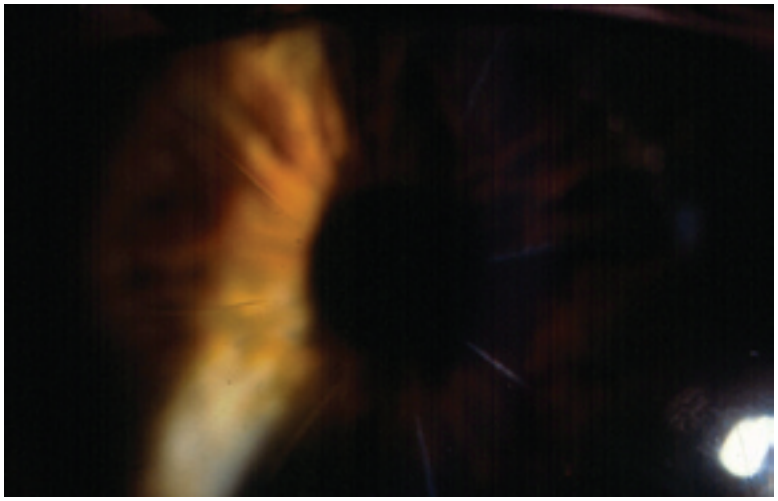
Whose profession is it anyway?

Mark Korolkiewicz takes a critical look at regulation in the laser surgery sector



Radial keratotomy: little seen today. Is regulation keeping up with clinical development?

It seems strange in 2005 to remember just how different the early days of laser refractive surgery were. Although laser refractive surgery has been available in the UK since the pioneering work of the early 1990s, the market significantly gained pace towards the end of that decade.

What a different time this was. No HealthCare Commission (HCC) to regulate treatment, no National Institute of Clinical Excellence (NICE) reports and indemnity companies welcoming refractive surgeons at rates compatible with the rest of Europe. There was no real enthusiasm back then from the Royal College of Ophthalmologists (RCO) or the College of Optometrists to give any formalised training for their members on refractive surgery, and any talk of a Private Members Bill being debated in the House of Commons that could become an Act of law, enforceable against non-compliers, would have quite frankly been laughed out of a clinic. It was a different era.

These days, the concept of regulation is never far away from the thoughts of most individuals within the refractive surgery industry. Does this mean the satisfaction levels of patients following treatment were unacceptably low prior to all this regulation in the late 90s and are sky high now as a result of the same? Of course not. Patient satisfaction has stayed consistently high throughout. While the quality of outcomes has inevitably improved over the past five years, so patient expectations have increased. In fact, patients go on being treated as they always have, almost removed from the concepts of the regulation that claims to put their safety at its heart. This is a busy time for would-be regulators – never before have so many pieces needed to be put into the same picture.

NICE WORK

NICE is a body that appraises technology and issues clinical guidelines for the NHS. It also provides guidance on whether interventional procedures are safe. Its creation essentially evolved from events over the previous decade; the early problems in the early 90s from specific types of surgery carried out without adequate training and the Kennedy Report into the Bristol scandal further emphasising not only the need for appropriate training, but the monitoring of complications and necessity of informed consent ultimately led to the NICE approach we know today.

NICE responds to the concerns of individuals regarding procedures it believes to be in need of investigating. Public consultation, provisional guidance and then definitive final guidance are of value in 'validating' a procedure.

Lasik was brought to the attention of NICE in autumn 2004, and a review body was asked to prepare an initial report of provisional guidance. Despite being no more than an initial report, take the NICE name, add some woefully out of date research, together with an ever-hungry attack-dog of UK 'consumer' journalism, and a press field day becomes a certainty. And it certainly did.

After the initial NICE document was released to a disproportionate publicity in December 2004, NICE subsequently commissioned further consultation and an enormous literature review. This order of events may seem odd – why issue the document before doing most of the work? Answers please. Whatever the rationale, the results of all this, the final definitive guidance, are now due. A more positive guidance document on the safety efficacy of Lasik is expected this time round. So expect less publicity.

