Laser refractive surgery grows up

The past decade has seen the field of laser refractive surgery evolve from standardised techniques to a more customised, wavefront driven approach, with all of the major manufacturers now marketing some kind of customised platform. This has been accompanied by improvements in hardware and software, diagnostics, registration and tracking.

EuroTimes Editor Sean Henahan talked to Raymond Applegate OD PhD about where the field is now and where it is likely to be in the near future.

Raymond Applegate

Dr Applegate is the Borish Chair in Optometry and Director of the Visual Optics Institute at the University of Houston, Texas, USA. Dr Applegate has served on the editorial boards of the Journal of Optometry and Vision Science and currently serves on editorial board of the Journal of Refractive Surgery, the Journal of Cataract and Refractive Surgery, and the Journal of Clinical and Experimental Optometry. He is a co-founder of the International Congress on Wavefront Sensing and Aberration-Free Refraction Correction. His research interests include the optics of the eye and early ocular disease detection and prevention.

ET: *Until fairly recently, cylinder and sphere were considered to be adequate for correcting refractive errors with contact lenses or glasses. Then came PRK, LASIK and wavefront sensing. How far have we come in the past few years?*

Applegate: One result of the arrival of wavefront sensing was that it became clear that refractive surgery was actually inducing aberrations. The companies are actively addressing issues relating to inducing new aberrations. As a consequence, fewer and fewer aberrations are being induced by refractive surgery procedures and in many cases the higher order aberrations are being reduced. Nonetheless, there are still a limited number of eyes that do not respond to refractive surgery in the anticipated manner.

One issue still remaining is the question - How good is good enough? Clearly patients as a rule are delighted that they have gotten rid of the need for contact lenses or glasses. This wow factor is good for the profession. However, I am not an advocate of the idea that 20/20 and happy is good enough. As a profession, we have an obligation to not induce new adverse aberrations even though patients are 6/6 and happy. Instead we should reduce all adverse aberrations. Why not have patients that have at least average acuity of 6/4.5 or better yet routinely better than 6/4.5 and happy. We now know that when we minimise the sphero-cylindrical error and at the same time reduce the higher order aberrations, patients have improved visual performance.

ET: *And yet not all surgeons seem to be convinced that it is worthwhile to take the time and make the investment necessary to do wavefront-guided procedures. You spoke in Lisbon recently at the XXIII Congress of the ESCRS on why wavefront is important. What did you talk about?*

Applegate: There has been a lot of talk that wavefront is not important, based on observation that high contrast acuity is not improving dramatically. The problem with measuring high contrast acuity is that it has a lot of redundant information. Therefore, it is not very sensitive to aberrations. What we need to remember is that we do not live in a high contrast world. Consider going out to dinner at night and try reading the menu under dim illumination.

We conducted a study that confirmed that low luminance, low contrast vision is correlated with retinal image quality. In our study we showed that in normal eyes that saw well, 6/4.5 or better, all had relatively low aberrations. More importantly, the lower the aberrations the better they saw the low luminance low contrast targets. The correlation between retinal image quality (defined by higher order aberrations) and low contrast acuity, under dim lighting, accounts for about 40% of the variance in the data. On the other hand, the same retinal image quality metrics define less than 5% of the variance in high luminance high contrast acuity. This study in many ways supports what is obvious. Normal individuals with lower than normal amounts of higher order aberrations see better in everyday life than normal individuals with higher than normal amounts of higher order aberration. As we move to better corrections it is important that we also improve the way we test eyes. As we move to tests that are actually sensitive to small variations in retinal image quality (e.g., mesopic low contrast acuity), we will see the correlation between improving aberrations and improving visual outcomes.

ET: *What about the idea that wavefront procedures should be reserved for those patients with higher amounts of aberrations, and that a standard ablation approach could be used for patients with fewer problems?*

Applegate: If you have a patient that has really high aberrations, more times than not, you are going to be helping them with a wavefront guided correction. But that doesn't mean the person who doesn't have high aberrations should not have a wavefront-guided procedure. My philosophy is that eyes that are already good should definitely have wavefront-guided surgery because you don't want to take them in the wrong direction by inducing unwanted aberrations.

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ET: *Just when we were beginning to get comfortable with Zernike polynomials, we start hearing about Fourier analysis and other ways of measuring the wavefront. What is that about?*

Applegate: There is a lot going on in the area of how we extract the data and represent wavefront error. There are several methods of fitting wavefront error data. The Zernike polynomial system is the most common one and in the United States is the ANSI standard. More recently the Fourier technique has been applied to fitting wavefront data, and there are many other fitting functions and approaches that could be used. The Zernike expansion was not selected as the ANSI standard fitting function by accident. Individual terms of the Zernike expansion such as sphere, cylinder, axis, coma and spherical aberration are very familiar. With Fourier you are moving into the frequency domain, which is less familiar to clinicians. There is some research by Dr Steve Klyce and others to indicate that Fourier approach may have advantages in some settings, such as very highly aberrated eyes (e.g., penetrating keratoplasty, keratoconus). However, I am not convinced that the comparisons have been made under properly controlled experimental conditions. What is clear is that for normal eyes and the normal surgeon the Zernike expansion is excellent. This is not to say that there is no room for improvement. There is, particularly for the abnormal eye.

