



Proposed British law would make it a crime to perform refractive surgery unless registered

In what appears to be a world first, British legislators have proposed a law to ban physicians from practicing refractive surgery unless their names appear on a register.

If adopted, the law would also become the first of its kind in Europe or anywhere else to ban a licensed physician from performing a medical procedure.

London refractive surgeon Dan Z. Reinstein MD believes that if the law is successful it could prove a watershed in protecting the self-regulation of medicine throughout Europe and across other specialties.

"This law is certainly a wake up call," says Dr Reinstein, who is Medical Director of the London Vision Clinic and professor of ophthalmology at the University of Paris VI and Research Director of Refractive Surgery at Cornell University in New York.

"What this law is saying is that professional self-regulation only lasts as long as it is effective," Dr Reinstein says. "And this kind of law can apply to keyhole surgery of the gallbladder as it does to elective surgery on eyes that can already see – in other words, surgical procedures where the tolerance for error is essentially zero."

The Regulation of Laser Eye Surgery Bill, which was proposed in late February, would make it a crime for anyone to perform refractive surgery unless his or her name was on either the existing UK ophthalmology specialist register or on a new UK laser eye surgeon register. Those who practised without such registration would face a criminal fine.

As written, the law would also ban any ophthalmologist from outside of the UK from practicing refractive surgery in the UK without first obtaining the necessary specialist or refractive surgery registration.

If passed, the law would culminate the efforts of politicians, leading ophthalmologists, ophthalmic researchers and the Royal College of Ophthalmologists to make refractive surgery safer.

Much of the new law is based on increasing the role of the Royal College in setting the appropriate standards for performing refractive surgery.

Under the law, the Royal College would have an unprecedented legal duty "to promote the maintenance of high standards in the carrying out of laser eye surgery" in approved clinics and hospitals and "to promote the maintenance of high standards in the carrying on by ophthalmologists of activities relating to laser eye surgery" in those clinics and hospitals.

"The proposed law is eminently sensible and should be welcomed by everybody," says the College's president, Nick Astbury, FRCOphth. "The standards have to be very

New law would place unprecedented duty on ophthalmologist group

For what would appear to be the first time, a medical specialty group could be legally bound to produce and update requirements for a performing a clinical procedure.

If adopted as written, the proposed Regulation of Laser Eye Surgery Bill would require the UK Royal College of Ophthalmologists to certify training programmes in laser eye surgery.

Only those ophthalmologists who met the requirements of such training would be registered. And without registration on that register or on the existing ophthalmology specialist register, a physician could not perform refractive surgery in England or Wales.

To achieve the widest possible input in devising such training, the College has already taken the unprecedented step of seeking input from leading refractive surgeons, laser researchers, officials of United Kingdom and Ireland Society of Cataract and Refractive Surgeons and the British Society of Refractive Surgeons, and representatives of eye laser manufacturers, according to the president of the College, Nick Astbury, FRCOphth.

"We need to get together all of the people involved," Dr Astbury says. "We need to bring them together and see how we can agree on some training that the college that can accredit."

Although the College is the lead coordinator of the training, Dr Astbury emphasises that the College will not police clinics or ophthalmologists. That role will be left to a government agency known in England as the Commission for Healthcare Audit and

Inspection and to the National Assembly in Wales. As drafted, the law would not apply to Scotland or to Northern Ireland.

"The College cannot regulate," Dr Astbury insists. "What it can do is approve of and create a curriculum and organise training with other people helping."

In addition to its duty to certify appropriate training schemes, the College would also be required to set and update standards for the selection and post-operative follow-up of patients, the content and use of consent forms, and the provision of suitable guidance information on refractive surgery for ophthalmologists, optometrists, general practitioners and the public.

Under Section 4 of the proposed law, the College will be required to prepare guidance on:

- Information that must be included in a patient's guide;
- Appropriateness of certain contractual obligations between ophthalmologists, their clinics and clinic employees;
- Procedures for selecting prospective patients for surgery;
- Content of consent forms;
- Procedures for post-operative follow-up.

In preparing guidance for potential patients, the Royal College will be required by the law to include information about:

- The different methods of laser eye surgery available;

- The risks and benefits associated with each method of laser eye surgery;

- The particular benefits and risks associated with bilateral surgery;

In preparing guidance for potential patients, the College will be required by the law to include information about:

- Surgery outcomes generally;
- Surgery outcomes in particular clinics
- Qualifications and experience of individual ophthalmologists in individual clinics.

In preparing such guidance, the College must consult such government agencies as the General Medical Council, General Optical Council, and National Institute for Clinical Excellence. Also, the College is under a duty to consult with the British College of Optometrists.

Under Section 5 of the proposed law, the College will be required to:

- Prepare guidance on the training, qualifications, and other criteria necessary to be entered onto the laser eye surgery register;
- Arrange for members of the public to inspect the laser eye surgery register;
- Remove a name from the register when instructed to do so by the appropriate government authority.

high because we are talking about an elective operation on a healthy eye."

Dr Astbury adds that because unqualified physicians are carrying out refractive surgery, ophthalmologists have a duty to protect the public.

"If a procedure is not being carried out to the highest standard, we have a responsibility to ensure that there is a mechanism for training and accreditation – though we still have to decide what this will mean – in order to protect public safety," he says.

He added that he knew of no reason why other ophthalmology groups anywhere else in Europe shouldn't be doing the same thing.

Qualified refractive surgeons who practice anywhere in Europe would have little trouble in complying with the standards, adds

ophthalmic laser pioneer John Marshall PhD. "It's like a European ISO standard that everyone has to comply with."

