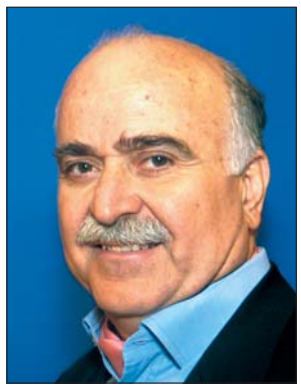
By Roibeard O'hEineachain

Refractive surgery - a ten year learning curve

Much has changed in the field of refractive surgery in the relatively short span of the last decade. For this anniversary issue, *EuroTimes* assistant editor Roibeard O' hEineachain spoke with three of the world's leading refractive surgeons about where refractive surgery has been and where it is going.

A decade ago, radial keratotomy was fading in popularity, following the publication of the PERK study by George Waring MD. PRK had only recently been approved in the US and LASIK was being heralded as the procedure of the future. Meanwhile phakic IOLs were becoming more attractive as a treatment for high refractive errors and laser thermal keratoplasty was showing promise as a treatment for hyperopia.

Ten years on, LASIK appears to have lived up to its promise, although not for the high refractive errors that had originally been proposed. At the same time, surface ablations have experienced a renaissance. In addition, the indications for phakic IOLs are beginning to overlap those of corneal refractive procedures, while laser thermal keratoplasty has now been abandoned in favour of conductive keratoplasty.



Ioannis Pallikaris

Thomas Kohnen

Jack Holladay

Learning from experience

The two main factors that have influenced the changing face of refractive surgery have been knowledge gained from experience and improvements in technology that have implemented that knowledge, said Ioannis Pallikaris MD, LASIK's inventor and current ESCRS president.

In the case of LASIK, patient outcomes showed that visual outcomes became more unpredictable and unstable as refractive error increased. For that reason, the procedure is seldom recommended for myopia over –8.0 D to -10.0D, as compared with up to –23.0 D that some had suggested.

At the same time there have been many developments in laser technology and improved laser algorithms and eyetracking system and topography and wavefront guidance systems which have greatly improved the predictability of the procedure within that range of refractive error, Dr Pallikaris said

"These technologies have helped us a lot in overcoming the problems we had in the beginning such as the small optical zones, problems with peripheral vision stability and large regression. As concerns excimer lasers we are very close to the optimum situation," he told EuroTimes.

In addition, there have been great improvements in the safety and accuracy of microkeratomes, Dr Pallikaris noted. When LASIK was first introduced, flap creation was regarded as the most hazardous aspect of the procedure. Nowadays surgeons can choose from a range of microkeratomes that provide very predictable flap thicknesses, including the new femtosecond laser keratomes.

"The creation of the flap with a laser is very good but the mechanical microkeratomes have also improved to a high level of accuracy. The two technologies are both very close, providing excellent levels of safety, good quality flaps and accuracy in flap thickness to around 15-10 microns."

A more homogenous beam

Ten years ago the only excimer lasers available for corneal photoablative procedures were broad beam lasers. Laser technology has since split in different directions and now the surgeon can choose between broad beam, scanning slit and flying spot lasers. However, all of the laser technologies seem to be converging on the same level of accuracy and efficiency, said Jack Holladay MD.

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Speaking to *EuroTimes*, Dr Holladay noted that among the most important improvements in all of the types of excimer laser technology has been the creation of a more homogenous beam.

"The laser energy of the excimer laser is very difficult to homogenise. It's like a fire hydrant; you take off the top and its just spraying out. If you put a sheet of glass in front, what you'd find is there is a large volume of energy at any given point on the surface of that glass and its quite variable how much energy is hitting each spot because its not what you'd call lamellar flow, its pretty erratic. Excimer lasers are exactly the same way,"

Current broad beam lasers now have apertures that fly in front of the beam that even out the beam to make it more homogenous. In flying spot laser and slit lasers, the smaller spots even out the variability in the amounts of energy put down throughout the course of a procedure.

"Broad beam, slit-beam and spot have all reached a level now where they have a nice homogenous treatment and the uniformity of the broad beam, slit beam and spot are all fairly equal today. Otherwise the technology of the broad beam lasers would have become obsolete. The three have all solved the problem of a homogenous beam"

Radial compensation function

Another important development in laser technology for corneal refractive procedures over the last few years has been the implementation of a radial compensation function by virtually all laser manufacturers, Dr Holladay noted. Initially the lasers did not apply enough energy onto the periphery because they were calibrated on flat surfaces. Therefore, as the beams progressed out from the centre it would hit the cornea increasingly obliquely, he explained.

