XXIV Congress of the ESCRS, London 2006

Assessing outcomes in refractive surgery

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in London

AT A symposium at the XXIV Congress of the ESCRS, researchers discussed the methods and technologies currently available for assessing outcomes of refractive surgery and how to interpret postoperative findings in ways that will improve the outcomes of future procedures.

Emanuel Rosen MD FRCS, Manchester, UK, commenced the session by emphasising that careful assessment of refractive surgery outcomes is essential for determining what benefits patients gain through the procedures.

"When we alter the quality of people's vision we alter the quality of people's lives, it's a life-changing experience," he said.

The information patients receive regarding the expected benefits and potential risks of refractive procedures must therefore be based on scientific evidence gained from prospective and retrospective studies.

"We're not guessing, we're studying, and that's why in refractive surgery it's very important to follow our patients and learn what the outcomes are in all its aspects," he said

Noel Alpins FRACS FRCOphth FACS followed with a presentation describing how the accurate assessment of the outcomes of refractive procedures can lead to improved nomograms and improved outcomes.

The parameters measured and the level of detail at which they are measured depend on the condition treated and the procedure used. Moreover, the parameters can generally be assessed in either a simple or advanced way

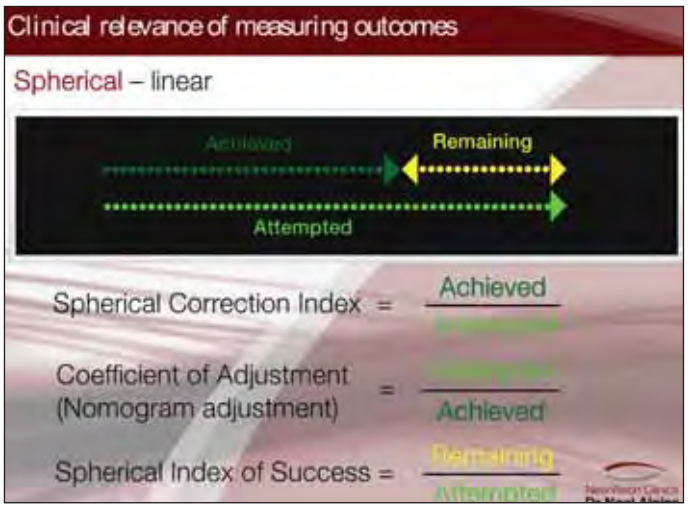
Common to most examinations is the performance of a manifest refraction and the testing of uncorrected and best corrected Snellen visual acuity. The next step is usually a corneal keratometry using a manual technique, he said.

More sophisticated techniques include cycloplegic and wavefront refraction, he noted.

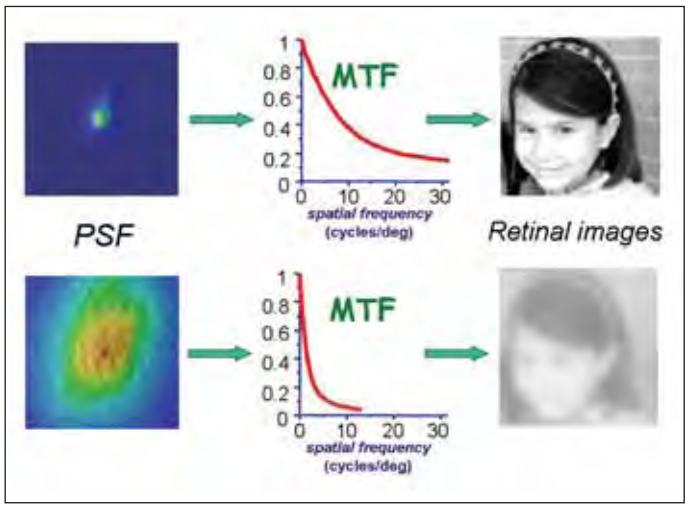
Cycloplegic refraction removes the accommodative element of visual function. It is therefore useful for detecting overcorrected myopia and undercorrected hyperopia in eyes that are plano on manifest refraction, and for detecting pseudo-overcorrected hyperopia in eyes that are myopic on manifest refraction.

Wavefront refraction enables the evaluation of higher order aberrations and when compared with topography it can determine whether the aberrations arise from the corneal surface.

