ZYOPTIX wavefront-guided LASIK and LASEK provide safe and predictable outcomes with enhanced visual quality, a large-scale study shows.

Jay Dermott MD presented data from an ongoing, single-surgeon, prospective trial using Zyoptix (Bausch and Lomb) wavefront-guided LASIK and LASEK during the XXIV Congress of the ESCRS.

“Our patient suffered losses of more than two lines of BCVA or continued to suffer disabling night vision symptoms at the six-month stage. About 96 per cent of patients reported zero, little or moderate night vision phenomena at the six-month stage, and were therefore, so to speak, in the ‘happy zone’. Iris recognition was achieved in 80 per cent of all patients with ablation depths until about 138 microns,” said Mr Dermott.

The study included 492 eyes of 246 patients with a mean age of 35 years. Group A included 314 eyes that underwent wavefront-guided LASIK. The mean sphere in this group was -3.25 D (range: -8.00 to -1.00 D), the mean cylinder was -0.81 D (range: -4.75 to 0.00 D), and the mean spherical equivalent was -3.78 D (range: -8.25 to -1.12 D).

Group B included 178 eyes that underwent wavefront-guided LASEK. The mean sphere was -3.78 D (range: -7.25 to -1.12 D), the mean cylinder was 0.89 D (range: -4.25 to 1.00 D).

Mr Dermott used the Bausch & Lomb Technolas-217x100 platform with iris recognition technology (with Zylink 61652 customised treatment calculation software Version 4.02). Iris recognition was achieved in 78.34 per cent of group A eyes and 79.21 per cent of group B eyes, he reported.

The LASEK group showed the typical and expected drop in visual acuity in the early postoperative stage. However, at the end of the final evaluation, Log MAR visual acuity achieved by the LASEK group actually superseded that of the LASIK group, he noted.

One week postoperatively, the LASIK group showed 100 per cent contrast Log MAR UCVA of 0.10 ± 1.48 D, while the LASEK group achieved 0.02 ± 1.75 D. One-month results revealed 100 per cent contrast Log MAR UCVA of 0.02 ± 1.75 D for the LASIK treatment group and 0.08 ± 1.42 D for the LASEK group.

The efficacy index at six months showed that 97.87 per cent of a total of 431 eyes achieved 6/12 (20/40) or better, and 89.32 per cent achieved 6/6 (20/20) or better - giving an index of 0.984, Mr Dermott said.

Predictability between the two groups was very close on the average, and equivalent in terms of the spherical equivalent achieved. At the six-month stage, 98.84 per cent of 431 eyes were within 1.00 D of the intended correction and 92.11 per cent were within 0.50 D.

Safety, measured in terms of the number of lines gained or lost, revealed a safety index of 99.8 per cent (0.998) at the six-month stage, in all 431 eyes, Mr Dermott observed.

The mean group A optical zone was 6.50mm (range: 6.00 to 7.20mm) and the mean ablation depth was 72.68 µm (23 to 138 µm). In group B, the mean optical zone was 6.54mm (6.10 to 7.20mm) and the mean ablation depth was 70.83 µm (23 to 123 µm).

Arthur Cummings MD remarked that if 26 per cent of patients improved low contrast vision at six months, then the evidence conflicted somewhat with the fact that 26 per cent of eyes lost one line of BCVA, as well.

Mr Dermott explained that a sub-investigation, which was built into the trial set-up, revealed that many of those patients lost visual acuity from 6/4 to 6/5. This evidence would be all the more relevant at the one-year stage, he said.

The substudy included an 18 per cent contrast screen of acuity using a subcohort of eyes with low contrast sensitivity. The substudy revealed that low contrast acuity was slightly better than the original values at six months’ time in both study groups, which again achieved equivalent outcomes.

Mr Dermott investigated the patient satisfaction and quality of vision by means of a questionnaire.

He observed that concerning the incidence of halos, 96.35 per cent of patients were in the happy zone pre-operatively (night vision scores 1-3), and 97.32 per cent scored absent to moderate starbursts in the happy zone at six months’ postoperatively.

Starburst-incidence scores revealed that 96.45 per cent of patients were in the happy zone pre-operatively, while 95.19 per cent scored absent to moderate starbursts at the six-month stage.

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