"The effect of that is substantial and it's the reason why we were originally making oblate corneas and inducing spherical aberration. Nowadays, a radial compensation function has been implemented into every single laser. There are variations among the companies in terms of how good they are and no-one today has a radial compensation function that is 100% effective."

Dr Holladay noted that while wavefront and topography-guided systems appear to induce the least amount of spherical aberrations, standard LASIK with lasers with highly accurate radial compensation functions do nearly as well in that respect. Moreover, most of the wavefront and topography-guided treatments still induce spherical aberration as the amount of correction increases, if the radial compensation functions are not sufficient.

"That means that they need the radial compensation function to be improved. If you reduce spherical aberration then it's a combination of the improved ablation profiles and the radial compensation function that allows you to deliver what you wanted."

Wavefront and topography

The new wavefront and topography guided systems that have evolved in recent years have not only helped design better ablation profiles for individual patients but have also provided a more objective means of measuring outcome, resulting in improved algorithms for future treatments, Professor Thomas Kohnen MD, told *EuroTimes*.

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"The laser companies had the advantage of basically titrating their algorithms from experience, not only from mathematics, and the same is true for wavefront-guided ablation this has made the procedures much more predictable."

Among the factors influencing the creation of new algorithms has been the need to compensate for the effects of corneal healing and corneal mechanics. Up to now this compensation has derived largely from trial and error. However, the future may see a more predictive approach based on the improved understanding that has evolved in recent years with regard to corneal healing and corneal mechanics.

"As we learn more about it we will include it more and more in the algorithms because we can more predictably say, for example, that a thin cornea will have this response and a thick cornea will have that," Dr Kohnen said.

Surface ablations

Despite the ascendancy of LASIK as refractive surgery of choice for myopia up to –8.0 D, surface ablations have not gone away. Conventional PRK is still practised at many centres and new variations of the technique have emerged as possible contenders for LASIK's supremacy.

Many of the new techniques, such as LASEK and epi-LASIK attempt to minimise the pain and the potential for haze of conventional PRK by first removing epithelium with alcohol or newly developed epithelial microkeratomes and then replacing it after the photoablation.

Proponents of the new techniques point out that the creation of a LASIK flap irreversibly reduces the optical quality of the corneal surface. As surface ablations do not involve the creation of a flap, the surface tension and therefore the optical quality of the cornea is better maintained.

"The main reason why there has been a resurgence of surface ablation is the need for the best possible optical outcome at the end of the day," said Dr Pallikaris, who is now pioneering his new technique of epi-LASIK.

His technique involves the mechanical separation of the epithelium from the stroma, he explained, adding:

"Epi-LASIK seems to be more natural because you cover the cornea with something which is vital and healthy and I think the concept is probably the future. However we need to understand better corneal healing and what is happening with the epithelium in the first couple of hours. We are working in that direction and many companies are developing epi-LASIK systems."

The new surface ablation techniques may raise the amount of refractive error that can be corrected with photoablative procedures, Dr Pallikaris added.

"I think with epi-LASIK you can go to higher corrections. In some corneas you are limited with LASIK by the thickness of the cornea whereas you could still make a surface ablation for another 2-3 dioptres without having any problem," he said.

Haze and regression

One of the downsides of surface ablation procedures is that they destroy Bowman's membrane, Dr Holladay noted. Removal of the membrane leaves the cornea more vulnerable to infection. It also allows intercommunication between the healing epithelial tissues and the keratocytes, which can in turn give rise to haze.

Furthermore, surface ablations are more prone to regression and it can take over a year before a patient's refraction stabilises after such procedures, he said

"Surface ablations will become more popular but they will never replace LASIK because LASIK is faster and people want quick results. And though we may end up getting better results in one or two years with PRK than with LASIK, rapid recovery and no pain is more attractive to patients than pain for a few days and longer recovery," Dr Holladay added.

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Dr Holladay speculated that the future may see the marrying of surface ablations and LASIK through the creation of ultra-thin flaps with femtosecond lasers.

"In the future, I believe we will be making LASIK flaps, just below Bowman's membrane with femtosecond technology and a concave applanator that "fits" the cornea and does not require making the cornea flat," he said.

Phakic IOLs

Dr Holladay concurred with Dr Pallikaris' view that photoablative procedures will probably be able to correct higher refractive errors in the future. However, he pointed out that the refractive error for which phakic IOLs are indicated will also come down.

