By Cheryl Guttman in London

CUSTOMVUE presbyLASIK (AMO) appears to be a safe and effective technique for treating hyperopic presbyopia, according to reports at the XXIV Congress of the ESCRS.

The patented ablation profile combines the wavefront-guided hyperopic treatment with a presbyopic shape and steepens the central cornea for near vision while treating the periphery for distance. In a keynote lecture, W Bruce Jackson MD, professor and chairman of ophthalmology, University of Ottawa, Ontario, Canada, reported the one-year outcomes from a Canadian multicentre study of CustomVue PresbyLASIK.

Dr Jackson reported data for 93 eyes of 56 patients. Sixty-four eyes of 32 patients were treated at his own institution. Among the remaining patients enrolled at the other investigational sites, some underwent monocular treatment only. Fifty-nine eyes (63 per cent) have been seen at the one-year follow-up visit. Based on outcomes from comprehensive efficacy and safety analyses, Dr Jackson concluded the treatment could achieve spectacle independence in a high proportion of patients without causing significant loss of contrast acuity. Importantly, patients continue to be highly satisfied over time.

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"These patients have been really delighted with their vision. Negative comments have been limited and have been restricted to a few requests for more near vision or sharper distance vision. However, when the latter patients were given the option for retreatment with a caution that they would have to give up some near vision, all declined to proceed," said Dr Jackson.

Pre-operative mean sphere for the 93 eyes in the multicentre study was +1.67 D (range +0.50 to +3.50) and mean cylinder was +0.43 D (range +0.00 to +1.50). The patients had a mean age of 55 years.

"The original protocol's inclusion criteria required patients be at least 51 years of age, but it was subsequently amended and we have now enrolled patients as young as 43 years old," Dr Jackson said.

The ablations were performed with the Star S4 excimer laser and consisted of a WaveScan driven treatment for hyperopia combined with a pupil size-dependent presbyopic correction. There was one retreatment after nine months. Early half of the eyes (50/93) underwent ablations with the AMO/Wix iris registration technology. All eyes at the University of Ottawa had flap creation using the Amadeus microkeratome. The femtosecond laser (Intralase) was used at the other study sites. There were no monogram adjustments in the series.

Dr Jackson noted that the monocular uncorrected distance visual acuity (UCDVA) outcomes improved over time. By 12 months, 70 per cent of eyes achieved 20/20 or better and 92 per cent could see 20/25 or better. Pre-operatively, those levels of vision were achieved by one per cent and five per cent of eyes, respectively. In binocular testing after bilateral treatment, 90 per cent of eyes were 20/20 or better and 100 per cent achieved 20/25 or better UCDVA at 12 months.

"The monocular results are comparable to those achieved with standard CustomVue hyperopic treatment, and the binocular data show a clear additive effect," Dr Jackson observed.

Near vision outcomes have remained fairly stable throughout follow-up, although at 12 months, there has been some loss in the proportions of patients achieving J1 and J3 vision relative to earlier follow-ups. At 12 months, monocular UCNVA was J1 or better in 63 per cent of eyes and J3 or better in 81 per cent. Binocular UCNVA after bilateral treatment was J1 or better in 85 per cent of patients and all could read J3.

Results for monocular distance corrected near vision have remained stable during follow-up. At 12 months, 56 per cent of eyes could read J3 or better and 88 per cent could read J3 or better.

Dr Jackson said the stability of those outcomes over time is consistent with the refractive results. At one month, mean MRSE was close to emmetropia (0.30 D), and it changed less than 0.5 D by 12 months when mean MRSE was +0.06 D and 81 per cent of eyes were within 0.5 D of emmetropia.

In binocular testing, 100 per cent of subjects achieved UCDVA of 20/25 or better and J3 at near while 85 per cent were 20/25 or better and could read J1 or better.