NICE therefore provides a brief guidance document on the efficacy and safety of Lasik, but this is where its real influence ends. So what else in the growing field of regulation? The General Medical Council (GMC) already serves a regulatory purpose. Effectively, all doctors are regulated by the GMC. Revalidation will take this further still. Being a Fellow of the Royal College of Ophthalmologists and appearance on the Specialist Register are universally-accepted qualifications ensuring a standards of general ophthalmology skills. So why need more for refractive surgery specifically? To understand why laser refractive surgery is seemingly singled out, you have to understand the background against which the industry has evolved in the UK.

KNOWLEDGE GAP

The UK professional bodies responsible for ophthalmologists and optometrists have largely ignored refractive surgery. A small number of refractive-relevant surgical fellowships do exist in the UK, but outside these, ophthalmologists have not been assured skill and knowledge on matters relating to refractive surgery. Equally, UK optometrists have traditionally qualified with a far greater knowledge of factory lighting layouts than any aspect of laser surgery. In the US, by contrast, recognised fellowships in refractive surgery are common and have existed for many years. Refractive surgery is viewed as a legitimate speciality of ophthalmology and optometry.

An absence of standardised training for both ophthalmologists and optometrists in the UK, at a time that public demand for the procedure has been largely robust, has led to the industry needing to create their own. This inevitably leads to differences of approach and method. It is this very same lack of consistency that falls under the spotlight now. Training and accreditation are among of the aspects of regulation that are given the most airtime. A few biased lurid press articles tend to push all the 'we must act' buttons and multiple

parties to become involved.

The key players in the regulation of refractive surgery are likely to be the Healthcare Commission, responsible for the appropriate operating of private clinics, and the RCO. The Department of Health, local government, the Health and Safety Executive and the Department of Trade and Industry could all, at least in theory, have a role in the running of aspects of UK refractive surgery. As could The College of Optometrists.

With more than 100,000 treatments being carried out every year in the UK, most (along with the four or five times as many actively considering) will have their first questions answered by their optometrist. Indeed the College of Optometrists' role is to ensure their members are trained to a standard that serves the members of the public they seek to protect. In refractive surgery, there are many such members of the general public.

Perhaps one of the challenges for any co-ordinated approach is this very diverse nature to which refractive surgery extends. Advertising, consent, training, qualifications, appropriateness of facility and numerous other areas would need to be covered in a consistent way if patient safety really were to benefit. The RCO, charged with maintaining standards for the benefits of the public, set up a working party and in 2003 attempted to do exactly this, publishing their Standards for Refractive Surgery.

While welcomed in some quarters, many cited it as restrictive, anti-competitive and even potentially contravening human rights. A particularly contentious point was, and still is, the necessity that a surgeon appears on the specialist register. The pro-argument for the specialist register that it guarantees a level of general ophthalmology experience is strongly disputed by those who point out that no knowledge of refractive surgery whatever is guaranteed by obtaining Specialist Registration.

The RCO has never been a true regulator, but their influence over the industry could well be increased dramatically if the currently debated Regulation of Laser Eye Surgery Bill gets on the statute books. While this is still some way off (and by no means certain of ever doing so) the Bill in its current form would require the RCO to set the standards by which the industry runs, from training to advertising to audit to consent. Most importantly these same standards would be enforcably by the HCC whose power includes shutting down non-compliers. The RCO would keep a register of surgeons accredited to perform laser refractive surgery.

SLOW PROGRESS

Parliamentary process is slow, and a Private Members Bill for laser eye surgery is not the most pressing current concern for most politicians. Repeated postponements of several scheduled readings add further time to an already notoriously slow process. The industry waits, lobbies, debates and considers the implications of this Bill.

