lens was removed was around 20/40. However, the proportion with UCVA 20/25 or better rose from 55.5 per cent at one month to 89.1 per cent at six months, and over 90 per cent of eyes saw 20/40 or better throughout the follow-up period.

Best-corrected visual acuity also improved during follow-up, she noted. At one month's follow-up, 26.5 per cent lost one line of BCVA and 18.4 per cent lost

two lines, and only 8.2 per cent gained a line. But at six months' follow-up, no eyes lost two lines of BCVA and nearly 30 per cent had gained one line, 5.9 per cent gained two, and only 10.9 per cent lost one line.

All eyes were within 1.0 D of emmetropia throughout follow-up, although, after an initial improvement, the mean refractive error increased slightly after the third month. That is, the mean spherical equivalent improved from -0.26 D (range -0.75 to +0.75) at one month to -0.13 D (range -0.50 to +0.62) at three months, but at six months it was -0.42 D (range -0.87 D to +0.12 D).

"We attribute this to the fact that we targeted the higher myopes and also to a trace haze that occurred in some of our patients in the third to fourth month."

In most eyes where haze occurred, it improved during follow-up. The proportion with clear corneas or only trace amounts of haze increased from 67.6 per cent, at one month, to 89.4 per cent, at three months, and 95.1 per cent, at six months. The remaining eyes had only mild amounts of haze.

Contrast sensitivity on the Pelli-Robson scale followed a similar pattern. There was a mild decrease in contrast sensitivity at one month, which improved to 1.69 at six months, compared to a pre-operative value of 1.64.

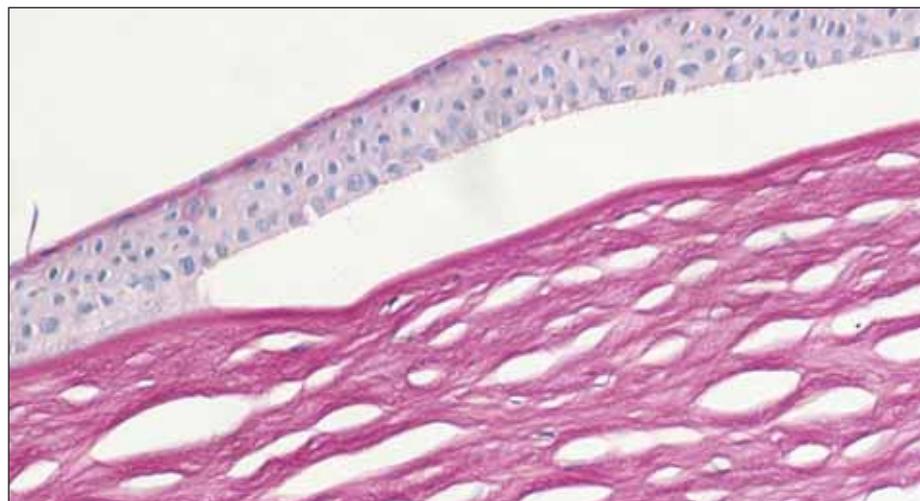
"We attribute this to the success of the CustomVue treatment and also because the PRK mode of customisation in any laser form is supposed to be superior," she said.

Patient satisfaction questionnaires indicated that nearly all patients were happy with the results of the procedure. The proportion of patients who described themselves as satisfied with their vision increased from 24.4 per cent, pre-operatively, to 84.4 per cent, postoperatively. In addition, the proportion of people describing themselves as slightly dissatisfied decreased from 34.7 per cent to 2.1 per cent. However, the proportion of people describing themselves as very dissatisfied increased from zero to 2.0 per cent.

"Although it is not a totally pain-free procedure and does not have the rapid visual recovery of LASIK, epi-LASIK provides reasonable visual performance in the early postoperative period with a majority of patients having very good vision minimal irritation and negligible haze," Dr Mathur added.

## Epi-LASIK vs LASEK

The results of another study presented at the ECSR Congress indicated that epi-LASIK with the Amadeus II epikeratome may produce slightly better refractive outcomes than LASEK in eyes with low to



Optical microphotograph of the epithelial disc and underlying Bowman layer after mechanical separation. Complete separation of the undamaged epithelium from Bowman's layer is achieved (HE colouring, original magnification x20)

moderate myopic astigmatism.

The study involved 25 eyes of 13 patients treated with epi-LASIK and 50 eyes of 25 patients treated with LASEK. In the epi-LASIK group the mean pre-operative spherical equivalent was -3.46 D (range: -1.25 D to -6.25 D), and in the LASEK group it was -3.71 D (-1.75 D to -6.5 D). All eyes in both groups had more than 1.5 D of cylinder, said Carlo Lackerbauer MD, University of Munich, Munich, Germany.

In the LASEK-group epithelial separation was performed with 20 per cent ethanol for 30 seconds. In the epi-LASIK-group the epithelium layer was separated with the AMADEUS II epikeratome (AMO).

Dr Lackerbauer performed all ablations with a 200 Hz Wavelight Allegretto laser. The ablations had a 6.5mm optical zone and used the standard nomogram with an aspheric ablation profile.

At three months' follow-up, 96 per cent of the epi-LASIK group were within 1.0D of attempted correction and 93 per cent were within 0.5 D. The LASEK group had the same percentage of eyes within 1.0 D of attempted correction but only 88 per cent were within 0.5 D.

In terms of efficiency, UCVA at three months' follow-up was within one line of pre-operative BSCVA in 81 per cent of eyes in the epi-LASIK group and 79 per cent of eyes in the LASEK group. In addition, UCVA at three months' follow-up was better than pre-operative BCVA in 36 per cent of the epi-LASIK group and 33 per cent of the LASEK group.

As regards safety, no eyes in the epi-LASIK group lost any lines of BSCVA, while eight per cent in the LASEK group lost one or more lines. Best-corrected acuity improved by more than one line in 18 per cent of the epi-LASIK group and 16 per cent of the LASEK group.

"The AMADEUS II guided epi-LASIK group presents a slightly better refractive outcome concerning efficiency, precision,

stability and safety. This could be due to a faster wound healing process because of the smooth separation of the epithelium layer and the lack of ethanol vapour with its influence on the energy absorption," Dr Lackerbauer added.

## Under the microscope

In another study, microscopic examination showed that epi-LASIK flaps created with the AMADEUS® II microkeratome have good structural integrity and that the stromal surface below was smooth and free of irregularity, said Aris Kollias MD, also at the University of Munich.

The study involved the examination of cross sections of corneal tissue obtained from two human donor eyes that had undergone epithelial separation with the epikeratome. Light microscopy of the specimens showed that the epithelial sheets were thoroughly separated with no evident anatomical abnormalities. It also showed that stratification of the separated epithelium layer and cell shape were well conserved and that the cleavage plane was located at Bowman's membrane.

In addition, scanning electron microscopy showed a very consistent transition from adherent epithelium to the denuded area.

The Bowman's layer in the specimens had a very smooth surface without any remains of basal lamina or basal cells.

Moreover, examination of Bowman's layer with transmission electron microscopy showed only minor superficial irregularities at high magnification (x4500).

"Using the epi-LASIK separator of the microkeratome Amadeus® II, our in vitro study demonstrates a high cut quality. The resulting cleavage plane at Bowman's membrane is well suited for following excimer laser ablation.

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