Manual keratotomy is a convenient, quick and inexpensive way of determining changes in corneal shape, he noted. Although it is a very simple technique, it is very useful for detecting irregularities suggestive of ectasia and for determining whether changes in vision are corneal or lenticular in origin, he said.



Courtesy of Noel Alpins FRACS FRCOphth FACS



Courtesy of Pablo Artal PhD

Consistent lighting essential

When comparing postoperative and pre-operative visual function, it is necessary to ensure that the lighting conditions and instrumentation used are identical at all pre-operative and follow-up visits, Dr Alpins stressed.

Testing under controlled photopic and mesopic conditions can reveal subtle changes in the quality of vision. Using charts with varying contrast and under varied lighting conditions yields further data on visual function, he pointed out.

"With both of these modalities we can break visual function down and eke out any differences between any two particular groups that are under study and control."

Dr Alpins noted that of all the different methods of expressing visual acuity findings, LogMAR values lend themselves best to statistical analysis. LogMAR is the logarithm of the minimum angle of resolution. It is obtained by taking the inverse of the visual acuity in decimal notation and finding what exponent of 10 it is, he explained.

So, for example, the decimal value of 6/24 is 0.25. The inverse of that (1/0.25) is four, which is 10 to the power of 0.6, making 0.6 the logMAR value of that level of acuity. As acuity improves the logMAR number gets lower in linear steps. Visual acuity of 20/20 has a logMAR value of zero, and acuity better than that has negative logMAR values, Dr Alpins explained.

"The logMAR converts the geometric sequence of Snellen visual acuity to a linear scale, which makes it easier to do a statistical analysis of such things as gains or losses of lines of visual acuity."

Comparing pre-op with postop

To determine whether nomogram adjustments are necessary in refractive procedures, pre-operative and postoperative refraction can be compared using fairly simple formula, Dr Alpins said.

In terms of sphere, dividing achieved correction by that attempted yields the spherical correction index. The inverse of that is the nomogram's coefficient of adjustment. The spherical index of success of a procedure is the residual spherical error (absolute) divided by the attempted correction.

As regards astigmatism, Dr Alpins noted that a vectorial analysis approach that he devised can be very useful in assessing outcomes and adjusting algorithms.

"The key to the vectorial analysis of astigmatism is the target induced astigmatism vector (TIA) where the treatment is constant regardless of whether you use refraction, keratometry, or topography, so parallel analysis can be done," he explained.

Dividing the surgically induced astigmatism vector (SIA) by the TIA gives the correction index (CI) of the treatment. Dividing the uncorrected astigmatism – the difference vector (DV) by the TIA gives the index of success, while dividing the TIA by the SIA (inverse of CI) yields the nomogram's coefficient of adjustment to improve future outcomes.

"Data collection is more than a record of results. You want to be able to use that information not only to get a score card and determine how you are proceeding and how you might be proceeding compared to other doctors and other centres, but also to then use this information to do a better job in the future."

Objective assessment of optical quality

A correct evaluation of the optical quality of the eye requires an objective and true-to-life assessment of the retinal image, said Pablo Artal PhD.

Factors affecting the retinal image quality include aberrations and light scatter. Aberrations cause light from a point source to diverge at small angles from the visual axis and expand the retinal image. Scatter causes a wider angle distribution of light, producing a wide-angle halo. An important cause of scatter in refractive surgery is cornea haze. However, scatter can arise from anywhere within the ocular media.

As wavefront sensors cannot detect or measure light scatter, they can overestimate image quality, Dr Artal pointed out. He maintained that the OQAS (Visiometrics) double-pass system that he and his associates developed can provide a more accurate description of the eye's optical quality, Dr Artal said.

The system records images of a point source of near infrared light after reflection in the retina and double-passed through the ocular media. The eye's optical quality can then be interpreted in terms of its modulation transfer function.

He noted that studies using OQAS double pass-system show that its measurements correlate more closely with visual acuity results than those of aberrometers. The OQAS measurements can also often explain why some patients complain of poor vision despite a good outcome in terms of aberrations.

Neural adaptation is an aspect of vision which neither aberrometers nor double pass instruments can measure but which can actually enhance visual function in the absence of any changes in the optics of the eye.

He noted that the neural component of the visual system adapts to the aberrations that are native to the eye. Following corneal surgery it takes time for the brain to adapt to the new set of aberrations.

