Wavefront-guided refractive surgery worth the effort

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in London and Las Vegas

CLINICAL trials and computer modelling agree that wavefront-guided surgery should be the procedure of choice for laser vision correction in patients who otherwise meet the indications for that procedure, asserted Steve Schallhorn MD, speaking at the XIV Congress of the ESCRS.

Dr Schallhorn presented a computer modelling study that was performed to predict visual performance after wavefront-optimised and wavefront-guided LASIK in eyes with low levels of pre-operative higher order aberrations (HOAs). The wavefront-guided procedure was consistently found to be statistically and clinically superior. Compared with wavefront-optimised surgery, it induced less HOAs, and it had advantages relative to conventional surgery for better refractive and visual function outcomes.

"It's well appreciated that wavefront-guided LASIK provides an effective therapeutic modality to reduce HOAs in eyes with high amounts of pre-operative aberrations. Our computer model suggests patients with low amounts of pre-operative HOAs will benefit just as much and perhaps even more considering that patients who have minimal HOAs pre-operatively may be especially susceptible to be adversely affected by induced HOAs after refractive surgery," said Dr Schallhorn, who is director of refractive surgery, US Navy, Naval Medical Centre, San Diego, California.

Dr Schallhorn explained that the wavefront-optimised treatment, which is based on sphere and cylinder and designed to be spherical aberration neutral, has some practical advantages compared with custom ablation since it requires less equipment and is easier and less expensive to perform.

"However, we were interested to see if there is any trade-off for those benefits in terms of outcomes in eyes with low levels of pre-operative HOAs," he said.

Dr Schallhorn and colleagues created a computer model for predicting postoperative HOA outcomes using baseline and one-month postoperative data from 327 eyes that had conventional LASIK and a matched group of 266 eyes that had wavefront-guided LASIK. Based on the HOA distribution in the study population, 10,000 random pre-operative wavefront maps were generated using a 6.0mm pupil and including terms through the Zernike 6th order.

The HOA RMS values for those maps exhibited a normal distribution and matched well with a plot based on actual maps from a population of 488 normal eyes. The researchers then used the computer model to determine the HOA outcomes for the 10,000 maps after wavefront-optimised and wavefront-guided surgery. The model was constructed to generate postoperative results based on two assumptions. First, wavefront-optimised treatment induces zero change in spherical aberration, and second, if the wavefront-optimised treatment induced or reduced any other types of HOAs, the changes would be the same as with conventional LASIK. The model eyes were randomly assigned to be within one standard deviation of the predicted induced HOA depending on the surgery type (wavefront-optimised vs. wavefront-guided) and the amount of pre-operative HOA.

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The results were also analysed with the eyes divided into subgroups according to amount of pre-existing HOA RMS (<0.3, 0.3-0.4, 0.4-0.5, and >0.5 microns). Those data showed the amount of induced HOA with either procedure decreased with increasing level of pre-operative HOA. However, the amount of decrease in that pattern was greater for the wavefront-guided procedure.

To determine whether the difference between procedures had clinical relevance, further investigation was performed to identify what represents a measurable difference in HOAs. Aberrometer repeatability was evaluated by examining 200 virgin eyes twice on two different days but at the same time of day. The data showed there was an average difference of 0.009 microns between examinations with a standard deviation of 0.033 microns. A value of 0.1 microns, representing three standard deviations off the average change, was chosen as the amount of HOA change that could be reliably measured using the aberrometer.

Using that benchmark, the data from the model were reanalysed and the results showed that about twice as many eyes would have a significant amount of induced HOAs after the wavefront-optimised treatment compared with the wavefront-guided procedure. Subgroup analyses with the eyes categorised based on amount of pre-existing HOAs showed the same difference between procedures persisted regardless of the amount of pre-operative HOAs.

Dr Schallhorn said that the benefit of the wavefront-guided procedure is explained by the fact that it induces less of other types of HOAs compared with the wavefront-optimised procedure. He presented data comparing induced HOAs at one month post-op in eyes with pre-operative HOA RMS of not more than 0.3 microns for cohorts treated with wavefront-guided LASIK using the Visx platform and conventional treatment using the Alcon, Nidek, Bausch and Lomb, and Visx systems.

Mean induced total HOA RMS ranged from 0.1842 to 0.2484 microns for the conventional treatments compared with only 0.0917 microns for the Visx custom treatment. After subtracting spherical aberration, the custom treatment was shown to induce 0.0672 microns of HOA RMS compared with between 0.1398 to 0.1972 microns for the other procedures.

