By Paul McGinn

Government report spurs surgeons to correct LASIK misconceptions

Leading UK refractive surgeons are poised to launch a campaign to prove that LASIK is safe and effective in their hands.

The battle plans follow last month's release of an unprecedented government agency report that claimed that LASIK surgery could weaken the cornea and cause keratectasia.

The report, by Britain's National Institute for Clinical Excellence, is the first of its kind by a governmental agency in Europe. Because of the unprecedented nature of the report, UK refractive surgeons worry that misleading statements by the Institute could seriously undermine the future of LASIK surgery throughout Europe.

In addition to focusing on LASIK's potential role in weakening the cornea, the report highlighted a number of post-operative complications. Those complications included: reduced vision, dry eye reaction, difficulty with night vision, flap problems, retinal haemorrhage, retinal artery occlusion and loss of the eye. Because of the risks of such complications and the elective nature of the procedure, the Institute said that LASIK must have "excellent safety to be suitable for use."

The report added that LASIK could also endanger future, necessary eye care. "The effects of the procedure can make it more difficult to detect glaucoma and to measure accurately the intraocular lens power required for cataract surgery."

In light of such risks, the Institute, known by the acronym "NICE," recommended that surgeons follow a rigorous patient consent procedure, perform ongoing audits of their surgery results, and conduct long-term post-operative follow-up.

Despite its worries about the long-term safety effects of LASIK, NICE did rate the procedure as effective "where the degree of refractive error was within the accepted criteria for surgical treatment."

Although NICE report failed to specify what constituted the "accepted criteria," the agency cited results only from a handful of studies of patients with myopia in its report, titled, Interventional Procedure Guidance: Laser in situ keratomileusis for the treatment of refractive errors.

"Current evidence on laser in situ keratomileusis for the treatment of refractive errors suggests that it is efficacious in selected patients with mild or moderate myopia," the report states. "Evidence is weaker for its efficacy in patients with severe myopia and hyperopia."

According to NICE, the guidance report represents only the latest step in an ongoing assessment of refractive surgery procedures. The next review of refractive surgery procedures, which will include PRK and LASEK, is expected by this summer.

When it was released just before Christmas the NICE report provoked criticism from leading UK refractive surgeons about the evidence and expertise on which the agency made its findings.

"NICE is an internationally renowned and respected body, but in this case it has been either misinformed or ill-advised about LASIK," said Paul Rosen FRCOphth, President of United Kingdom and Ireland Society of Cataract and Refractive Surgeons.

In a letter to NICE, Mr Rosen and five other UKISCRS officers said the report placed too much reliance on outdated clinical studies in assessing the efficacy of LASIK.

"The evidence with the regard to efficacy is based on randomised controlled trials done 6 years ago with very small numbers of patients: there is little reference to the more recent large studies with good outcomes," Mr Rosen and the other UKISCRS officers wrote. "This is even more incongruous when one considers that 8 million people world-wide have had this surgery."

In their letter, the UKISCRS officers also commented that the report exaggerated the risk that LASIK posed to the strength of the cornea.

"There is much emphasis placed on ectasia, which so far has been a very rare complication," the UKISCRS officers noted. "In apparently otherwise normal eyes, treated within the currently accepted limits of the procedure, this has been until now an important but theoretical concern."

The UKISCRS officers added that the report could induce unnecessary worry in patients and promote lawsuits against physicians.

"These statements are likely to cause significant distress for patients and increase spurious litigation claims," the officials wrote. "We have already seen misinterpretation by the press and there is consternation from European colleagues and societies, who up until now have held NICE in high regard."

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Sheraz Daya FRCOphth said that refractive surgeons should share their latest study results and expertise with NICE to prove that LASIK was safer and more effective than NICE said in its guidance document.

"They need to pay attention to us and to use us as part of the consultation process," said Mr Daya, who serves as medical director at the Centre for Sight and director of the corneo-plastic unit and eye bank at the Queen Victoria Hospital in East Grinstead. "I don't believe that NICE's advisors were up to speed on LASIK, and that's a pity really."

Mr Daya noted NICE appears to have assessed the efficacy of LASIK largely on the results from four randomised controlled trials that involved a total of 250 patients and which were published in 1998 and 1999.

Those studies showed that between 63% and 79% of eyes with low to moderate myopia achieved UCVA of 20/20 or higher after LASIK. In eyes with the moderate to high myopia, the percentage of eyes achieving a UCVA of 20/20 or higher dropped to between 26% and 36%.

