

Letter to the Editors

Clinical trials for LASIK

Editors,

In the Jan 2005 issue Clive Peckar writes in his editorial that NICE did a disservice to 8 million people who underwent excimer laser surgery worldwide. The shame about LASIK is that it is done on millions of people without even a modest effort to prove its long term safety and efficacy.

Hardly any study is published with a follow-up longer than a year and with a prospective character. This is because the total information stream has been orchestrated by the industry. Anyone who owns or participates in a laser has by this fact alone a huge financial bias. Unbiased reporting is hardly possible. It is the task of Institutes like NICE or the NIH to safeguard the public from such unproven medical treatment. To state that the studies cited in the NICE report were old is a sign of the profound error that has crept into the system. All new technology that was introduced since has not been proven by prospective randomised

studies with independent reporting without financial bias. The fact that in the meantime this new technology has been marketed to ophthalmologists the world around, pushing them deeper in financial dependence is the very reason that NICE is critical. The sheer numbers of treated patients, who suffer from no more than the desire to be free of glasses and contact lenses, urges governments to regulate this technology where the professionals have failed to do so.

The ESCRS should urge governments to set up a multinational study into the effects of excimer laser surgery in which a cohort of patients is treated according to the latest technology and is followed up for five years in a rigorously controlled protocol. At least 10,000 patients should be included. This is how it was done with PERK and it effectively ended RK. It was relatively easy to throw away a diamond knife and a small set of instruments. To get rid of the excimer lasers if necessary will be more painful.

Very best regards
Oscar Lopes Cardozo MD
The Netherlands

long-term ten-year study disclosed a high incidence of drift into hyperopia chiefly due to faulty techniques in the early years.

I have called for such an impartial study free from financial conflict of interest at successive ASCRS meetings. The call has been met with silence. Little wonder then that regulatory bodies have expressed their concern.

Yours faithfully,
William Jory
London Centre for Refractive Surgery, UK

Editors,

The objections to the preliminary report to the UK National Institute for Clinical Excellence (NICE) on the safety and efficacy of LASIK are widely quoted in EuroTimes, January 2005.

The arguments of the Laser industry and its practitioners would be more persuasive if the Excimer Laser had undergone the rigorous testing of Radial Keratotomy (P.E.R.K. 1984). This study established the safety of R.K. in reducing myopia but its

Italian perspective

Editors,

Similarly to what happens in Great Britain where Government exerts pressure on ophthalmologists in order to increase the number of operations while at the same time is over-burdening them with bureaucracy and paperwork, private ophthalmic surgeons in Italy are asked the same from the managers of private clinics. Many private clinics in Italy are accredited with local national health service authorities and are paid by them according to the number of operations that are performed within the system of DRGs.

For this reason private ophthalmologists are forced to organize more lists during the week and to increase the number of patients during one surgical session (up to 15 or 20). At the same time it is necessary to see the patients before and after the operation and generally the patients prefer to be seen by the surgeon who performed the operation. Moreover, private hospitals do not generally have in-staff specialists paid from the clinic so the surgeons are almost always on call.

Since the private clinics decide the percentage to pay to the ophthalmologist per operation (generally only 10-12%) this is a very efficient system for private businessmen to make money from public need for medical care.

The surgeons provide private hospitals with patients who need an operation but also they have the responsibility for it and many times they are forced to buy themselves some instruments because the private clinics have old or not adequate ones (like operating microscope or phaco). In no cases private clinics own a number of instruments adequate to the number of the operations performed. To make an example, to perform 1,000 cataract operations in one year there is only one operating microscope and one phaco machine. As a consequence, surgeons have to invest money to pay their staff and purchase surgical instruments.

Moreover, with the increasing number of requests for reimbursement from patients, surgeons have to face the problem of not

being covered from their professional insurance because in Italy they cover up to 500.00 euro per single case and per year. It would be really dramatic for an ophthalmologist to have in one session more than one case of panophthamitis because he could be covered only for the first or second patient and he should pay himself for the others.

In conclusion, ophthalmic surgeons working in private clinics in Italy are professionally satisfied for the number of cases they see and treat, but from the economic point of view it is a disaster. Moreover, they are stressed from overwork, responsibility and constant need to be on call.

Who is the responsible for all this situation? No doubt that the inability of the Government to take care of the public health inside public hospitals is the main reason. In fact the waiting list for a cataract operation before this situation was as long as three years. In order to decrease waiting lists instead of increase the numbers of consultants and the staff in public hospitals to make them more efficient or to build more modern structures, they created the system of contract with private companies. In Italy, Government needs private clinics while in Great Britain patients are transferred to a South African company for the same purpose.

It is time that not only we ophthalmologists but also Governments and patients realise that eye operations are still a risk procedure, a long training is required to become a skilled surgeon, an adequate number of staff is necessary to prepare, treat and follow the patients. As we all know even a "simple" cataract operation could be the cause of devastating consequences for patients. This big responsibility that ophthalmic surgeons have for every single operation cannot meet political needs to reduce costs and it's not morally correct for the Government to pay competitors of public hospitals and shift large amounts of money into private companies.

With best regards
Sebastiano Cavallieri
Noto, Italy