

German investigators call for evidence-based approach to laser refractive surgery

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in Nürnberg

HAS wavefront lived up to its early promise? German investigators aired conflicting viewpoints on the utility of wavefront based ablation during a symposium devoted to evidence-based medical analyses of LASIK during the 18th Congress of the German Ophthalmic Surgeons (DOC).

Some speakers said that wavefront-guided LASIK lacks the high standard of predictability required of modern refractive surgery. Others believe that this treatment modality needs to be investigated by randomised, prospective trials to set down the guidelines required to help reduce laser-induced aberrations, while still others maintain that wavefront aberrometry is misused in the eye.

"Wavefront guided LASIK treatments so far have enabled an uncorrected vision of 1.0 and better and have shown preferable results to eyes treated with conventional LASIK alone. In some patients, reductions of higher order aberrations were achieved, however, for the most part, aberrations were increased. The treatment of higher order aberrations needs more evidence-based study," said Thomas Kohnen MD, Frankfurt University Eye Clinic, Frankfurt, Germany.

Good results with wavefront in prospective trial

Dr Kohnen conducted a prospective trial that included 98 eyes of 51 patients, all of which underwent wavefront-guided LASIK with the goal of emmetropia, using the Zyoptix™ 3.1 system, the Technolas® 217z laser, and the Hansatome® microkeratome (Bausch&Lomb). He used no nomogram adjustment.

Preoperatively, the mean spherical equivalent in the patient collective was -5.23 D (-1.0 D to -9.5 D), the mean sphere was -4.77 D (-0.25 D to -9.0 D), and the mean cylinder of the trial patients was -0.91 D \pm 0.65 D (0.0 D to -3.0 D). Follow up



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evaluations occurred at one month and one year following surgery.

Dr Kohnen found that the predictability of surgery was relatively good one year postoperatively, with very few under and over corrections. He noted exceptions to this at about -8 D, but found the results otherwise to be very satisfactory.

The mean postoperative spherical equivalent was -0.15 D \pm 0.46 D. Seventy-seven patients achieved +0.5 D and 95 achieved \pm 1.0 D SE, which showed very good predictability, Dr Kohnen reported.

Twenty-six percent of eyes had a postoperative uncorrected visual acuity greater than 1.25, while 83% had postoperative visual acuity greater than 1.0. However, six percent of patients lost one line of best corrected visual acuity at one year, 49% remained unchanged, 40% gained one line of visual acuity, and 5% gained two lines or more.

There was a marked improvement in vision when comparing the results at one month and at one year, he noted. Dr Kohnen noted that other published studies involving various excimer laser systems have similarly revealed a 5-10% rate of patients losing one or more line of best corrected acuity following wavefront ablation.

Increase in higher-order aberrations in most eyes

In Dr Kohnen's study, higher-order aberrations (HOA) increased by a factor of 1.52

\pm 0.63. He pointed out that HOA were seen to increase in most published studies, by a factor of 1.22 ± 0.84 and 1.44 ± 0.74 in two separate Wavelight prototype studies, and by a factor of 1.23 in a trial investigating the LADARVision® (Alcon) system.

The percentage of eyes with decreased HOA in Dr Kohnen's study was 20.6%. By contrast two separate Wavelight prototype studies revealed divergent results, with decreased HOA in 66.7% and 22.5%, respectively, while 70.3% of patients in the VISX FDA study showed decreased HOA.

In terms of predictability for patients with defocus, Dr Kohnen noticed that the correction of primary spherical aberrations often resulted in under-corrections that left patients unsatisfied.

Topography-guided optimisation

Paul-Rolf Preussner MD PhD, Mainz University Eye Clinic, Mainz, Germany, maintains the much disputed viewpoint that wavefront aberrometry is misused in the eye. He claims that there is a much easier solution.

"It is not necessary to correct aberrations using wavefront aberrometry. The surgeon needs only do a corneal topography, which will give the precise shape of the cornea. From there, all he needs to do is choose the most suitable optic, take the difference, and ablate it. The results are ideal and much easier," he said.

While most surgeons would argue that wavefront is much more precise in practice than topography-guided aberrometry alone, Dr Preussner explained that wavefront aberrometry measures the entire optical system, which is an error. It is only the cornea that is cut and wavefront technology is not suitable to measure the cornea alone.

"Wavefront aberrations are aberrations in the optical path that range from 10-100 μ m in the human eye. Researchers, who measure

aberrations as fractions of micrometers, are not measuring the actual aberrations but the Zernike coefficient. Although this is mathematically correct for telescopes for example, the principles here cannot be realistically applied to the eye. Even if it were tentatively realistic in the eye at the moment of measurement, physiological fluctuations would cause changes in the measurements," Dr Preussner explained.

Dr Kohnen agreed that efforts ought to be made to combine topography with wavefront systems. Still, as there are few evidence-based investigations on the subject of wavefront aberrometry, he felt that refractive surgeons must strive to run such trials, as the positive clinical effects of this treatment need to be substantiated.

Comparative trial favours wavefront

As a case in point, he noted a recent study that compared wavefront to standard PRK (Mastropasqua, J Refract Surg 2004) in which researchers split 60 patients into two groups, 30 for wavefront and 30 for PRK.

They found only a low rise in HOA in wavefront patients, especially in those with preoperative HOA greater than 0.4 microns, indicating that these patients in particular were found to profit from wavefront guided ablation.

Factors affecting the predictability of aberrometry can include accommodation and the tear film. Also, new eye trackers could improve registration. Adapting aspherical ablation profiles could help reduce the primary induction of both spherical aberrations and biomechanical effects, Dr Kohnen said.

Aberrometry depends on pupil diameter, as well. HOAs disturb vision increasingly with increasing pupil diameter. Furthermore, Dr Kohnen noted that visual quality was not only a function of visual acuity, but perhaps also of contrast sensitivity, for which there

were few guidelines.

Standard LASIK revealed a low reduction in contrast sensitivity (Holladay 1999; Mutyala 2000), while wavefront-guided LASIK gave no uniform results. Some studies proved little improvement under scotopic and photopic conditions (Lawless 2003), or no significant changes (FDA study-Koch; Kohnen 2004).

In studying the measurability of aberrations of Hartmann-Shack aberrometry in 2001-2002, Dr Kohnen noted a discrepancy of up to 1.66 D between the subjective manifest refraction and wavefront refraction. Most wavefront-based excimer laser systems are based on the Hartmann-Shack principle (CustomVue™ (VISX AMO), Zyoptix™ (Bausch & Lomb), CustomCornea™ (Alcon), Esiris (Schwind) with different resolutions (400 μ m, 700 μ m, 210 μ m, 250 μ m, 210 μ m, respectively).

He found reproducibility with the Zywave™ (Bausch&Lomb) wavefront sensor unsatisfactory as it decreased with increasing aberration order. He maintained that aberrometry measurements should be repeated several times and poor measurements excluded from calculations.

Dr Kohnen called for an 'evidence based medicine' approach to sorting out the various issues raised in the discussion. This should include randomised controlled trials, systematic reviews (of a series of trials), and meta-analyses.

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