"As we move forward we'll be able to do larger corrections without shrinking the optical zone or inducing spherical aberrations. The only limitation will be the thickness of the cornea. But while the laser treatments will be able to treat higher amounts of refractive errors, phakic IOLs on the other hand will try to push that limit down because no matter what we do with excimer laser surgery it can never be as good as the surface of a phakic IOL."

Dr Kohnen noted that there is already some overlap in his practice in the indications for corneal and lenticular procedures.

"From -6.0 to –7.0 D I ask them what they would prefer I tell them they can choose between a subtractive procedure like LASIK, which removes something from the eye or an additive procedure like a phakic IOL which adds something to the eye. Some prefer one and some the other."

Better treatments needed for hyperopia

While the number of procedures for myopia has increased, treatments for hyperopia have lagged behind, Dr Kohnen noted. Photoablative procedures are only useful for lower amounts of hyperopia and hyperopic eyes are often unsuitable for phakic IOLs.

"I think that for hyperopia we really have no good options. I would only go 3.5 D with LASIK and out of 450 phakic IOLs I have implanted I had only 20 hyperopes. Meanwhile, thermal keratoplasty procedures have two downsides, one is predictability and the other is they depend on regression and these two things aren't what patients want."

"One thing on the horizon would be better intracorneal implants. But we would need a long follow-up. What we found with some of the older inlays was that after twelve to eighteen months they became opaque in the cornea."

Refractive lens exchange

The situation changes for hyperopes when they become presbyopic, Dr Kohnen said. Presbyopic hyperopes are often ideal candidates for refractive lens exchange with one of the newer models of multifocal IOLs, he added.

"I now use the Restor implants in my cataract patients with low astigmatism and in my presbyopic hyperopes and high myopes when I do refractive lens exchange. Work still needs to be done to see if it works as well in high myopes as presbyopes. So far, from what I see, patients are very happy."

The accommodative IOLs, however, have not quite lived up to their name, Dr Kohnen said.

"The accommodating IOLs I have used so far are not as good as normal IOLs, they have much more PCO and capsular shrinkage and once the capsular bag is fibrosed the whole effect is gone. I would rather have a proven monofocal in the bag because I want longterm outcome, in 10 years time patients will still need good vision."

He added that there is much basic science yet to be done before an effective presbyopic treatment will become available.

"The whole accommodative process in the human is not 100% understood. We don't know how long it persists, or how the action of the ciliary muscle compares between a 20-year-old and a 70-year-old. If we have solved the problem of accommodation we will be able to think about earlier lens removal and perhaps some type of re-filling of the capsular bag. All of this will change the whole business of refractive surgery."

Dr Holladay was more upbeat about the prosepects for presbyopic treatments, citing recent research into dual-optic accommodating IOLs and presbyopic corneal implants.

"I think in the next five years we will move past the juvenile stage where we are right now. It will mature to the point where we don't have sacrifices as with multifocal lenses, aspheric surfaces and CK. All of those things end up with some negative effect and trade-offs but within the next five years there won't be trade-offs; it will be presbyopic treatment and good optical results without loss of contrast acuity or anything else so it's an exciting time," he said.

Optics and visual function

One basic question that remains unresolved for all types of refractive surgery is the ideal optical outcome that surgeons should try to achieve in their patients, said Dr Pallikaris

"We are probably very close to the goal of optical perfection with super aspheric corneas without aberrations but I'm not sure this is ideal from the functional point of view. Nature has provided us with a multifocal system. My philosophy is that we need it that way. The functionality of the system is based on psychophysics, how the brain evaluates the information. The brain can select and interpret from the multiple projections on the retina to provide a wider depth of focus," he added.

Dr Kohnen maintained that the visual optics a patient should have after refractive surgery would ultimately be what will make a patient happy.

"We are still trying to find out what makes people happier. We look at people who are emmetropic and have less prolate and more prolate shapes and they are both happy. We can theorise that the ideal aspheric profile should bring us to an asphericity of -0.25 on the cornea. Is it really true? I don't know. We still need to get more information on that and more study on outcomes so we can really find out what the patient wants."

Primum non nocere

Dr Kohnen stressed that the biggest challenge for refractive surgery in the years to come will be to improve safety and efficiency to the point where patients can be guaranteed that they will not lose vision as a result of such procedures.

"What we all have to achieve, day by day, patient by patient, a hundred patient per hundred, a thousand per thousand, there should be no exception, is to make the patient as good as he was with contact lenses or glasses. If we can guarantee this 100% of the time then refractive surgery is the procedure worldwide. Because if people are fearful of losing vision they will still have to think about it. But if people can be sure they will see as good as they currently can with glasses, then they will have refractive surgery."