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Near vision was also evaluated with reading performance tests. Compared with results from pre-operative testing with correction, there were improvements in both reading acuity and critical print size when testing was repeated at three months without correction, and maximum reading speed was maintained.

Patients completed an extensive questionnaire asking them to rate satisfaction with their vision before surgery (with correction) and after surgery (without correction). Highlighting a few of the results, Dr Jackson noted that compared with pre-operatively, more patients at 12 months were satisfied with their overall visual sharpness and clarity, near vision, and distance vision under bright lights.

"The latter finding was a little surprising because we expected that with the centre of the cornea treated for near, these patients would be less satisfied with their distance vision under conditions when the pupil was smaller," Dr Jackson said.

The questionnaire results did reveal a decrease in satisfaction with near vision in bright lights, probably reflecting changes in near vision over time.

Almost half of the group reported being totally spectacle free at 12 months, while the rest wore glasses for reading and about one-third used glasses when working at the computer. There was a single patient who preferred to wear glasses whenever driving.

At 12 months, two eyes had a loss of more than two lines in BCDVA and three eyes lost more than two lines of near vision. Those events were related to ocular surface problems, including dry eye and punctate epithelial keratitis.

"However, none of those eyes was worse than 20/32 at distance or J1 at near," Dr Jackson reported.

Contrast sensitivity is also being tested and showed an initial drop. However, it improves over time but remains within the population norms for the study age group.

"We would not expect much of a change since we were aiming for about 1.25 to 1.5 D of near correction," Dr Jackson said.

In wavefront evaluations, mean spherical aberration changed from positive to negative, which was consistent with...
creation of a more prolate cornea. Coma was increased slightly by the surgery but has been stable over time.

**Benefits of iris registration**

Comparisons of outcomes in eyes treated before and after the iris registration (IR) were available suggested that the new technology contributed to better outcomes.

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“These results are still preliminary, but through six months, the refractive outcome was significantly better in the IR-treated eyes and they also had relatively better distance-corrected near acuity, although the difference between groups was statistically significant only at six months. We will be conducting more analyses as we go forward,” Dr. Jackson said.

Considering that some patients indicated a desire for more near reading vision, the researchers have also begun to analyse to see if there are any factors predictive of a better outcome. The variables considered so far include age, K value, add, pupil size, pre-operative spherical aberration, and pre-operative higher order aberration, but none has been found to correlate significantly with results at 12 months.

Follow-up in the multicentre study is still ongoing and the data collected will provide some insight to answer existing questions, including how long the benefits last. Further investigations with more patients will be needed to address the questions of whether the multifocal treatment can be reversed, what is the best ablation profile, and what are the risks of unwanted visual symptoms and loss of contrast acuity or best spectacle corrected distance and near acuity.

Based on experience to date, Dr. Jackson suggested the CustomVue presbyopia treatment might be a good alternative for the young presbyope with a low refractive error who does not want intraocular surgery. He proposed it might be ideally suited for patients with residual hyperopia after IOL implantation.

“Looking ahead, I think we can anticipate improving results as a benefit of refined ablation profiles and new technology for registration and centration,” he said.

**Egyptian experience**

Egyptian ophthalmologist Mohammed Hosny MD reported outcomes achieved up to six months in his small study of LASIK in 10 eyes. Conducted at Dar el Oyoun Eye Hospital, Cairo, Dr. Hosny’s study evaluated visual acuity outcomes, subjective quality of vision, and higher order aberrations for presbyopic LASIK with the CustomVue system. The 10 eyes in his series had a mean pre-operative SE of +2.7 D with a range up to +4.0 D and mean cylinder of +0.4 D with a range up to +1.5 D. All required more than +1.5 D reading add pre-operatively.

At three months, SE values ranged from +0.5 to -0.5, all eyes achieved UCVA of 6/6 at distance and N5 (J3) or better at near, and all patients scored their responses as “good” in a questionnaire asking about quality of overall vision, near vision, and night vision.

