

# **UKISCRS 2008 Refractive Surgery Day**

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### **The Dome, Brighton**

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Lecture Room 2 was packed with many delegates standing at the back. The day opened with a session chaired by Sheraz Daya and Steve Schallhorn entitled "Controversies in Laser Vision Correction". Concepts raised in the keynote lecture, "LVC flaps or no flaps" delivered by John Marshall, were further developed by David O'Brart advocating surface laser treatment and Bruce Allan advocating LASIK. Both agreed on the importance of long term results. Undoubtedly, LASIK is speedier in terms of the procedure and visual recovery, is associated with relatively little post-operative pain, and retreatment (so called enhancement) is easier to do. On the other hand, surface treatment does not weaken the mechanical strength of the eye (less risk of keratectasia) and is particularly suited for patients with thinner corneae and those involved in contact sports. Surface treatment may also be more suited for the occasional laser refractive surgeon and those who do not have access to thin flap technology be it a microkeratome or a femtosecond laser. Modern surface laser treatment was said to be suitable for +3 to -8 spherical treatment and up to 3 dioptres of cylinder. The larger corrections may require the use of mitomycin-C, a powerful drug shunned by many surgeons in case of very long term complications.

Next came a debate on flap-making technology. Is the microkeratome better (A. Cummings) or is the femtosecond laser superior (W Crewe-Brown)? Dr Cummings said he is keen to adopt new technology which provide better outcomes. He argues that current femtosecond lasers are not superior to the best modern mechanical microkeratomes and do not justify the not insignificant expenses of purchasing, using and maintaining one. He argues that a mechanical microkeratome is faster, gives a smoother bed, is just as safe and provides equal outcomes to femtosecond lasers, and does not give rise to transient light sensitivity and energy-dependent DLK. However, Dr Crewe-Brown says that there is no doubt that femtosecond flaps have more consistent geometry in terms of being plano, predictability of thickness, with flap diameter, hinge size and position, and edge profile that can be specified. A manhole type flap is more secure and reduces the risk of epithelial ingrowth especially when retreatment is necessary.

The next debate was whether it is worthwhile treating measured higher order aberrations. Chad Rostron argues that wavefront-optimised treatment, essentially a strategy to reduce laser-induced spherical aberration, is more than sufficient. Measured higher order aberrations are dynamic and changes with time, especially in the older age group with early lens changes. Of course the lens-induced aberrations will be removed at the time of cataract surgery. He also argues that the amount of spherical error we usually have to correct would change and drown slight amounts of higher order aberrations. He said very few patients would benefit from wavefront-guided treatment. David Anderson, on the other hand, argues that personalised

treatment should be preferred to treatment based on data derived from a population. He explained that perfect registration and tracking including rotational tracking are important so that the correct treatment is given. This would result in better contrast sensitivity. All agreed that nil higher order aberration may not be the most desirable outcome.

Shehzad Naroo demonstrated the capabilities of the Oculus Pentacam, a rotating Scheimpflug camera. Not only is it a corneal topographer using height measurements, it is also capable of providing measurement of corneal thickness throughout the entire cornea, it can analyse the anterior chamber in 3D and it is also a cataract analyser. Although it can take 50 scans in 2 seconds for higher resolution, usually only 25 scans are taken in one second which is just about as long as anybody can hold their eyes still. In comparison, the Orbscan takes approximately 1.4 seconds. For the refractive surgeon, the Pentacam is capable of answering the two key questions: Can I treat this patient? Does the patient have keratoconus or keratectasia?

Jean-Pierre Danjoux and J Vryghem chaired the next session on “Latest Technologies”. Jan Venter reviewed the latest models and results of phakic IOLs, which are predictable in terms of refractive outcome, but have associated complications such as endophthalmitis, retinal detachment, cataract formation and endothelial cell loss. Phakic IOLs allow correction of high ametropia including cylinder in pre-presbyopic patients. Long term follow up results are important in terms of these complications and patients need to be watched. Some lenses such as the Vivante have been withdrawn recently. Professor Venter now prefers iris-fixation phakic IOLs.

Mr Danjoux updated us on the Bausch and Lomb Zyoptix 100 platform. It is “personalised” based on wavefront and topography of each individual eye, feeding through a networked Zywave machine as well as an Orbscan. It allows asymmetric treatment. It has improved treatment speed (100 Hz) and a faster eye tracker. The laser is also connected to Bausch and Lomb through the internet allowing remote diagnostics. Algorithms and nomograms have been updated which have translated to improved patient outcomes.

Dr Cummings explained how he used the Wavelight Allegretto platform in terms of which type of treatment to use. Those who are happy with the quality of vision especially night vision with their spectacles will simply have wavefront-optimised (aspheric) treatment. Those who aren't are analysed further including using subjective tests such as how they see a point light source and a large white rectangle. Treatment can then be given based on wavefront or topography. When in doubt, he advocates using common sense, never to make the corneal more irregular and to conserve tissue. He also showed an interesting concept of simultaneous laser correction and cross-linking. The Allegro BioGraph is a new machine which can marry all available data including wavefront, topography, and biometry. It can eliminate nomograms and help the treating surgeon select what ablation profile to use. Finally, he extolled the virtues of the Rondo mechanical microkeratome and introduced the new Allegretto UltraFlap femtosecond laser.

