



UK legislators seek unprecedented regulation of refractive surgery

UK parliament members have become the first legislators in Europe to seek greater governmental control of refractive surgery.

In an unprecedented report, four members of the British House of Commons have announced they will press the UK's government to pass strict laws to regulate advertising practices, safety standards, and the training of ophthalmologists to increase the safety of refractive surgery throughout the UK.

The regulations would essentially prohibit any ophthalmologists from practicing refractive surgery unless they were specially trained and certified. The regulations would also create mandatory procedures to assess the ongoing safety and quality of each refractive surgeon throughout the UK.

"The Panel believes that these recommendations will lead to better patient care and safety, and a rise in consumer confidence," the MPs stated in their report.

If the British government ultimately adopts such regulations, other European Union countries will come under increasing public and political pressure to adopt similar regulations.

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Paul Rosen

In their report, sponsored by an ophthalmic company, the MPs, who were led by Labour MP Gwyneth Dunwoody, said they hoped their call for stricter regulation by law and by the Royal College of Ophthalmologists would dovetail with an ongoing safety and quality assessment of refractive surgery by the UK National Institute for Clinical Excellence (NICE). *Details of the College's recommendations on refractive surgery and NICE assessment of refractive surgery appeared in the January issue of EuroTimes.*

The president of the United Kingdom and Ireland Society of Cataract and Refractive Surgeons welcomed the thrust of the report.

"More regulation is generally a good thing, protecting both patient and surgeon," said the UKISCRS President, Mr. Paul Rosen FRCS, FRCOphth. "But this must be realistically achievable and should be done as a partnership."

"UKISCRS and the ESCRS could be involved in organising the training of refractive surgeons, and the College of Ophthalmologists could be involved in their regulation, playing to the strengths of each organisation" Mr. Rosen added.

Drawing heavily from recommendations from the UK's Royal College of Ophthalmologists, the MPs identified what they termed "current gaps" in how the law and profession now fail to regulate how refractive surgeons:

- Advertise their services;
- Counsel patients about surgery;
- Offer incentives for surgery;
- Obtain consent to surgery;
- Undergo training to perform refractive surgery;
- Qualify to perform refractive surgery;
- Identify and dissuade unsuitable patients from undergoing surgery;
- Retain their skills and update their competence in the latest refractive surgery techniques;
- Ensure that the facilities where they perform surgery meet minimum standards;
- Conduct post-operative patient follow-up.

In calling for such reforms, the MPs – who named themselves the "All-Party Parliamentary Panel of Enquiry into the Safety of Eye Laser surgery in the UK" – emphasised that more money and staff were needed for the UK Healthcare Commission to implement and monitor any changes in the practice of refractive surgery.

"There is a clear need for the Healthcare Commission to be given training and resources to properly regulate and monitor the industry," the panel's report stated. "This agency must be able to apply serious and meaningful sanctions where clinics or surgeons fail to comply with new standards."

In addition to calling for general reforms

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Optometrists told to respect refractive surgeon's patient relationship

In what appears to be a European first, UK optometry groups have told their members not to interfere in the relationship between refractive surgeons and their patients.

New guidelines published at the end of last year by the UK's Association of Optometrists and Federation of Ophthalmic and Dispensing Opticians forbid optometrists from interfering with the patient counseling role of the refractive surgeon.

"The patient should be advised to refer all the questions of prognosis and side effects to the operating surgeon," the guidelines read. "The optometrist should not be drawn into any discussion as to the outcome of the surgery."

"Patients must only be advised on procedures which can be undertaken within the professional competence of an optometrist," the guidelines add. "Patients should not be advised on surgical procedures; they should be referred to an ophthalmologist for such advice."

in the training and certifying of refractive surgeons, the report also calls for a number of novel and specific reforms that would regulate virtually every step that refractive surgeons take – from pre-operative counselling through surgery and onto post-operative follow-up care.

For instance, the report calls for the Royal College of Ophthalmologists to police the referral process for refractive surgery to ensure that only suitable patients choose refractive surgery willingly. To achieve this, the report calls on the College to ensure that:

- No incentives be offered to patients to encourage them to sign up immediately for surgery;
- No incentives be offered to staff to encourage them to enrol patients;

For instance, the report states that surgeons should not perform a refractive procedure on patients within 10 days of the first contact with the patient. Specifically, the report recommends that the UK adopt regulations that would

The guidelines also call on optometrists to acknowledge the limits of their practice in pre-operative assessments and post-operative follow-up of refractive surgery.

In particular, the guidelines instruct optometrists to ensure that any pre-operative measurements that they may take not be relied on for planning the actual refractive procedure.

