



LASIK: Why Doing Better is Important



Dr. Rick Wolfe

LASIK has arguably become the safest and most effective surgery of all time, but it wasn't always that way. It came about because of a confluence of technologies and needs. José Barraquer developed the lamellar refractive surgery in the 60s in Columbia. His procedure – myopic keratomileusis (MKM) – involved the freezing, lathing and replacement of a corneal cap, which was much like the flap in modern LASIK, except there was no hinge.

In 1983, Dr. Trokel showed the excimer laser could be used to reshape the cornea. PRK worked well, but slow recovery and postoperative pain were serious problems.

Professor Ioannis Pallikaris first performed excimer laser under a corneal flap in 1991 at Crete University. This was pivotal for refractive corneal surgery. Visual recovery mostly occurred quickly with no pain. Without this development laser vision correction would not have taken off to the same extent. Professor Pallikaris coined the term laser in-situ keratomileusis and its acronym LASIK. The irony is that Crete has one of the world's highest incidences of keratoconus, the natural enemy of the LASIK procedure.

Since then nearly 45 million LASIK procedures have been performed (Source: Market Scope, LLC St Louis MO USA) but this represents only the tiniest proportion of the world's ametropes.

Efficacy was very high in the early days of LASIK and PRK and safety was also very high. In one of the biggest published studies Hammond reported on 32,068 eyes treated in the US Army Warfighter Refractive Eye Surgery Program.¹ While three cases of bacterial keratitis were reported (0.009 per cent), loss of more than a line of BCVA was seen in only 0.06 per cent with no case worse than 6/12. Not a single member had their visual status downgraded.

PROBLEMS WITH LASIK

LASIK enjoyed enormous popularity over the years after its development, but it eventually became evident there were problems. Seiler, in 1998, reported three highly myopic post LASIK eyes developing central steepening, which she correctly interpreted as corneal ectasia.²

It became evident that many LASIK and PRK patients, even those who had low myopic ablations, had significantly reduced night vision with halos. In Germany, where a night vision simulation is used in drivers' licence testing, some who had had PRK were denied the right to drive at night.

Quality of vision, particularly night vision, is critical in military environments. Capt. (retired) Steven Schallhorn developed the United States Navy (USN) refractive surgery program. I had the privilege of working with him at USN Medical Center San Diego as part of a RAN Reserve exchange some years ago.

Other forces followed the USN lead in developing their own programs because of remarkable efficiency gains following surgery. A half a million procedures have now been performed in forces centres all over the USA. The USN has been responsible for excellent studies in visual quality after laser refractive surgery, which have shaped our thinking.

Dr. Schallhorn put 105 USN personnel, who had had myopic PRK, many for low corrections, through the Ginzberg Night Driving Simulator in Los Angeles. He found 40 per cent were "significantly worse" than before surgery and staggeringly, every single one was "worse" in the simulator than the preoperative visit! (Schallhorn SC Presentation 2004 ESCRS Munich Germany)

Other studies of conventional ablation found worse night vision in 33 per cent³ and 60 per cent⁴ of cases. Contrast sensitivity was found to be worse than spectacle wear⁵ and others showed a permanent reduction of contrast in low light.⁶⁻¹²

The problem related to the increase in spherical aberration (SA) and other higher order aberrations (HOA) induced by the ablation. HOA are associated with poor night vision with glare and halos¹³ and were increased in proportion to the attempted correction.¹⁴⁻¹⁹ SA was increased by a factor of up to 36.6²⁰ and, in one study where the measurement was for a 7mm pupil, the factor SA increase was three hundred fold.²¹ HOA magnitude is proportional to the radius

It was not so long ago that we performed conventional laser treatments that sadly produced good visual acuity, but were diminished by a visual result that was often poorer in other ways. LASIK should aim to improve vision in every measurable and subjective way.

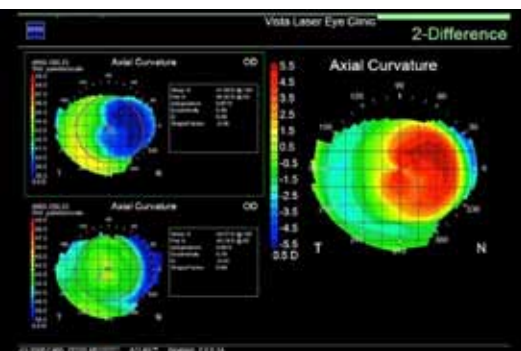


Figure 1. Top left shows right eye topography following a grossly decentered PRK for high myopia (original refraction unknown). BCVA was 6/15. Bottom left is final result with 6/7.5 BCVA. Right is the difference map showing both steepening of the flat area and flattening of the steep area achieved under TG control.



