

Experts divided on the benefits of IntraLase

Dermot McGrath in Paris

DOES LASIK flap creation with the IntraLase femtosecond laser give better results than with a standard mechanical microkeratome?

The answer, according to a number of presentations by investigators at the XXII Congress of the ESCRS, is yes, no, and maybe.

Guy Kezirian MD, Arizona, US said he believed that the flap generated by the IntraLase system ultimately yielded better visual outcomes for patients compared to the same procedure performed in eyes with a mechanical microkeratome.

Dr Kezirian presented data from a six-month follow-up of a randomised, prospective, contralateral eye comparison study carried out by Dan Durrie MD. The trial included 102 eyes of 51 patients; in one eye of each patient the LASIK flap was created using the Hansatome (Bausch & Lomb), and in the fellow eye it was created with the IntraLase. The same laser (Alcon LadarVision 4000) was used for ablation in all eyes so that the only variable between groups was the method of flap creation.

The results showed a slight tendency for undercorrection with the Hansatome, noted Dr Kezirian. Cylinder results were also significantly better with the IntraLase, confirming previous reports. Moreover, the cylinder differences were not associated with differences in higher order aberrations, such as coma, and had a significant effect on uncorrected visual acuity, he said.

Although wavefront outcomes for higher order aberrations were similar in both groups, comparison of eyes with similar spherical equivalent refractive outcomes showed better results in the IntraLase group. When eyes with postoperative manifest astigmatism were excluded from the analysis these differences disappeared.

Dr Kezirian stressed that while he believed that the flap created by the IntraLase resulted in better visual

outcomes, he was not trying to suggest that there were any major quality issues with the mechanical keratome used in this study.

"It is important to emphasise that the results for both keratomes were excellent. The visual outcomes were higher in this series than others that have been reported and I think a lot of that can be attributed to Dan Durrie's excellent and consistent surgical technique," said Dr Kezirian.

Contradictory findings

In a separate presentation, Trevor Woodhams MD, Atlanta, Georgia, US, said that his study showed that patients treated with a mechanical keratome (Amadeus, AMO Inc.) recorded better visual outcomes even though the IntraLase created more accurate and predictable flap thicknesses.

"Our study showed that the IntraLase produced a more uniform and predictable flap with a final uncorrected visual acuity (UCVA) at three months that compared to the Amadeus microkeratome. However, there was better early UCVA achieved with the Amadeus and postoperative photophobia was more severe and more frequent with IntraLase," he said.

Dr Woodhams' study included 100 eyes of 100 patients whose keratectomies were performed using the Amadeus microkeratome, and a similar number of patients whose flaps were created using the femtosecond laser.

At three months, 95% of the Amadeus eyes enjoyed uncorrected visual acuity of 20/20 or better versus 82% of the IntraLase eyes. A greater number of eyes in the Amadeus group (74%) achieved UCVA of 20/16 compared to those in the IntraLase group (52.3%).

In terms of intraoperative complications, Dr Woodhams said that both approaches recorded excellent results.

"There was no significant difference between them. The incidence of epithelial abrasions in the Amadeus eyes were all very minor, usually less than 10% to 15% of the diameter of the flap. There

were two suction losses in the case of the IntraLase. This did not abort the procedure, however, because one of the beauties of the instrument is that you can reapply suction and continue with the flap creation," he said.

Dr Woodhams noted that the IntraLase performed better than the Amadeus for flap predictability.

"This is a different data set. We looked retrospectively at about 150 patients, both right and left eyes consecutively. The interesting thing is that with the Amadeus set at 140µm, we were actually cutting a mean of 110µm to 120µm, with a standard deviation of about 30µm. When looking at the IntraLase set at 110µm, we were cutting between 110µm and 115µm, so the standard deviation is about one-third that of the Amadeus," he said.

Transient light sensitivity

While there were no significant complications in the immediate postoperative period for either the Amadeus or IntraLase, Dr Woodhams said that he had experienced a worryingly high incidence of the syndrome known as transient light sensitivity associated with IntraLase flap creation.

"About 40% of our patients on a scale of zero to nine reported significant photophobia at one month," he said. This photophobia can range from mild to severe and often occurs in the late postoperative period, several weeks to two or three months after surgery.

The condition appears to respond to steroids, although Dr Woodhams remarked that he has had to use extensive steroids for a few weeks in some cases.

The results for uncorrected visual acuity showed that patients treated with the Amadeus had significantly better outcomes than IntraLase patients at one-day postoperatively.

"This difference was statistically significant, although this did tend to even out over time so that statistically at three months the results were excellent with over

90% seeing 20/20 or better in both groups," said Dr Woodhams.

Dr Woodhams acknowledged that the evaluation may have been skewed somewhat by the fact that he has extensive experience involving thousands of eyes with the Amadeus microkeratome compared to IntraLase.

"There is undoubtedly a much steeper learning curve with the IntraLase. We had quite a bit of variation in the energy settings as we adapted to the machine, especially in terms of the edge cut which may well account for the greater inflammation that we saw postoperatively that was presumably the cause of the late onset photophobia," he said.

Summing up, Dr Woodhams said that there were pros and cons to bear in mind for both approaches to flap creation.

"We had no serious flap complications for eyes treated with either the IntraLase or the Hansatome."

Stephen Slade MD

"In terms of safety, they are really equal; in terms of the predictability of the flap there is no doubt that the IntraLase is better; the brevity of procedure is probably a slight edge for the Amadeus. Photophobia, at least in this series, was a significant problem for the IntraLase. Refractive outcomes were equal at three months with a slight edge for speedier visual recovery in the Amadeus group," he said.

Similar safety profiles

A further study presented by Stephen Slade MD, Houston, Texas, concluded that there was very little

difference between flap creation with a laser or a mechanical keratome in terms of safety or efficacy.

The prospective, randomised, contralateral eye study included 42 eyes of 21 patients randomised to undergo keratotomy with a Hansatome microkeratome (Bausch & Lomb) in one eye and keratectomy with an IntraLase femtosecond laser in the contralateral eye prior to conventional ablation.

While the IntraLase resulted in more predictable flap thickness, Dr Slade concluded that visual outcomes were not different in eyes undergoing either corneal lamellar resection via microkeratome or femtosecond laser keratectomy at one month follow up.

"We had no serious flap complications for eyes treated with either the IntraLase or the Hansatome. In my opinion there is no difference in serious flap complication rates between the two and I don't think that you could design a study with enough eyes to pick up a statistically significant difference in serious flap complication rate between an experienced user of both methods," he said.

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