"If the optometrist performs pachymetry and topography, it must be clear to the patient and to the surgeon that these measurements are for screening purposes and must be repeated for the purposes of surgery," the guidelines state.

In addition, the guidelines will now require optometrists to disclose financial ties that they have with any refractive surgery centres to which they refer patients. That disclosure rule parallels a similar call made by the "All-Party Parliamentary Panel of Enquiry into the Safety of Eye Laser surgery in the UK."

require a surgeon to wait at least three days between the first meeting with a potential patient and the signing of the consent form to the procedure. The regulations would also require a further cooling off period of another seven days between signature of the consent form and the performance of the surgery.

In addition to criticising the way in which some surgeons and clinics may attract patients, the report also criticised the way in which some surgeons discharge their patients. In particular, the report criticised the way in which some patients who experience complications after private laser surgery are "bounced" between surgeons or even are referred to the publicly-funded National Health Service for follow-up care.

To ensure that patients receive appropriate follow-up care and that the National Health Service receives adequate compensation for any follow-up care, the report recommended that:

- Guidelines describing mechanisms for dealing with complications must be included in the patient counselling

Panel report: greater governmental and professional commitment needed to ensure safety of refractive surgery

In its 23-page report on refractive surgery, the "All-Party Parliamentary Panel of Enquiry into the Safety of Eye Laser surgery in the UK" identified a number of issues that require government and professional regulation.

Advertising

On advertising, the panel of enquiry called for a number of changes, including:

- Refractive surgery advertisements to include warnings on possible negative elements such as night vision complications.
- The Royal College of Ophthalmologists to set out control and guidelines for all promotional and advertising materials promoting laser eye surgery.

Patient counselling

To promote more comprehensive counselling of potential patients about refractive surgery, the panel report recommended regulations to require that surgeons provide unbiased and user-friendly written materials to patients. Such information materials should be made available for dissemination by GPs, optometrists, and ophthalmologists. These materials should provide standard details about:

- Patient selection for refractive surgery;
- Pros and cons of each technique presented in a properly balanced manner;
- Risk and benefit assessment of two eyes at once versus one at a time;
- Clear differentiation between the terms "enhancement" and complication;
- Overall outcome statistics for each procedure;
- An individual surgeon's qualifications, experience and outcomes for each procedure;
- Outcomes for the individual clinic where the surgery will be performed.

Prohibit incentives

The panel also recommended that regulations prohibit the use of incentives to encourage patients to sign up immediately for surgery and to prohibit incentives for clinic staff members for enrolling patients. Also, the panel called for regulations to define the role of GPs and optometrists in referring potential patients to refractive surgeons and how GPs and optometrists manage those patients post-operatively.

Obtaining consent

The panel called for special regulations to ensure that in obtaining consent to refractive surgery procedures, an ophthalmologist must:

- Use a universally accepted consent form;
- Explain fully the procedure to be undertaken, including its potential side-effects, risk of failure, and limitations.
- Set out a process to ensure that patients confirm their understanding and comprehension of the procedure. This process would:
- Allow for a cooling off period of three days between counselling and signature of the consent form
- Allow for a cooling off period of seven days between signature of the consent form and surgery.

Surgeon Suitability and Qualifications

To ensure that only qualified refractive surgeons perform laser surgery, the panel has

called for regulations requiring:

- The College of Ophthalmologists and NICE to set out strict guidelines regulating clinical practice. These guidelines will, in turn, be monitored and policed by the UK's Healthcare Commission.
- Each refractive surgery clinic to employ the necessary number of surgeons with specialist knowledge, training, and experience in cornea and refractive surgical techniques.
- All laser eye surgeons to be listed on a special register maintained by the Royal College of Ophthalmologists.
- Refractive surgeons to assume ultimate responsibility for any patient treated by a resident under their supervision.
- Sanctions where refractive surgeons or their clinics flaunt these guidelines.

Training

To promote appropriate training of all refractive surgeons, the report states that:

- All surgeons must be trained to an agreed standard. This training standard should be

approved by the Royal College of Ophthalmologists and be certified by an appropriate training board of the College.

- The College should also consider introducing new academic and surgical courses as technologies develop;
- Clinics and manufacturers must collaborate with the College to set up and implement an UK-wide training programme for ophthalmologists.
- The College must approve individual clinic and manufacturer system-based training.

The report also recommends regulations to ensure that optometrists and GPs are suitably educated about refractive surgery to ensure that they make appropriate referrals for eye laser surgery.