Figure 2. The WaveLight EX500 excimer laser.

of the aperture so with a poor ablation, vision can rapidly deteriorate as the pupil dilates.

The realisation that LASIK was far from perfect, despite excellent uncorrected visual acuity (UCVA) and near instant visual recovery, was of concern to many, not least of all consumers. Many clinicians were looking for ways to do better, while others were in denial. LASIK could have had a bleak future without a vast improvement.

THE SOLUTION

The error of conventional ablation profiles should have been blindingly obvious, but it took some years to understand. The more peripheral the excimer laser ablation, the greater the angle of incidence of the beam. The energy density of the incident beam in the periphery of the optic zone was therefore lower, being spread over a greater area. Some of the energy was reflected. It was called the 'cosine rule' and algorithms were adjusted to put more energy in the periphery to compensate.

The quality of vision after surgery has little to do with the how the flap is made or other surgical factors. It is all about the details of the ablation strategy. I will concentrate on the details of LASIK ablation.

WAVEFRONT-GUIDED TREATMENTS

A solution came with the development of wavefront-guided (WFG) and wavefront optimised (WFO) treatments.

A WFG treatment is based on whole eye aberrometry and is a true customised treatment. The aim is to treat SA, coma, trefoil and other HOA detected on

aberrometry to reduce them or to reduce induction. A WFO treatment only seeks to induce as little SA as possible and is not a customised treatment.

Most surgical platforms developed WFG capability. Early outcomes were mixed but all induced less HOA and SA than conventional treatment. Some had poorer results in managing SA.²² The Wavelight platform, in one of the early studies,²³ demonstrated most encouraging results with only an increase on HOA by a statistically insignificant factor of 1.4 and only a doubling of SA.

This was a turning point for LASIK, when vision was routinely improved rather than routinely diminished in some way.

Schallhorn had done much work on WFG LASIK and PRK in the USN. He authored an official American Academy of Ophthalmology meta-analysis of WFG treatments in 2008.²³ He found of WFG over conventional, less induced HOA, and with the Wavelight platform a reduction HOA in those eyes with preop HOA over 0.3 μ . He also found less halo and glare, better contrast sensitivity and similar or better refractive accuracy and UCVA with WFG treatments.

There are several difficulties with WFG treatments. They require an expensive aberrometer with which treatment is determined. Often an adequate acquisition is not possible and the whole process takes considerable staff time. Many surgeons don't bother for these reasons, claiming WFO treatments are quite adequate. WFO ablation patterns were developed to address these problems. They don't consider pre-existing HOA but aim to compensate for the induced SA of conventional treatments.

WFO treatments are certainly better than conventional treatments. Eight studies,²⁴⁻³¹ though show WFG superior to WFO and in three no difference was demonstrable.³²⁻³⁴ WFO is simpler and cheaper to perform but possibly inferior to WFG.

Q ADJUSTED TREATMENTS

A probable improvement on WFO, and our choice when a customised modality is not possible for technical reasons, is a Q adjusted treatment.³⁵ These are like WFO treatments in that there is peripheral compensation to reduce SA induction of conventional treatment, but the amount of compensation can be varied. This facility is available on the Wavelight platform. A corneal Q value, often, but not always the Q of the cornea to be treated, is targeted and entered into the treatment. While selection of too negative a Q increases ablation depth significantly; SA can be eliminated in ablations of -1.00 D to -10.00 D.³⁶

TOPOGRAPHIC-GUIDED TREATMENTS

Topographic-guided (TG) treatments are a further strategy to produce optimum corneal shape. Instead of using

aberrometry as in WFG, the corneal topography is used to calculate the ablation pattern. I think TG provides all the advantages of WFG customisation without some of the difficulties.

TG treatments were mainly used for treatment of very irregular corneas. Early reports^{36,37} detailed successful corneal regularisation and improved vision following corneal trauma, keratoplasty, central islands and other laser ablation problems, such as decentered zones and small optic zones. Since then other applications of TG such as keratoconus treatment have been used in association with corneal collagen cross-linking.³⁸

As an example of TG ablation, a grossly decentered PRK ablation is depicted in Fig. 1. Following TG ablation the patient achieved 6/7.5 in this eye. The difference map on the right shows simultaneous flattening of the steeper area and steepening of the flatter area. The performance of the TG software on the Wavelight platform can produce amazing results.

ALCON WAVELIGHT TG LASIK - CONTOURA

TG LASIK for untreated ametropic eyes is not new and several reports of satisfactory outcomes exist.³⁹⁻⁴⁷

We have been using this modality in conjunction with the newer EX500 excimer laser in virgin eyes undergoing refractive surgery. We feel it has all the advantages of WFG over WFO, in that the treatment is truly customised. An additional advantage is that it is combined with the Q adjustment facility.