Marcus Blum gave an overview of the Zeiss VisuMax femtosecond laser. It has a low pressure curved contact lens. FLEx or femtosecond lenticule extraction is an

additional capability of the VisuMax apart from use as a flap maker. The deeper cut is first made followed by the more superficial cut and then a side cut for extraction the lenticule effecting a refractive change. Preliminary results in terms of predictability and stability were encouraging. A nomogram is being developed. A number of cases had visually insignificant microstriae. It is possible to remove the lenticule without creating and lifting a flap, and with the help of visualising the anatomy of the corneal nerve plexus, it would mean little denervation can result.

Jérôme Vryghem is clinical investigator for the Ziemer LDV femtosecond laser. It is a compact machine with an articulated arm. It has a shorter focal length compared with the Intralase and gives rise to less shockwaves. The higher frequency of 1MHz and a lawn mowing type coverage result in no tissue bridges. It was FDA approved in November 2008. Dr Vryghem has now purchased a machine and uses it in 99% of the cases. He said there was a learning curve and he had helped the company develop the laser. Of the three available thickness foils, he has given up the thinnest 80 micron foil as it created striae.

Dr Swart explained that whilst there is usually initial resistance, surgeons embrace the SurgiCube very quickly after using it. The SurgiCube is a relatively inexpensive way of creating an addition operating theatre with laminar flow. A sterile operating field can be had in any room with the need for the whole room to have positive pressure. It is mobile. The larger unit allows space not just for the operating surgeon, but also an assistant, a scrub nurse and trolley as well as variation in how the patient is positioned.

Jan Venter and M Wevill chaired the first afternoon session on Audit and Quality of Vision. Dr J Güell shared with us his experience of the Artisan Artiflex lenses. He explained that when comparing laser refractive surgery and IOLs for the correction of high myopia, we need to look at efficacy and predictability, stability, safety and complications, reversibility, acceptability by patients, and quality of vision. Point spread function and modulation transfer function allow easy comparison of quality of vision. Patient complaints following IOL surgery is more to do with scatter than higher order aberrations. Post-LASIK or PRK corneal power of less than 37 to 38 dioptres can have poor quality vision. He feels the cornea should only be used for low myopic correction. However, most phakic IOLs have some way to go to meet long term safety standards.

Steve Schallhorn dealt with the evaluation and management of the dissatisfied patient. Patients with good visual acuity may be very vocal and unhappy complaining of glare, starburst, and difficulty with driving. They may have consulted websites created by unhappy patients. A thorough examination is essential including refraction, high and low contrast acuity, flap problems, dry eye and topography to look for a decentred ablation. Measurement of wavefront is also advisable. Therapeutic approaches include full spectacle correction, Alphagan drops to constrict pupils, the PreVue lens of the Alcon platform, or fitting rigid gas permeable lenses. A large study of patient satisfaction was carried out on over 400 patients. Satisfaction after LASIK is related to post-op glare, cylinder, double vision, and uncorrected visual acuity. However, it is difficult to explain why the majority of unhappy patients are unhappy. The Morse Model includes pre- and post-op expectations, patient-surgeon communication, psychosocial profile, patient understanding and recall of informed consent and

chronic pain. Non-verbal cues of surgeon and staff are important. Team member training to interact successfully with dissatisfied patients is important to reduce the risk of litigation. Never be angry!

David Gartry explained that clinical audit is part of clinical governance. The Royal College of Ophthalmologists' Laser Refractive Surgery Assessment requires a portfolio which includes an audit of the candidates' cases. IBRA (Internet Based Refractive Analysis) is user friendly, net-based, very flexible, can create Waring's six graphs and allows easy retrieval of data subsets (e.g. low myope vs compound myopic astigmatism). There is no need for laptops, USBs, or CDs as the database is kept up to date on a server which can be accessed by multiple authorised personnel. It also allows adjustments of algorithms. Visit [www.zubisoft.com](http://www.zubisoft.com).

Dr Mats Lundström explained that the EU and ESCRS co-funded the EUREQUO with aims to improve treatment and standards of care for cataract and refractive surgery, and to develop evidence-based guidelines for cataract and refractive surgeries across Europe. It has similar capabilities to the above software but it is also good for cataract surgery. Please see [www.eurequo.org](http://www.eurequo.org).

