**REFRACTIVE LASER**

**QUEST FOR PERFECTION**

LASIK banks on mature technology and reduced complication rates to stay ahead of the competition

by Dermot McGrath

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Laser-assisted in situ keratomileusis (LASIK) has been assessed and improved by more than a decade of clinical studies and technological innovation since the procedure was first introduced. As one of the most popular elective surgical procedures in the world, with one of the highest safety profiles, LASIK remains the primary dynamo driving today’s global refractive surgery market.

However, given the huge volume of procedures performed since its inception, with an estimated 17 million procedures in the US alone, it is hardly surprising that LASIK complication rates have attained a higher visibility than many other refractive surgery procedures.

Even allowing for high overall patient satisfaction rates for LASIK of around 95.4 per cent – based on Dr Kerry Solomon et al’s 2008 meta-analysis of 19 studies from 13 countries encompassing 2,198 patients who underwent LASIK between 1995 and 2003 (Ophthalmology, 2009 Apr;116(4):691-701) – the remaining 4.6 per cent equates to a sizeable and frequently vocal minority of dissatisfied patients.

The type of complications that determine which patients end up in the disgruntled minority are familiar to all refractive surgeons. Corneal ectasia, dry eye syndrome, epithelial ingrowth, buttonholes, free caps, night vision problems, haloes, glare, regression, decentred ablation, light sensitivity, inflammation, infection, make up a representative but far from exhaustive list of the more common complications associated with the procedure.

While many of these complications are known to resolve spontaneously or after treatment in the first six months or so after surgery, a small percentage of patients, for whom re-treatment or enhancement is not an option, may face enduring or lifelong problems associated with their LASIK surgery.

Although there are no reliable figures for how many patients fall under the terminally dissatisfied category over the long term, the fact that the FDA in the US received just 140 “negative reports relating to LASIK” for the time period 1998-2006 suggests to some observers that LASIK complication and/or dissatisfaction rates are probably under-reported.

A 2008 study on LASIK complications carried out at Wills Eye Institute (J Cataract Refract Surg. 2008 Jan;34(1):32-9), for instance, found that only 29 per cent of patients referred for problems after LASIK were referred by their LASIK surgeon, and a majority (54 per cent) were referred by another eye doctor, while 17 per cent sought a second opinion themselves by searching the Internet or asking friends for referrals.

Christopher J Rapuano MD, lead author of the Wills study on LASIK complications and director of the Cornea Service and co-director of the Refractive Surgery Department at Wills Eye Institute, told *EuroTimes* that many patients clearly felt uncomfortable “complaining” to their own surgeons, so often sought a second opinion, even soon after surgery.

“I still believe many patients disappear from their surgeon’s practices after the one year of ‘free’ follow-up care that most provide. Consequently, I do believe we have been underestimating refractive surgery complications,” Dr Rapuano said.

In Dr Rapuano’s view, the introduction of the femtosecond laser has played a fundamental role in reducing flap-related complications and corneal ectasia.

“The thinner flaps and predictable thickness of flap creation with the femtosecond laser has undoubtedly contributed to the reduction in post-LASIK ectasia. I started using the femtosecond laser in 2006 and I have had absolutely no ectasia cases since making the switch from the mechanical microkeratome. Intraoperative pachymetry has also helped in this regard, even though the benefit is probably as much psychological as practical since we have usually found very little deviation from the intended flap thickness anyway,” Dr Rapuano told *EuroTimes*.

Michael Knorz MD, medical director of the FreeVis LASIK Centre in Mannheim, Germany, also highlighted the improvement in excimer laser technology with much better ablation algorithms now available compared to first-generation laser devices.

"Modern lasers now more or less all use either aspheric ablations or wavefront-guided ablations. Surgeons also increasingly understand that optical zones should not be small in order to save tissue, but sufficiently large to provide better quality of vision. This has definitely improved the optical quality of the outcomes,” he said.

Prof Knorz also emphasised the hard lesson that has been learnt over the years
in trying to push the limits of excimer laser ablation for high myopes or hyperopes.

"In terms of patient selection, we have learned a lot about the poor optics created by the correction of higher refractive errors and subsequently have stopped treating these patients with LASIK," he said.

Allon Barsam MA, FRCOphth, a cornea and refractive surgeon at the L&D University Hospital and the Western Eye Hospital in London, UK, agrees that better patient selection has made a critical difference in reducing LASIK-induced complications such as corneal ectasia.

"We now have much better imaging technology for improved detection of ectasia and forme fruste keratoconus, and are much more proficient at interpreting the topographical data that we obtain and screening out suspect cases," he said.

Characterising patient factors such as young age, residual stromal bed, corneal thickness and so forth have also improved outcomes and helped to reduce the risk of postoperative complications, he added.

Epithelial ingrowth

Epithelial ingrowth is yet another complication that may still occur with femtosecond use, added Dr Agarwal, although its incidence is less than with mechanical microkeratomes.

"The best solution for this is to lift the flap, clean it and apply fibrin glue at the edge of the flap which will prevent any further ingrowth occurring. Another effective option is to perform YAG laser as suggested by Jorge Alio. This low-energy procedure uses the YAG laser to spare patients more invasive surgery and avoid the risks of further complications from a flap lift," he said.