As a requirement for FDA registration of the Alcon Wavelight platform for performing TG treatments on irregular corneas, results of surgery on normal ametropic eyes had to be presented first. An important study resulted and was reported in the 2016 FDA pre-market approval document⁴⁸ and part of which is reported by Stulting.⁴⁹ The results were so good, perhaps even unexpectedly good, that Alcon dubbed the procedure 'Contoura'.

CONTOURA STUDY RESULTS

The study was a prospective multicentre trial involving 249 myopic eyes with spherical correction up to -9.00 D and cylindrical correction up to 6.00 D.

Topographic acquisition was with the Alcon Wavelight Topolyzer. The data, including the calculated ablation was transferred to the Allegretto excimer laser. The subjective refraction was also input.

Key outcomes of the study were:

- Forty per cent of cases gained lines of before corrected visual acuity (BCVA)
- Mean contrast sensitivity values at every spatial frequency for mesopic, photopic,

with and without glare, were greater post than best-corrected contrast sensitivity before surgery

- Three times as many gained contrast sensitivity as those who lost for photopic and mesopic illumination
- On wavefront aberrometry at pupil size 5mm, SA was unchanged pre- to post-op
- On corneal wavefront analysis total HOA increased median value by only 2.5 per cent
- On the questionnaire light sensitivity, night driving difficulty, reading difficulty and glare were less than before surgery
- Halo, starburst, dryness and foreign body sensation were unchanged by surgery.

These are exceptional outcomes, however it is only possible to prove Contoura is superior with comparative studies. I suspect other platforms will now investigate this modality given the success. It is important that LASIK provides as many patients as possible with better UCVA than BCVA before surgery, as satisfaction doubles for every line of vision improved.

WHY ARE THE RESULTS SO?

The reasons for the excellent results are probably several:

- WFG seeks to treat the aberrations in the crystalline lens and the cornea on the cornea. The lenticular aberrations change with time and accommodation. TG only uses corneal aberrations to determine the shape of the cornea
- The zone of acquisition on the cornea in TG is generally greater than for WFG and is more reliably acquired
- Perfect registration of the corneal topographic data with the eye at the time of surgery avoids the registration errors inherent in WFG treatments. Imperfect registration will affect the outcome
- TG treatment is centred on the corneal apex, as is the topographic acquisition. This is the closest point to the corneal intercept of the visual axis of the schematic eye. This might confer optical advantage.

ALTERNATIVE CORNEAL TREATMENT TO LASIK-PRK

PRK was the original treatment modality and all ablation alternatives described for LASIK are available for PRK, but there are very few reasons to perform PRK today. Sure, it is as efficacious in myopic treatments and as safe, in terms of loss of BCVA as LASIK, but recovery is slow and painful in the first few days. A recent Cochrane Review⁵⁰ comparing LASIK and PRK confirmed these beliefs.

The oft-claimed benefits of PRK over LASIK, of less dry eye induction and a lower risk of

ectasia, are unsupported by the literature. Bacterial keratitis, probably the most serious complication of either procedure, in a recent study⁵¹ was found to be up to eight times more likely in PRK than in LASIK. A study by the ASCRS Cornea Clinical Committee of post refractive surgery infectious keratitis (Donnenfeld E Presentation ASCRS 2008 Chicago IL USA) found the incidence following PRK was six times that following femtosecond LASIK. Because the potential complication is so serious, my view is PRK is reasonable only but when LASIK or SMILE are not indicated.

ALTERNATIVE CORNEAL TREATMENT-SMILE

SMILE or small incision lenticule extraction is a novel and most interesting procedure. A femtosecond laser is used to create a lenticule that is extracted through a small corneal incision. What is certain is that the small incision makes a complication like LASIK flap dislocation impossible.

The purported advantages are that more superficial and stronger, arching corneal collagen fibres are undisturbed, compared with LASIK, resulting in better biomechanics of the cornea and possibly preventing ectasia.

Because fewer nerve fibres are cut than in LASIK, corneal sensitivity might be less reduced and post-operative dry eye less of a problem.

The visual results are generally good and comparable with LASIK. Biomechanical studies of SMILE and LASIK pre- and postoperatively show mixed results.

One problem is that after only a few years of SMILE there are now nine eyes reported as developing corneal ectasia.⁵²⁻⁵⁶ None was highly myopic, as were all Seiler's three cases¹ when he first described ectasia

seven years after the introduction of LASIK, but many, but of concern not all, of these SMILE cases showed abnormal topographic features before surgery. The dream of SMILE eliminating, or markedly reducing, this most serious complication by the possibly superior biomechanics is diminished.

It is fairly clear SMILE has an advantage over LASIK with postoperative dry eye. The fact is, we are very good at diagnosing and treating ocular surface disease pre LASIK and dry eye is not the problem it was.