The four studies also showed that all of the eyes with low to moderate myopia had a UCVA of 20/40 or higher; among eyes with moderate to high myopia, the proportion of patients with post-operative UCVA of 20/40 or higher ranged from 56% TO 85%. The studies also showed that

LASIK patient leaflet could frighten away patients

The President of the United Kingdom and Ireland Society of Cataract and Refractive Surgeons has voiced concern that the new LASIK information leaflet published by the National Institute for Clinical Excellence could make patients unnecessarily anxious.

While welcoming the concept of a patient information leaflet, Paul Rosen said the Institute should have chosen its words more carefully. "It's a good idea to produce these patient leaflets, but the way it is written will frighten people," he warned.

Mr Rosen criticised the Institute – known by the acronym "NICE" – for using two old studies as its basis to inform patients about the risks and possible problems associated with LASIK. One of the studies cited in the patient leaflet was based on results from LASIK performed in 1995 and 1996. That study recorded 56 problems in 1,062 treated eyes and 50 eyes that lost two of more lines post-operatively. The second study, which was based on patients who underwent LASIK between 1998 and 2000, documented flap problems in 4% of eyes, corneal inflammation in 5% of eyes, and post-operative tissue growth in 2% of eyes.

"If I were a patient and read that I would be very concerned," he said.

If that wasn't bad enough, NICE expanded the list of complications later in the patient information leaflet, highlighting the possibility that LASIK surgery could weaken a patient's cornea.

"The experts said the main problem was that the cornea becomes weakened by the laser treatment," the booklet reads. "This may lead to the cornea bulging outwards, and further surgery may be needed. They listed other possible problems as: a reduction in vision, dry eyes, problems affecting vision at night, flap problems, bleeding in the eye, and blockage of the artery that supplies blood to the retina. Infection was also a possibility and so were problems that could lead to the total loss of the eye."

"After reading that, patients are going to start wondering if their eyes are going to fall apart," Mr Rosen said.

between 90% and 100% of treated eyes with low to moderate myopia were within 1.0 dioptre of the attempted correction; among eyes with moderate to high myopia, 41% to 54% of treated eyes were within one dioptre of the attempted correction.

"It's apparent that the basis of the guidance is derived from randomised controlled trials of old technology during the learning curve for the procedure," Mr Daya said. "We have learned a lot since then. In fact, LASIK is now one of the safest operations that's performed, and it probably has a better track record than cataract surgery for complications and rates of infection."

In addition to voicing its concerns about the longterm evidence underpinning LASIK safety, NICE also called on individual refractive surgeons to ensure that they took every possible precaution before operating. Those precautions include:

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>
> ***Sheraz Daya UK***

- Being adequately trained in the procedure;
- Following appropriate professional standards;
- Conducting ongoing self-assessment of their own LASIK efficacy and safety through audit and long-term follow-up of patients;
- Informing patients in writing about the possible risks from LASIK. In particular, NICE urged LASIK surgeons to "ensure that patients fully understand the specific risks associated with the procedure and provide them with clear written information."

To facilitate ophthalmologists in providing appropriate information about LASIK to their patients, NICE drafted a special patient information booklet. The 12-page booklet explains the indications for LASIK, how a surgeon performs LASIK, how well the procedure works, the risks and possible problems associated with the surgery, and recommendations from NICE about the procedure.

Despite his misgivings about some of the evidence and advice behind the NICE report, Mr Rosen said that he and other members of UKISCRS were hopeful that the controversy spawned by the report might fuel a professional discussion about how to improve standards for LASIK throughout the UK and even into the rest of Europe.

"There is huge potential to create a safe environment for refractive surgery and we must seize this opportunity. What we would like to see is some type of regulation, appropriate training and accreditation," he says. "After all, this is a highly skilled procedure. It's not just a question of 'push a button and off you go.'"

Ophthalmology College standards underpin NICE LASIK report

The new LASIK quality assessment report published by the UK National Institute for Clinical Excellence is underpinned by standards developed by the Royal College of Ophthalmologists.

The College's "Standards for Laser Refractive Surgery" focus on such issues as the training and competence of surgeons, the places where they operate and the patient consent procedures they follow.