Because of that, similar regulation may soon filter its way into practice throughout Europe, predicts Dr Marshall, who is Professor of Ophthalmology at St. Thomas's Hospital in London. "There will be a large number of European countries and ophthalmologist bodies that will say this is the way to go."

In addition to its requirements for the registration of ophthalmologists under the existing specialist register or new eye laser surgeon register, the proposed law would also require refractive surgery clinics to register and meet minimum standards.

To maintain standards in such clinics, the

law would require each registered clinic to appoint a person to be legally responsible for ensuring the ophthalmologists and staff members who worked there complied with the law. That "registered person" could face criminal charges and fines for failing to do so. In particular, the law states that the registered person "shall ensure that prescribed activities relating to laser eye surgery are only carried on in that establishment by or under the supervision of an ophthalmologist who is registered."

As part of their legal duties, registered persons will be required to prepare documentation for potential patients that includes:

- The types of laser eye surgery provided by the clinic;

- The qualification and experience of the ophthalmologists performing refractive surgery at the clinic;
- The costs of the different types of refractive surgery offered by the clinic and any additional costs for follow-up

“The standards have to be very high because we are talking about an elective operation on a healthy eye.” *Nick Astbury FRCOphth*

care;

- A summary of the consent process.

To reduce the risk that patients make a hasty decision to undergo refractive surgery, the law would prohibit clinics from offering any discounts to patients who agree to undergo refractive surgery within a particular period of time.

Also, the law prohibits a clinic from offering to its staff members “an undue financial incentive to encourage potential patients or persons authorised to act on the behalf of potential patients to enter into a contract for the provision of laser eye surgery.”

The law would also require clinics to file annual returns with the appropriate government agency. Those returns would include reports of surgical outcomes and complication rates as well as any information recommended by the Royal College of Ophthalmologists.

The law also will require clinics to follow any advertising regulations that may be promulgated by the appropriate government agency. In addition, the law would also require the government agency to set up a so-called “protection fund.” The fund would be used to pay for the treatment of any patients whose complications required

New law only way to curb ‘rogue’ physicians

For ophthalmic laser pioneer John Marshall PhD, governmental regulation is the only way to protect the public effectively from “rogue” physicians.

“Everyone’s heart sinks when the media coverage is about another eye ruined by an incompetent surgeon,” says Dr Marshall, who is Professor of Ophthalmology at St. Thomas’s Hospital in London. “Everyone gets dragged down by the few rogue individuals.”

If the Regulation of Laser Eye Surgery Bill were adopted by the UK Parliament, that would change, Dr Marshall predicts. “If the rogues can’t comply they’ll be forced to drop out.”

Such regulation, he adds, is particularly important when a person could ruin or lose their sight at the hands of an untrained physician.

“Refractive surgery is really the first form of surgery in the ophthalmic field that is

elective and almost exclusively practised on what would be described as ‘non-diseased’ eyes,” says Dr Marshall. “It is also a phenomenally successful form of surgery. But because of bad practices – such as inappropriate patient selection, poor surgical techniques and poor follow-up procedures in a very, very small subset of clinics, there has been a groundswell of public discontent that has generated an enormous amount of bad publicity.”

Bad publicity – and worries about the possible risks that laser eye surgery could pose to patients from poorly trained physicians – led to a number of members of the UK Parliament to set up the “All-Party Parliamentary Panel of Enquiry into the Safety of Eye Laser Surgery in the UK.” Dr Marshall served as a special advisor to the panel

In a report published last December, the parliamentary panel recommended that the UK government introduce a new law to

regulate the practice of refractive surgery to protect the public. In publishing its report, the panel said it wanted to make the UK “the safest place in the world to have laser eye surgery.” On February 22, the seven members of that parliamentary panel introduced the Regulation of Laser Eye Surgery Bill to the UK Parliament as a so-called “Private Members Bill.” The panel members say they hope to persuade the Labour Party-led government to support the bill. (For more details about the UK parliamentary inquiry, please see the February issues of *EuroTimes*.)

The publishing of the parliamentary inquiry report and proposed bill take place against the background of an ongoing safety and quality assessment of refractive surgery by the UK National Institute for Clinical Excellence (NICE). (For more details about the NICE assessment of refractive surgery – and recommendations on refractive surgery by the Royal College of Ophthalmologists – please see the January issue of *EuroTimes*.)

follow-up care in the National Health Service of other health care provider outside the clinic where the original surgery took place. As part of their registration, clinics would be required to contribute to such a fund annually.

For Dr Reinstein, such a path makes perfect sense. And ophthalmologists need look no further than the airline industry for obvious parallels.

“Pilots of 737s are not allowed to fly 747s,” he notes. “You would think they could because the instrumentation is largely the same and they’re both made by Boeing. But a 737 pilot isn’t allowed to fly a 747 under any circumstances. Why? Because the consequences of non-routine situations may be catastrophic if not handled expertly – an argument for exclusivity in specialisation and scope of practice within ophthalmology.”

The same type of rules should apply to refractive surgery, he insists. “At the risk of sounding self-serving – which I am not – I do believe that refractive surgery should be performed only by specialised expert ophthalmic surgeons, simply because the consequences of damaging someone’s vision are so far-reaching. The argument extrapolates further to the non-ophthalmologists performing refractive surgery – it is amazing to me that some people doing eye surgery are not even qualified eye surgeons.”

Contacts

For a copy of the Regulation of Laser Eye Surgery Bill, contact the bill’s sponsor, **Gwyneth Dunwoody, MP**, at: dunwoodyg@parliament.uk or at +44 (0) 207 219 3490.

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