SMILE, like LASIK, induces only low levels of HOA, and because there is no laser ablation, SA induction is particularly low or absent in SMILE. It has not the option of customised ablation profiles of LASIK like WFG and TG. It has not the option of customised ablation profiles of LASIK like WFG and TG. The excimer laser has sub-micron accuracy to create customised ablations. In a recent prospective study of 664 eyes⁵⁷ having either femtosecond LASIK, WFG LASIK or femtosecond lenticule extraction (FLEX- a related procedure to SMILE, but with a larger corneal incision like LASIK) WFG LASIK induced fewer HOA than SMILE or non-customised LASIK and had better



Figure 3. The WaveLight Topolyzer is a placido topographer that sends data to the excimer laser for topographic-guide treatment.

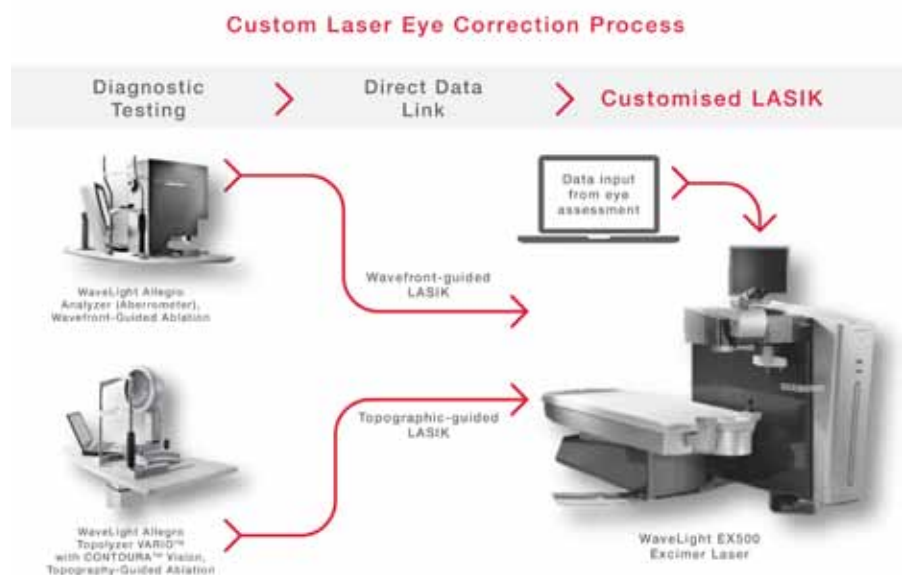


Figure 4. Customised LASIK is either: wavefront-guided, using the WaveLight Aberrometer for source data and the subjective refraction or topographic-guided (Contoura) using the WaveLight Topolyzer and the subjective refraction. Non-customised treatments, such as wavefront-optimised use subjective refraction as the only input.

mesopic contrast sensitivity with and without glare.

In addition there might be optical compromise in SMILE due to wrinkles that are often found in the cap. This makes sense because the cap is larger than the ablated corneal base upon which it sits and is thrown into wrinkles. A LASIK flap does not have this problem. These wrinkles can be seen on OCT (Presentation Dr Rohit Shetty APACRS 2016) and on Bowman's membrane when the epithelium is removed for PRK enhancement of the SMILE procedure. (Personal communication Prof Michel Knorz.) This problem needs to be addressed, if possible.

Another disadvantage of SMILE is the often slow visual recovery, often taking

some time for good UCVA to be achieved. The cause is not clear, but might relate to settling of the cap.

SUMMARY

Conventional LASIK seeks to neither correct aberrations nor compensate for induced SA. It should never be performed.

WFO LASIK corrects for SA induction, but is possibly inferior to WFG and TG because it is not customised.

PRK still has a small role in corneal refractive surgery and whether SMILE represents the future is yet to be established.

All modalities of treatment get good results, but our patients deserve the very best and we should aim to have no element of their vision compromised by

our treatment. WFG, or probably better TG treatments are preferred to the non-customised treatments like WFO. [mi](#)

Dr. Rick Wolfe MB BS FRACS FRANZCO is one of Australia's most experienced cataract and refractive surgeons. He has performed more than 30,000 cataract, RLE and LASIK procedures during the past 30 years while practising as an ophthalmic surgeon. Dr. Wolfe has provided more than 30 years' service to the Royal Australian Navy Reserve, where he holds the rank of Lieutenant Commander. In 2004 he performed live surgery in front of 2,000 of his colleagues at the American Society of Cataract and Refractive Surgeons (ASCRS) in San Diego.

Dr. Wolfe regularly speaks at local and overseas conferences. His private practice, at Peninsula Eye Centre, Mornington, Victoria and at VISTAeyes Elsternwick Victoria, is limited to cataract and refractive surgery.

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