US FDA adopts Aust-developed laser technique as its standard

The United State Food and Drug Administration has adopted a laser-surgery outcomes technique developed by an ophthalmologist and researched with an optometrist in Australia as the benchmark for its ANSI standard (equivalent of the Australian design standard) for measuring performance of lasers for laser vision correction when treating astigmatism, because the vector analysis technique is considered to be so accurate.

The technique was also employed to evaluate the results of laser vision correction treatments for mild keratoconus.

A paper on the 'vector planning' treatment technique that was developed by ophthalmologist Noel Alpins and studied together with optometrist George Stamatelatos, both of Melbourne, was published recently in the peer-reviewed 'Journal of Cataract and Refractive Surgery'.

Unlike most laser eye surgery, which is guided by spectacle astigmatism, the technique adds a new dimension to the treatment – the corneal shape. Vector planning uses ocular residual astigmatism (ORA), which is the vectorial difference between refractive and corneal astigmatism, to calculate ablation parameters.

The manuscript reviewer for the journal noted that this world-first research successfully "challenged current dogma" in the treatment area prior to Dr Alpins' work and that the technique can be adopted by any eye surgeon who undertakes laser procedures.

The results of the research were presented by Dr Alpins on 11 September at the European Society of Cataract Refractive Surgeons conference in Stockholm, Sweden (ESCRS <http://escrs.org/EVENTS/07Stockholm/default.asp>.

Mr Stamatelatos was the co-author of the published paper and has been instrumental in the success of both the trial and the application of the technique.

The new vector-planning method is a significant advance on current laser techniques and its accuracy allows laser eye correction to be considered for patients with keratoconus who would previously have been considered unsuitable candidates for the surgery. There are estimated to be 300,000 patients in Australia who could potentially benefit now from surgery.

Vector planning puts emphasis on reducing both corneal and refractive astigmatism, with the resultant astigmatic treatment more closely aligned to the principal corneal meridian, enabling corneal-shape to change more favourably, with less astigmatism remaining.

In the study, 45 eyes of 29 patients with mild or forme fruste keratoconus were treated for myopia and astigmatism using PhotoAstigmatic Refractive Keratectomy (PARK). All were over 25 years of age, had a best corrected visual acuity of 6/12 or better, with no visible signs of keratoconus at slit lamp, mean keratotomy less than 50D and had corneal and refractive stability for at least two years.

All treatments were optimised, directing only part of the neutralisation to the cornea and a theoretical part to the refraction,.

Uncorrected visual acuity of 6/6 or better was obtained in 56% of eyes, 6/9 or better in 89% of eyes and 6/12 or better in all eyes.

BCVA was 6/6 or better in 89% of eyes and 6/9 or better in all eyes. Overall, 16 eyes gained BCVA and seven eyes lost BCVA.

A total of 32 eyes had five years of follow-up and nine eyes had 10 years of follow-up. At last follow-up, the group's corneal and refractive outcomes were stable with no progression of ectasia, which may have been the result of careful patient selection.

Vector planning was used in every case to enable treatment parameters to combine topographic and refractive data in a systematic paradigm.

The treatment is less likely to create distortion of optics resulting from excess cross-cylinder effect induced by the change. The reduction in corneal astigmatism substantially exceeds the theoretical increase in measurable refractive cylinder remaining. That has the overall effect of minimizing the total amount of astigmatism (refractive + topographic) after laser surgery that is required to neutralize the ORA (the eye's internal or non-corneal astigmatism).

The authors of the paper say that to their knowledge there are no [previously] published reports of using both manifest refraction data and topography or keratometry data in a systematic treatment plan for keratoconus patients having PARK.

Also, that in the past refractive excimer surgery in patients with keratoconus has generally been approached with some hesitancy, with much of the uncertainty stemming from adverse visual outcomes and complications induced with both ablative and incisional surgery as well as the uncertainty of accelerating the natural progression of the ectatic disease.

The paper concludes that photoastigmatic refractive keratectomy in eyes with forme fruste and mild keratoconus is safe and effective for correcting myopia and astigmatism in carefully-selected patients, with refractive and corneal stability.

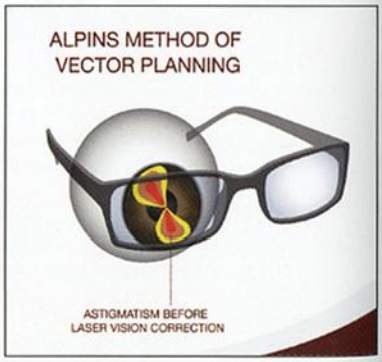
Also this advancement of incorporation of the corneal astigmatism data into the applied treatment parameters improves visual and total astigmatism results.

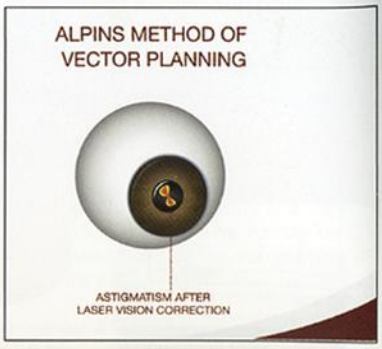
The potential for reducing HOAs (coma and trefoil) exists with a greater likelihood of achieving an improved BCVA more frequently and avoiding adverse symptomatic effects. Patients who suffer from mild keratoconus can now enjoy the benefits of laser vision correction that has not previously been available to them.

The 10-year trial of the technique was personally financed by Dr Alpins.

In the paper in the 'Journal of Cataract and Refractive Surgery', Dr Alpins states he has a financial interest and Mr Stamatelatos is a consultant to the ASSORT ® program used to calculate the treatment parameters and examine outcomes.

George Stamatelatos and Noel Alpins





The technique of vector planning targets the cornea more favourably than conventional laser treatments resulting in less astigmatism demonstrated by the smaller bow-tie and spectacle freedom.