Identifying the unsuitable patient

The report specifies that regulations must include clear and standardised procedures for accepting suitable patients for refractive surgery. Only patients who meet defined criteria should be routinely treated, the report states. The criteria should include:

- Safe operating parameters. Only prescriptions between a range of +3 to -8 should be routinely operated on;
- Patients should be aged 21 years or older, not have recently changed their eye prescriptions, or have a medical condition such as diabetes or rheumatoid arthritis;
- The provision of clear information to patients about adverse conditions and syndromes that could lead to complications and increase the risks associated with laser eye surgery;
- How to identify and assess issues involving patients with significant mental health or emotional problems and how such issues should be resolved before undertaking surgery on such patients.

Regulation

The report also calls for new laws to regulate the clinics where ophthalmologists perform refractive surgery. The report recommends that the UK Healthcare Commission take on the role of regulator to police the industry. Such regulation should ensure that:

- All clinics providing laser eye surgery must carry out annual audits for success rates, surgical complications and infection rates. These statistics should be published annually and must be made available to The Healthcare Commission.
- Complications of laser eye surgery which are ultimately referred to the National Health Service must be recorded and sent to the Healthcare Commission to be added to the complication rates for the referring clinic.
- The Healthcare Commission issues an annual licence to practice to clinics and to individual surgeons. This license must be based on:
- Proper inspection of premises;
- Verification of surgeons' registration on the College of Ophthalmologists' register;
- Acceptability of published data on outcomes and complication rates; confirmation of compliance with continuing medical education requirements;
- Regular safety checks on the laser device.

Also, the report specifies that the Healthcare Commission must have the power and authority to enforce the new regulations. Surgeons who fail to comply with the agreed standards should be removed from the College of Ophthalmologists' register. Any clinic that fails to comply with the agreed standards would lose its license.

In addition, clinics will be required to pay an annual licence fee to the Healthcare Commission to cover the costs involved in regulating and policing the industry. Part of this regulation by the Healthcare Commission should include annual follow-up checks for laser safety.

Refractive Surgeons

All surgeons practising laser eye surgery should be approved by the College of Ophthalmologists. To ensure that such surgeons maintain their skills, the panel called for regulations to require that:

- The College set out and require a programme of continuing medical education for refractive surgery.
- The number of procedures conducted by an individual surgeon be monitored and published by the Healthcare Commission on an annual basis, including complication and enhancement rates.
- Adverse incidents, including any system failures, should be recorded and reported.
- A senior refractive surgeon should be appointed at each clinic and made ultimately responsible for outcomes and patient care.
- Clinics and individual surgeons should pay an annual fee to the College of Ophthalmologists to audit and monitor their practice annually.

Patient Follow-up

To promote appropriate post-operative patient follow-up, the panel called for the College of Ophthalmologists to set out transparent guidelines of surgeon responsibility, the practice of co-management, and payment of fees to optometrists. As part of the follow-up process:

- The Healthcare Commission must monitor and assess compliance to these transparent guidelines.
- Surgeons should be mandated to

undertake a one-year to two-year follow-up on all patients.

- Clearer definition of complications and the difference between 'enhancement' and complication must be set out

information.

- Laser clinics pay a levy to provide a protection fund for patients who suffer complications and are referred to the National Health Service (NHS). The NHS would be able to draw on these levies where necessary in private cases.
- Clinics receive an annual "no claims" refund where there were no referrals to the NHS.
- Clinics provide an annual audit and publication of complications, outcomes and adverse incidents for submission to the Healthcare Commission.
- Clinics and surgeons report adverse incidents to the Royal College of Ophthalmologists.
- The Ophthalmic Surveillance Unit of the Royal College of Ophthalmologists review clinics every three years and provide a publicly available quality rating of those clinics.

The report also calls for greater regulation to ensure the disclosure of any financial relationship between optometrists and surgeons. The report said that patients must be informed about the nature of any financial relationship between the referring optometrist and the refractive surgeon who operates on them. Patients must also be informed about any co-management or follow-up monitoring fees that the referring optometrist receives from that surgeon or clinic. The call for greater disclosure of financial ties between optometrists and laser eye centres parallels a similar call by two leading UK optometry groups, the Association of Optometrists and Federation of Ophthalmic and Dispensing Opticians. (*For details, see related article.*)

Gwyneth Dunwoody, MP
Chairperson
All-Party Parliamentary Panel of Enquiry into the Safety of Eye Laser surgery in the UK
E-mail: dunwoodyg@parliament.uk
Telephone: +44 (0) 207 219 3490

Paul Rosen
President
United Kingdom and Ireland Society of Cataract and Refractive Surgeons
phrosen@compuserve.com

Association of Optometrists