"Neural adaptation will initially further reduce visual performance, since the subject will have different than normal aberrations. However, if the visual system re-adapts to the new modified aberrations, vision may partially improve after surgery, even with relatively poor optical outcomes," Dr Artal added.


Emanuel Rosen


Noel Alpins


Pablo Artal


Jorge L Alió


Michael W Belin

Assessing biomechanical change

Close analysis of the postoperative radius of curvature in eyes that have undergone PRK and LASIK indicates that the surface ablation procedure induces less biomechanical change in the cornea than LASIK, said Prof Jorge L Alió MD, PhD,VISSUM Instituto Oftalmológico de Alicante.

In a series of patients who had undergone PRK or LASIK with well-tested nomograms, Dr Alió used topography to determine the effect of corneal biomechanics on corneal curvature at one month's follow-up. He obtained a coefficient of the biomechanical response by dividing the difference between the post surgical corneal radius of curvature and the calculated sculpted curvature radius by the calculated sculpted radius.

"The coefficient characterises the change in corneal curvature due to such factors as flap relocation and the ablation profile by the excimer laser. Therefore, if it is greater than zero it means the cornea has been excessively flattened, that, for myopic correction, is overcorrected. If on the other hand, the value is less than zero it means the cornea remains steeper than planned, or under-corrected," Dr Alió explained.

The researchers found that the biomechanical response to both LASIK and PRK had a steepening effect on the corneal curvature, but that the amount of steepening was lower for PRK in all myopia groups.

Among the low myopes the biomechanical response coefficient was -2.3 per cent for LASIK and -1.9 per cent for PRK. Among intermediate myopes it was -3.7 per cent for LASIK and 2.7 per cent for PRK and among high myopes it was -9.6 per cent for LASIK and 8.7 per cent for PRK.

"That is the reason why we at first had so many re-treatments with LASIK. Later on the nomogram was adjusted based on the refractive results."

Avoiding complications

There are three essential requirements for reducing risk and improving outcomes of refractive surgery, said Michael W Belin MD, Albany Medical College, Albany, New York, US. They are careful pre-operative screening, careful selection of surgical parameters and equipment and the knowledge of how to manage and/or correct adverse events after they occur.

"A good surgeon knows all three. A very good surgeon only uses the first two," he told the symposium.

Pre-operative screening should include such anatomical measurements as topography and pachymetry. In the future, biomechanical properties like hysteresis and biochemical properties that influence corneal strength may also be factored in, he said.

Dr Belin said that elevation-based topography provides a more complete and clinically useful picture of the corneal anatomy than Placido-based systems. The curvature data provided by Placido-based systems is inherently limited because it can change depending on the angle of the reference axis. It also provides no data about the posterior surface or corneal thickness distribution.

"We do not look through the "apex" of our cornea. The apex, line of sight, pupillary centre, and the curvature reference axis are all different. Elevation data represents the true shape of the cornea and it is independent of axis, orientation or positioning."

Elevation topography is therefore a more sensitive means of identifying corneal abnormalities, such as keratoconus and forme fruste keratoconus in patients who are candidates for refractive surgery. Refractive surgery in these patients may lead to rapid progression of disease.

Pachymetry guidelines

As regards pachymetry, Dr Belin said he avoids LASIK in eyes with a pre-operative pachymetry less than 500 microns and he avoids any corneal refractive surgery with pre-operative of less than 475 microns. He added that he tries to leave a minimal residual bed thickness of at least 275 microns and minimal final corneal thickness of 400 microns.

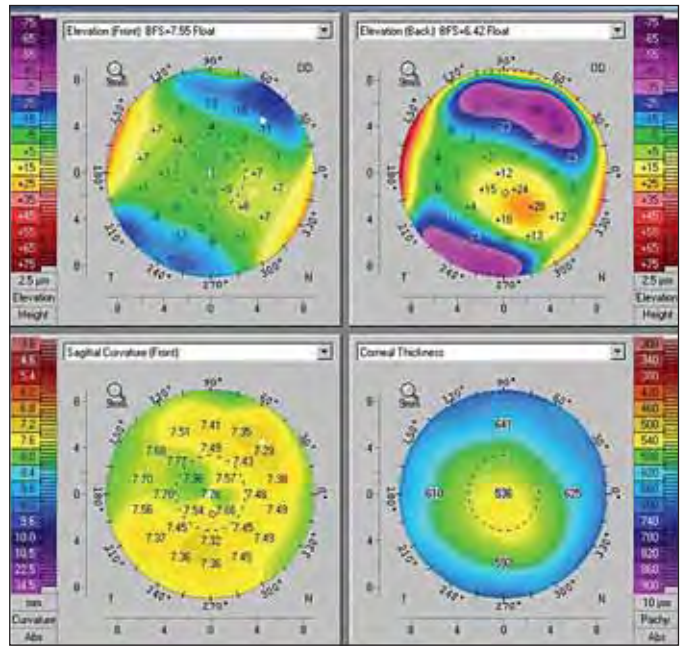
He noted that guidelines are based on a combination of consensus, personal observations, and on what constitutes the "norm" of corneal thickness.