“These results exceed those achieved in the Canadian study, although our study group is very small,” Dr. Hosny said.

By six months, the excellent outcomes were maintained in seven eyes, but refraction had regressed in three eyes and was accompanied by deterioration in vision outcomes. The SE in those eyes ranged from +1.25 to +2.45 D, UCVA was 0.7, and near vision was only N8. W hile the patients continued to score their vision and night vision quality as good, near vision was rated only as fair.

“Based on their pre-operative cycloplegic and manifest refractions, we knew the three eyes that regressed had more hyperopia than what they were corrected for. Perhaps the regression observed may be an unmasking of latent hyperopia that was not included in the treatment,” Dr. Hosny said.

Wavefront evaluations showed no statistically significant change in spherical aberration, total higher order aberrations, or coma.

Dr. Hosny observed that eyes undergoing this aspheric ablation need to have large flaps, even larger than would be created for a standard hyperopic treatment, and he hoped that Prevue lenses and cards would become available in the future.

“These tools are strongly needed so that patients can be shown what to expect after surgery,” Dr. Hosny said.

**Positive outcomes with a “back to the future” approach**

Canadian D Keith W illiams MD, a private practitioner in Vancouver, BC, presented six-month analyses from his single centre study in which 30 patients underwent bilateral CustomVue surface ablation.

All 60 treatments in Dr. Williams’ study of wavefront-guided multifocal surface ablation for hyperopic presbyopia were performed using iris registration and without any nomogram or physician adjustments to the ablation profile.

“Iris registration is really a critical component for these presbyopia treatments because it ensures proper placement of the central add zone both rotationally and with respect to pupil centroid shifts,” Dr. W illiams said.

The procedure for the surface ablation treatment involved epithelial removal with an Amoils brush, irrigation of the cornea with chilled BSS after ablation, application of a bandage soft contact lens until re-epithelialisation, and use of eye shields while sleeping during the first week after surgery. The medication regimen consisted of postoperative topical treatment with a fourth-generation fluoroquinolone, NSAID, and corticosteroid along with oral analgesics and artificial tears as needed. In addition, patients began oral vitamin C two weeks before surgery and continued it for nine months postoperatively. The 30 patients in this study ranged in age from 46 to 61 years old and had pre-operative sphere and cylinder values averaging +1.27 D (maximum +2.75 D) and +0.37 D (maximum +1.00 D), respectively.

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D Keith W illiams MD

Similar to the results reported by Dr. Jackson, the serial outcomes from follow-up visits at one, three, and six months in this study showed that UCVA and UNVA outcomes continued to improve over time. Results from the six-month visit showed that monocular UCVA was 20/20 or better in 44 per cent of eyes and 20/25 or better in 77 per cent; pre-operatively only five per cent of eyes could see 20/20 or better and only 17 per cent achieved 20/25 or better monocular UCVA. In binocular testing, UCVA was 20/20 or better before surgery in 17 per cent of eyes compared with 85 per cent of eyes at six months.

For monocular UNVA, no patient was able to read J3 preoperatively whereas 85 per cent of eyes achieved that outcome at six months. With distance correction in monocular testing, 15 per cent of eyes could read J3 or better near vision in binocular testing was only three per cent pre-operatively, while it was 98 per cent at six months after surgery. At the six-month visit, no eye had lost more than two lines of BCVA at distance or near.

Patients were initially myopic after surgery. MRSE analyses showed. At one month, mean MRSE was -0.93 D, but it slowly regressed over time to reach -0.16 D at six months. Patients are also being evaluated with a questionnaire. The results show that when asked pre-operatively about best-corrected vision and postoperatively about uncorrected vision, patient satisfaction rates are higher six months after surgery for overall distance vision (57 per cent vs. 77 per cent), near vision (30 per cent vs. 81 per cent), and overall vision (37 per cent vs. 85 per cent).

bjackson@ehri.ca

dkwident@telus.net

info@mohammedhosny.com