Dry eye still an issue

The perennial issue of dry eye syndrome is another complication that has the potential to cause problems after LASIK, irrespective of whether the flap has been created by blade or laser, said Howard M Neff MD, director of refractive surgery, Henry Ford Health System, Michigan, US.

"I think dry eye remains one of the major complications of LASIK. For many patients, the problem usually resolves with treatment a few months after LASIK, but I have certainly seen a small percentage of people where the dry eye persists and they are still complaining years down the road," he said.

To head off potential problems with dry eye, Dr Neff said he pays close attention to the tear film and ocular surface in preoperative assessment and prescribes topical administration of cyclosporine (Restasis, Allergan Inc.) for four to six weeks before surgery if signs of dry eye are present.

The perverseness of the dry eye issue was also borne out by the Wills Eye Institute study, with ocular dryness (19 per cent) reported as the second most frequent complaint of patients unhappy with refractive surgery. The study authors noted that patients with persistent dry eyes after LASIK were among the unhappiest of all patients.

Despite ongoing problems with dry eye, the situation has probably improved somewhat since 2008, believes Dr Rapuano. "I think surgeons are much more aware these days that dry eye syndrome is an issue and we are screening out patients better. We are also doing a better job telling patients before surgery about the possibility of dry eye. Additionally, I think we are being more aggressive both pre-op and post-op in treating these patients with cyclosporine, plugs and so forth," he said.

While surface ablation procedures have been touted as less likely to induce dry eye than LASIK, Dr Carones said that he has not noticed any significant difference between PRK and LASIK.

"I think the dry eye problem is more related to the excimer laser than the flap. This issue has taken on such a proportion because of the high volume of LASIK especially in the United States and Europe, so everybody attributed the responsibility of the dry eye to LASIK. But if we look at those countries where PRK has been performed on a routine basis as a primary procedure in a lot of public hospitals we know that dry eye may occur as well," he said.

Quality of vision

Another commonly reported complaint after LASIK, particularly for those patients treated with early versions of the excimer laser, related to quality of vision issues such as night vision difficulties, glare and haloes. This was reflected in a 2005 study (J Cataract Refract Surg. 2005 Oct;31(10):1943-51.) conducted at the Academic Hospital Maastricht in The Netherlands, for instance, which found that night vision was considered worse or much worse than before surgery by 33.8 per cent of patients.

Seven years on from that study, Rudy Nuijts MD, PhD, who was one of the co-authors of the research, believes that the figure would be significantly reduced today thanks to improved technology.

"Those were the days when we had big issues in terms of tissue consumption on some of the old lasers and where we could not go out far in terms of optical zone size. That meant that while providing a
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Howard M Neff MD

I think some of these problems with haloes and glare are down to the fact that some surgeons push the limits. I still believe that you have to respect the mesopic pupil size.

Rudy Nuijts MD, PhD

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Amar Agarwal MS, FRCS, FRCOphth

Cover Story
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With the increasing trend towards ever-more sophisticated technology, some surgeons have warned of the danger of refractive surgery shifting towards a primarily ‘technical’ procedure in which surgical skills play second fiddle to machine-driven automation.

Dr Agarwal, however, believes that this will ultimately mean faster, safer lasers, with more diagnostic bells and whistles, and greater interoperability between devices.

“Every laser system has its unique selling point and the companies all sell their lasers based on that particular capability,” noted Dr Barsam, who said he would ideally like to see a single system that incorporates all of the best features of the various models currently available.

Dr Neff said that better iris registration capability would be appreciated on his own laser system.

“The current iris registration is great when it works but there are a small percentage of patients in the range of around five per cent where we cannot get a good registration. It would be nice if it were a little more reliable than that,” he said.

For Dr Agarwal, the number one priority would be to improve the reliability of aberrometry technology.

“What I would really like is to have a better aberrometry machine which can diagnose any small aberration that could then be corrected and treatable on the excimer laser. If these aberrometers are seamlessly linked to the excimer laser, it will allow us to better fine-tune the quality of vision,” he said.

Dr Carones said that he would also like to see a single platform capable of performing all the necessary steps in refractive surgery procedures, as well as greater interoperability between all the various technologies that make up the average refractive surgery practice.

In terms of future developments, Prof Knorz said that the good news is that the pace of innovation shows no sign of slackening in the coming years.

“I expect to see new lasers designed to create corneal flaps such as the nanosecond laser being developed by Schwind which offers a new approach that could prove exciting. We will also see the further development of multi-purpose platforms such as the Bausch + Lomb/Technolas VICTUS and the Alcon LenSx system which are able to perform flaps, AK-cuts and cataract surgery,” he said.

Improved eye tracking and iris registration would also be a welcome boon to refractive surgeons, said Prof Knorz.

“We really need to address tilt and rotation of the eye, and we have to make sure that the treatment is delivered exactly at the right place,” he said.

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Dr Agarwal, however, believes that surgeons should embrace rather than resist the possibilities of technology and not be afraid to move with changing trends.

“I think the future will still see surgical skills at the heart of our refractive and cataract practices, despite all the trends towards automation. While you might have the best machine in the world, it will make no difference if the surgeon who is operating it does not know what he or she is doing. They need to be able to use their experience, to analyse the condition, the individual needs of the patient and weigh so many factors to decide on the optimal treatment. The machine helps of course, but if I have to make a choice, I will choose a doctor ahead of a machine every time,” he concluded.

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