"Although we know spherical aberration is the most commonly induced HOA after conventional surgery, conventional surgery and wavefront-optimised surgery induce other types of HOAs. Looking at the amount of those HOAs induced using results from large populations treated with multiple laser platforms, we see there is more induction of HOAs with the conventional procedures compared with wavefront-guided surgery using the Visx CustomVue system," Dr Schallhorn said.

He added the benefit of the custom ablation was based on analyses using data from the first generation procedure. With subsequent advances, the benefits of the wavefront-guided treatment should be increased, he said.

Further evidence for superiority of custom ablation

Speaking in Las Vegas at Refractive Surgery 2006, the refractive surgery subspecialty day sponsored by the International Society of Refractive Surgery/AAO, Dr Schallhorn reported on a study comparing clinical outcomes in large groups of matched eyes undergoing either wavefront-guided versus conventional LASIK or wavefront-guided versus conventional PKR.

The retrospective study compared three-month results from 238 eyes treated with...
wavefront-guided LASIK and 841 matched eyes that underwent conventional LASIK. Mean MSE at three months was +0.01 D in the wavefront-guided eyes and -0.03 D, in the conventional group. However, the standard deviation results showed there was less variability in the wavefront-guided group than in the conventional group (±0.31 vs. ±0.42 D, respectively) so that the custom ablation offered significantly better predictability.

In the analysis of UCVA outcomes, the significant difference favouring the wavefront-guided procedure was the result of its association with a much higher proportion of eyes achieving a 20/16 or better result compared with the conventional treatment, 88 per cent vs. 68 per cent, respectively. A difference was also seen favouring the wavefront-guided treatment in the analysis of proportion of eyes achieving UCVA of 20/12.5 or better, 39 per cent vs. 30 per cent, respectively.

“No eyes lost two or more lines of BSCVA, and so certainly both procedures can be considered safe according to existing criteria. However, BSCVA can also be considered a measure of quality of vision with loss of one or more lines representing a measurable loss.”

Wavefront-guided treatment also provided significantly better improvement in BCVA. Differences were seen between the wavefront-guided and conventional groups in an analysis of mean improvement from pre-operative (+0.4 lines vs. +0.2 lines, respectively) and in comparing the proportions of eyes with a one line or greater improvement (45 per cent vs. 29 per cent, respectively), and with a one line loss (four per cent vs. nine per cent, respectively).

“No eyes lost two or more lines of BSCVA, and so certainly both procedures can be considered safe according to existing criteria. However, BSCVA can also be considered a measure of quality of vision with loss of one or more lines representing a measurable loss. From that perspective, the wavefront-guided procedure is better,” Dr Schallhorn said.

Low contrast visual acuity testing similarly showed significant benefits favouring the wavefront-guided procedure over the conventional treatment in analyses of mean change from baseline (+0.1 vs. -0.3 lines, respectively), the proportion of eyes gaining two or more lines (seven per cent vs. five per cent, respectively), and the proportions of eyes losing two or more lines (three per cent vs. 14 per cent, respectively).

Wavefront benefits also found for surface ablation

The PRK analyses were based on pre-operative and six-month postoperative data from 292 eyes that had wavefront-guided treatment and 1,042 eyes treated with conventional PRK. All eyes were targeted for emmetropia, and mean MSE values at six months in the wavefront-guided and conventional groups were -0.05 D ± 0.28 and -0.04 D ±0.40 D, respectively. Again, the wavefront-guided treatment was significantly more predictable due to its smaller standard deviation.

As after LASIK, the wavefront-guided PRK procedure was associated with a higher proportion of eyes achieving UCVA of 20/16 or better compared with the conventional treatment (88 per cent vs. 77 per cent, respectively). In addition, more wavefront-guided compared with conventional eyes achieved UCVA of 20/12.5 or better (55 per cent vs. 48 per cent, respectively).

While both types of PRK procedures resulted in a mean improvement in BCVA, again, the mean improvement was greater with the wavefront-guided procedure (+0.6 vs. +0.2 lines, respectively) and more wavefront-guided eyes than conventional eyes gained one or more lines of BCVA (55 per cent vs. 34 per cent) while fewer lost lines (four per cent vs. 19 per cent, respectively). Only in the conventional group were there any eyes with a greater than one line loss.

On average, eyes undergoing either the wavefront-guided or conventional PRK procedure achieved an improvement in five per cent low contrast acuity (+0.6 vs. +0.4 lines), but the difference favouring the custom procedure was statistically significant.