Dr Schallhorn discussed the effect of LASIK on night vision with special reference to night driving. Mesopic conditions along with glare sources and requirement for concentration and awareness make night driving a particularly visually demanding task. A study of 59 young subjects had pre- and post-LASIK night driving simulation tests and a questionnaire following treatment on different platforms. The test was done each eye in turn using best spectacle correction. Identification and detection tasks were presented with and without glare, after a training period. 144 threshold measurements were done per eye with the observer masked. There was no difference with different platforms. There was a reduction in night driving performance although there was a wide spread in the results. Ablation profile was the most important factor in that wavefront-guided ablation resulted in far fewer eyes with reduced performance and more eyes with improved performance. This was compared with standard treatment, not wavefront-optimised treatment. Pupil size did not predict performance.

Paul Rosen and Tayo Akingbehin chaired the final session on Ethics and Minimising Risks in Refractive Surgery. Steve Schallhorn discussed patient selection and assessment for laser vision correction. The standard indications and contraindications are well known, but patients must be able to understand and provide an informed consent and have reasonable expectations. They must also be able to lie flat, fixate steadily and can tolerate topical anaesthesia. He went on to discuss low light pupil measurement using the Colvard and Procyon pupilometers, as well as an instrument developed in house within the US navy. In theory, mesopic is probably more important than scotopic pupil diameter. Forward stepwise regression analysis revealed a good correlation with pre-operative complaints of glare and night halos, the amount of myopic spherical error, and UCVA to pre-op BCVA, and no correlation to mesopic pupil size. The majority of studies do not support large pupils being a risk factor for post-operative glare and night halos. Regarding thin corneae, whilst those with forme fruste keratoconus are at risk of keratectasia following LASIK, those with thin corneae and normal corneal shape probably are not at additional risk as long as

the residual corneal bed is of sufficient thickness. His personal limit is a pre-operative central corneal thickness of 480 microns.

Dr J Holden of the MDU explained the concept of “multiple jeopardy” from local complaints escalating to the Healthcare Commission and onwards to the Ombudsman, police investigation, the GMC and so on. He said it is perfectly OK to say sorry if something had gone wrong, and that an apology does not of itself amount to an admission of liability. He gave an overview on consent, a very large subject, referring to the GMC’s recently revised (2008) guidance, noting that an effective doctor and patient relationship requires openness, trust and good communication. He explained that the GMC state that discussions with patients should be tailored according to: the patient’s needs, wishes and priorities; the patient’s level of knowledge and understanding of the condition, including the prognosis and treatment options; the nature of the condition and the complexity of the treatment and the nature and level of risk associated with the investigation or treatment. The responsibility of obtaining consent lies with the treating doctor, but can be delegated to a suitably trained and qualified person. Clinical negligence claims can arise when something goes wrong, and that harm had been done and had been caused by failed duty of care. An ophthalmologist can expect a claim every 15 years with 1 in 3 claims resulting in settlement. A study done in 2003 by the MDU showed a 166% increase in claims relating to laser refractive surgery in the previous 6 years. Clinical complications and failure to provide appropriate information were amongst the allegations that gave rise to claims. As a result of the study, a differential rating followed in 2003 for those ophthalmologists performing laser refractive surgery. In 2002, 15% of MDU indemnified ophthalmologists carried out refractive surgery and the ratio of paid claims/paid subscriptions was 3 times higher in this group of doctors. An additional concern for refractive surgery is the potential severity of the incurred but not yet reported claims which is very difficult to quantify.

Mrs E Sideris shared her lay perspective on ethics and advertising in relation to laser refractive surgery. Advertising is part of marketing and has inherent commercial tension. Some companies spend a lot of money on advertising which informs and persuades, including recent aggressive campaigns on the internet and inserts in Sunday papers. The four P’s of marketing were discussed: product, place, price and promotion. She advocates ethical advertising in terms of social responsibility, dealing fairly and respecting clients’ rights. There is a tendency to downplay risks. All manner of creative practices such as price plans, competitive rates and introductory discounts exist. Testimonials are hugely influential. Individual clinicians are recommended along with “celebrity” endorsement, with more realistic and balanced testimonials used by smaller “second tier” providers. Pre-requisites for ethical advertising should create realistic expectations. They should also comply to GMC and NICE guidelines and the Standards document of the Royal College of Ophthalmologists.

Andrew Morrell analysed claims from 1999 – 2007. Those settled comprised cases of DLK and infection (delayed and inappropriate treatment with operating surgeon not available in the post-operative period), dry eyes (with pre-existing dry eye), ectasia, night vision problems and flap complications. All the cases settled for ectasia had pre-operative risk factors. Other cases included amblyopes running into trouble with

their good eye, inadequate or lack of consent, inappropriate treatment, decentration, under and overcorrection, and monovision with incorrect dominant eye.

Milind Pande presented a case of refractive surgeon offering free treatment to a professional golfer in exchange for marketing endorsement. There was inadequate documentation for the treatment of the high hyperopia (probably out of range), and despite a problem with the tracker, the surgeon decided to proceed with treatment. Retreatment was necessary in both eyes. The same consent form was used for the retreatment. Golf ball magnification with glasses was lost following surgery.

The day was polished off with an evening reception at the Corn Exchange.