At the time of writing, the next House of Commons reading of the Bill is several weeks away. Meanwhile the RCO working party continues to strive for standardisation of training, agreements of grandfather rights, a fair system of accreditation and perhaps most importantly, a system to ensure all ophthalmologists have adequate knowledge of refractive surgery in a way that best serves the public. The greatest chance of achieving this comes from appropriate consultation with all the relevant parties. The RCO should be credited with this approach, and the proponents of the Bill would do well to take heed of this example of appropriate consultation after its next reading.

Interestingly, while the refractive industry considers its own bubble, similar discussions have been happening over the last few years in the field of cosmetic surgery. The Department of Health has been actively looking at regulation, particularly over the last six months. Last year saw a great media interest in cosmetic surgery. Liam Donaldson, Chief Medical Officer, felt the rapidly expanding field was not being met with the equivalent expansion of regulation for patient safety. An expert group was put together. One of the key areas identified was professional performance, namely training, development and accountability. An inter-government body is currently liasing with the private sector stakeholders to implement. Sound familiar?

The story is far from over, the end result far from clear. Two points do ring out from all the discussion of this highly emotive area. I was involved in a conversation where a frank-talking Australian refractive surgeon was speaking with disbelief at how the UK is letting politicians, researchers, and just about anyone else decree how refractive surgery is run. Shouldn't this, he argued, be the surgeons that decide, you know, the ones that operate on their patients? No one disagreed.

The second point is the relevance of refractive surgery to optometry in the UK. The College of Optometrists is consulted by both the heavyweights in this area (the RCO working party and the Panel responsible for the proposed Bill). In other words, the optometry profession is considered relevant enough to be asked for their voice.

Standardised professional training is often at the heart of the debate. It seems sadly ironic that optometrists themselves can therefore currently qualify without an assured level of knowledge of how to advise the public on refractive surgery. This is despite the qualification process being recently revised while all this has been going on. Perhaps work is currently going on behind the scenes – one would certainly hope so. And quickly.

Optometrists need to be giving accurate information to the public. An expected accurate response is of course the reason they are asked in the first place. How else can this happen other than a standardised approach taken that requires optometrists to prove this knowledge when they qualify.

The example being set by the RCO, and indeed ABDO (actively working to promote this speciality to their members as they did with contact lenses many years ago) is admirable. The time for optometrists to follow it has never been better.

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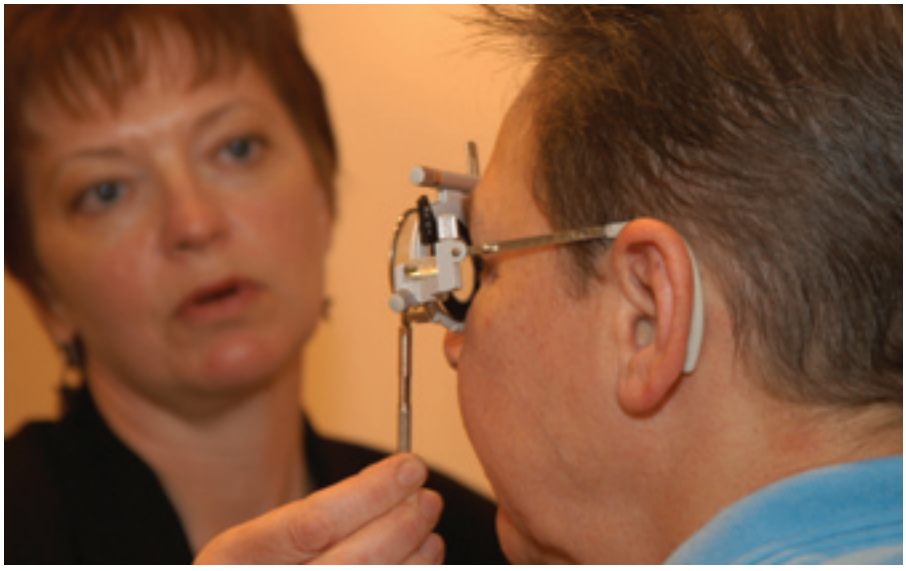

Optometrists currently qualify without an assured level of knowledge of how to advise the public on refractive surgery