ET: *Where does that leave us in terms of evaluating visual outcomes in refractive surgery patients?*

Applegate: One question is: How do we reduce all the information (e.g., numerous Zernike terms) to clinically useful data? We're now developing single value metrics of retinal image quality that are very predictive of visual performance under a variety of settings. What we really want are metrics that will predict whether or not a patient has the retinal image quality to be able to see that

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person in dark clothing walking along the side of the country road on a dark rainy night. What we do know, is that as retinal image quality improves there is a higher probability that an individual will see that person.

We have good data indicating that picking your test will definitely determine whether or not you see the effect of retinal image quality on visual performance. As already noted, but worth emphasising, high contrast, high luminance acuity charts are very forgiving over a large range of retinal image quality. If you wish to see the effect of decreased retinal image quality, you have to stress the visual system, put it in a situation where it is starved of information. One way to do that is to ask the patient to read low contrast letters in mesopic conditions. Mesopic low contrast acuity is a much more demanding task than traditional high contrast photopic acuity.

My lab as well as Larry Thibos' lab at Indiana University and David William's lab at the University of Rochester have been and are working on the problem of reducing wavefront error into a single value metrics of retinal image quality that reflects every day visual performance such as reading the low contrast type on the back on credit card agreements, or the menu in a dimly lit restaurant.

ET: *Doesn't this also have relevance for the design and conduct of clinical trials? What should the criteria be for a comparison trial among different laser platforms?*

Applegate: There are several issues relating to conducting meaningful clinical trials. Measurement issues involve the question of how we measure and quantify wavefront error as well as how we choose to express this error in terms of retinal image quality. This important issue combined with the issue of how to measure visual performance are two big issues that need better definition and better standardisation. It is my feeling that laser platform companies do not want standardised trials across platforms. They are, understandably, more interested in highlighting the particular features in their individual platforms than participating in a level field, head-to-head competition.

If I had all the platforms available to me, I would systematically evaluate each platform to determine the weakest link in each system. For example, I would evaluate the accuracy and precision of the wavefront sensing device by using test objects with known aberrations structures of increasing complexity. I would then evaluate the effect of small eye movements on the measured aberrations using a device to move a fixed wavefront error in a manner similar to fixational eye movements.

Once I had determined the limits of the wavefront sensor, I would evaluate the range of higher order aberrations the system was capable of correcting. A clinical trial would follow and minimally include measurements of corneal topography, wavefront error, and acuity at low and high contrast at photopic and mesopic light levels. The output measures would include, 1) the difference between the desired ablation profile and the achieved ablation profile; 2) the gain or loss in retinal image quality; 3) gain or loss in logMAR acuity (all four types photopic and mesopic high and low contrast acuity) defined as post surgical logMAR acuity - best corrected preop logMAR acuity where acuity is scored as all letters read correctly up to the fifth miss.

Notice that after surgery no residual correction is allowed. Refractive surgery will have truly matured when optical and visual performance after surgery without residual correction is routinely better than the same measures under best sphero-cylindrical correction prior to surgery. No patient wants to wear a residual correction (nor do they typically) after refractive surgery.

ET: *What are your thoughts on registration and tracking technologies?*

Applegate: Certainly people are paying more attention to the tracking issue. The goal is to make sure we ablate the exact pattern we want exactly where it should be on the cornea, removing only as much tissue as we need to. This gets really tough when you have an eye that is rotating and tracking is being performed in a plane considerably different than the corneal plane. The calculations are not trivial given changes in corneal curvature in two directions with location, a moving cornea in three dimensions, plus cyclo-rotation. We are seeing some improvements in dealing with cyclo-rotation of the eye that are reflected in improved outcomes

ET: *How does corneal topography fit in with customised ablation approaches?*

Applegate: Topography alone does not provide enough information for an ablation. If you've measured corneal topography and you know the refractive error sphere and cylinder, then you have enough information to guess at what you should do, but it not the best way to do it.

There are things that are not being done that could be done, including corneal topography, but not in the way it is used now. First, if you know true topography (elevations with respect to fixed reference surface) over a large enough area of the cornea and you know how laser beam is leaving your system, then you can predict the exact angle of incidence of the beam on the cornea. Knowing the exact angle of incidence allows the beam to be automatically programmed so that the desired energy at the cornea is as intended.

Secondly, I would love to see topography included in the wavefront measurement such that both wavefront error and corneal topography could be measured simultaneously along the exact same axis. The difference between corneal measurements pre and post-surgery define the surgically induced correcting lens. This surgically induced correcting lens could then be directly compared to the desired ablation profile to determine the ablation error. The ablation error can in turn be used in a properly constructed feedback loop to improve future surgeries. In my opinion, such a procedure is the next big step in improving refractive surgery outcomes.