In drafting its report, titled Interventional Procedure Guidance: Laser in situ keratomileusis for the treatment of refractive errors, the Institute – known by the acronym "NICE" – made special reference to the College's Standards, which were last updated in May of 2004 and which have been endorsed by ESCRS and the United Kingdom and Ireland Society of Cataract and Refractive Surgeons.

"With LASIK you do need a higher level of safety," explained Brenda Billington, FRCOphth, a College vice president and cataract surgeon in the English city of Reading. "That entails special arrangements for consent, more studies, and greater audit about its efficacy and safety in the long-term."

Miss Billington added that ensuring the longterm safety of LASIK may ultimately involve decades of postoperative follow-up research of LASIK patients. "You are talking about someone's sight," she says.

The Royal College's standards specify that:

Surgeons carrying out refractive procedures must:

a) Have enough knowledge about refractive surgery to "appropriately assess patients and manage complications";
b) Recognise and work within the limits of their professional competence.
c) Document on-going education in refractive surgery techniques;
d) Audit their refractive surgery results;
e) Regularly take part in continuing medical educational activities
f) Be personally responsible for patient care.
g) Maintain an outpatient service to assess patients pre- and post-operatively;
h) Be available or arrange appropriate cover for emergencies;
i) Not offer incentives to optometrists for patient referrals;
j) Regularly review all quality indicators;
k) Record, investigate and collate all clinical incidents, errors and near misses.
l) Discuss all clinical incidents on a regular basis at appropriate meetings;
m) Educate staff about clinical guidelines for refractive surgery procedures;
n) Be immunised against Hepatitis B.

Facilities where refractive procedures are carried out must:

a) Be registered;
b) Adhere to protocols for equipment maintenance and calibration;
c) Document, update and follow procedures within the facility for the use of all clinical equipment;
d) Train completely all staff who use equipment and document their competence;
e) Provide rooms for patients to have confidential discussions with clinical staff;
f) Insist that staff wearing badges that show their names and positions;
g) Provide a backup power supply in case of power failure during a procedure.

Information for patients should:

a) Be written in concise, plain non-technical language.
b) Include:
   1) The range of refractive surgery procedures stating which ones are available at the facility;
   2) Eligibility criteria for patients;
   3) Treatment options including relative advantages and disadvantages;
   4) Risks and complications associated with surgery, including their frequency, management course, and possible outcome;
   5) Statistical information regarding the probability of achieving the desired goal or probability of needing more than one procedure.
   6) Details about the operating surgeon, including his or her qualifications and experience.
c) Emphasise that bilateral same day surgery carries profound implications in the rare event of serious bilateral complications;
d) Include a price list of procedures;
e) Include written post-operative instructions and a 24-hour emergency telephone number.
f) Explaination how to complain or make suggestions about the surgery.
g) Include the following test results:
1) Pre-operative keratometry
2) Pre-operative pachymetry
3) Pre- and post-operative best corrected acuity
4) Pre- and post-operative intraocular pressure
5) Pre-operative and stabilised post-operative refraction.

The Consent Process should:

a) Be based on a system in which information is given to the patient at least 24 hours before the procedure is undertaken.
b) Involve a preoperative assessment in which a specially trained member of staff ascertains from the patient if there are any questions arising from information given and recap the treatment expectations, potential risks and alternative treatments before confirming that the patient fully understands the written and discussion material.
c) Include a pre-operative meeting between a prospective patient and the operating surgeon.
d) Be documented with a consent form that must be signed in the presence of the surgeon, or other suitably qualified and trained professional and which states:
   1) The elective nature of the procedures
   2) That glasses or contact lenses may still be required after surgery
   3) That pain or discomfort may occur
   4) Whether there are any specific increased risks pertaining to the individual patient in question
   5) That the surgeon is satisfied that the patient has fully understood the risks, benefits, alternative treatments and potential complications of the procedure.

Any advertising or marketing of services should:

a) Adhere to appropriate national standards and medical association guidelines.
b) Warn patients against unrealistic expectations of refractive surgery procedures.
c) Not offer discounts or financial incentives linked to deadline dates for booking.

Post-operative evaluation of patients should:

a) Evaluate the patient for the first post-operative visit or take responsibility for ensuring that postoperative management is carried out appropriately;
b) Be well versed in managing complications of refractive surgery.
c) Ensure that purported testing facilities are available;
d) Ensure that a patient with complications can be admitted to hospital should the need arise.
e) Inform the patient's general practitioner about the outcome of the procedure unless the patient specifically requests otherwise.