To determine the normal range of corneal thickness Dr Belin and his associates examined the corneal thicknesses of 1,448 eyes. They found that the thickness of the thinnest part had a mean value of 536.1 microns, a median value of 537 microns and a mode of 539 microns, giving a normal distribution of 462-610 microns.

Unusual asymmetry between the corneal thickness of left and right eyes is another potential indicator of possible corneal abnormality that may be exacerbated by laser surgery, he said.

He noted that in a retrospective analysis on 724 consecutive patients (1,448 eyes) evaluated with the Pentacam Eye Scanner (Oculus Optikgerate GmbH) for laser vision correction, fewer than five per cent had a pachymetric asymmetry greater than 17 microns and only 1.0 per cent had an asymmetry greater than 25 microns.

"Pachymetric asymmetry outside the normal range should alert the clinician to carefully examine for other parameters that may be more established surgical risk factors."



The 4 map composite display from the Oculus Pentacam reveals a normal anterior curvature but a distinctly abnormal posterior corneal surface and an abnormal pachymetric distribution

Courtesy of Michael W Belin MD

Technology is now available for the measurement of the cornea's bio-mechanical properties However, careful study with years of follow-up may be necessary to determine what such measurements will actually mean in terms of the eye's response to surgery.

He noted that the Ocular Response Analyzer, a non-contact tonometry device, can measure corneal hysteresis. The device derives IOP from the movement of the cornea in response to a rapid air pulse. Its dynamic nature makes possible the evaluation of the biomechanical properties of the cornea

"Corneal hysteresis is a measurement of bio-mechanical properties distinct from anatomical properties. Thickness may not directly correlate with strength. 'Soft' corneas may require a larger residual stromal thickness. 'Hard' corneas may be able to tolerate more aggressive ablations safely," he added.

Analysis of the cornea's biochemical properties may be the final frontier in the pre-operative assessment of patients for refractive surgery, he noted. He added that while anatomic analysis looks current changes in shape and biomechanical analysis looks for mechanical weakness, biochemical analysis will look for potential problems before they occur.

"Remember, discretion is the better part of valour. Not having refractive surgery is not the end of the world and we do not have an effective treatment for post-LASIK ectasia," he concluded.

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ESCRS Refractive Surgery Outcomes Information System

The ESCRS Refractive Surgery Outcomes Information System

To help raise standards in refractive surgery, the ESCRS has created The ESCRS Refractive surgery outcomes information system (RSOIS). The European web-based system enables surgeons to record, audit, and confidentially compare their refractive surgery outcomes with others across Europe, said Mats Lundstrom MD, Blekinge Hospital, Karlskrona, Sweden.

"Surgeons in units in Europe and also outside Europe may join this database and be part of a global network providing self assessment in the field of refractive surgery and 'confidentially' here means that only the surgeons themselves can see their own data," he said

Surgeons who wish to participate can access the site via the ESCRS home page (www.escrs.org). A link will take them to the system's page where they can log in to the system, download an application form or see a demonstration of how the system works.

When registering an operation, surgeons fill the boxes concerning the patient's characteristics and treatment parameters. When the report is complete, they click on the approval button and it goes to the database. Follow-up reports are registered in the same way from the follow-up list but also include a page on the patient's viewpoint on their treatment outcome.

The system also enables participating surgeons to obtain standardised reports on outcomes based on such parameters as time period, age of patients and type of surgery. It is also possible to obtain reports based on the region where they are performed enabling surgeons to compare their outcomes with those of others surgeons in their own region or in other regions.

"If you don't know where you are, how shall you ever improve? One method to help you is this new system created. It may be the light that can lead you to a better performance."