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Short term LASIK outcomes using the Technolas 217C excimer laser and Hansatome microkeratome in 46 708 eyes treated between 1998 and 2001

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ABSTRACT

Purpose To report the outcomes of a high-volume, multi-surgeon, multicentre LASIK corporation between 1998 and 2001.

Methods 46 708 eyes of 24 138 consecutive patients with myopic astigmatism had undergone LASIK using the Bausch & Lomb Technolas 217C excimer laser and Hansatome microkeratome. The study included 38 surgeons operating at 11 surgical centres. 31 surgeons underwent standardised training regardless of previous experience, which included didactic, observership and proctorship components. Mean attempted spherical equivalent refraction correction was −4.02±1.93 D (range −0.50 to −12.00 D). Mean attempted cylinder correction was 0.78±0.69 D (range 0.00 to 3.50 D). Median follow-up was 3 months.

Results Postoperative data with at least 1 month follow-up was available in 35 360 eyes (76%) of 18 195 patients. Predictability: mean deviation from intended spherical equivalent refraction correction was −0.21±0.47 D with 81% of eyes within ±0.50 D and 95% of eyes within ±1.00 D. Efficacy: uncorrected distance visual acuity was 20/20 in 71% of eyes and 20/40 in 95% of eyes. Safety: two or more lines of corrected distance visual acuity were lost in 0.57% of eyes. Postoperative corrected distance visual acuity was worse than 20/40 in 0.029% of eyes.

Conclusions The short-term results of a high-volume, multi-surgeon LASIK Corporation were comparable with those reported in the Food and Drug Administration clinical trials during the same period.

INTRODUCTION

LASIK is a favoured surgical treatment for the treatment of myopia and myopic astigmatism.[1] Although the safety, predictability and efficacy of LASIK has been well established, studies reporting outcomes of a large sample size (>10 000 eyes) from multiple surgeons are limited in the peer-reviewed literature with just two studies until now[2 3] (although one[2] of these was in a paid supplement). The lack of adequate, accessible data collection and storage systems that allow reliable statistical analysis, cost and logistics all represent barriers to reporting outcomes of large populations.

A corporate environment provides a structure on which to standardise and optimise processes and protocols, and manage quality control and assurance. LASIK Vision Corporation was one of the early rapidly expanding corporate LASIK entities started in Vancouver, Canada, in 1998. An active surveillance system was instituted to monitor outcomes and enable standards to be assessed across multiple clinics and surgeons. Standardised surgical protocols were developed and the majority of surgeons underwent a training scheme to implement these protocols. Due to excessive spending and expansion, LASIK Vision Corporation eventually became insolvent and filed for bankruptcy in April 2001.[4]

Although this study reports outcomes from approximately 10 years ago (ie, before the advent of flying spot excimer lasers, aspheric and custom ablation profiles, and femtosecond lasers for flap creation), the results are still relevant to current practice since the 217 excimer lasers (now Technolas Perfect Vision, St Louis, Missouri, USA) are still widely used for LASIK worldwide, including corporate LASIK providers in the UK (27 clinics, Ultralase, Leeds, UK), Canada (28 clinics, LASIK MD, Montreal, Quebec), and Spain and Europe (60 clinics, Clinica Baviera, Valencia, Spain). While there have been a number of improvements to the 217 excimer laser such as the inclusion of wavefront-guided ablations, the planoscan option remains essentially unchanged from that which was used for the present study.

This report provides an analysis of myopic treatments across all LASIK Vision clinics. This report acts as a historical evaluation of the results achieved in a corporate multicentre refractive surgery practice environment with multiple surgeons trained under the same protocol.

METHODS

This was a retrospective case series of patients undergoing myopic LASIK including 38 surgeons operating at 11 surgical centres. The majority of surgeons (31 out of 38) underwent standardised training regardless of previous experience that included a didactic course, 1 week's observership (approximately 150 cases) and proctorship (supervised for the first 50 cases). There were seven surgeons who declined to participate in the training course as they considered their prior experience to be sufficient. Surgeons were also given direct access to a medical advisory board and attended biannual surgeons' conferences. All in-house optometrists were required to have an optometric degree from either a US or a Canadian university, where optometrists are trained in both diagnostics and therapeutics. All optometrists had also undergone the same didactic and observership training as the surgeons and were considered to be equally well

trained and competent for pre- and postoperative diagnosis and management.

Inclusion criteria comprised patients with myopia between 21 and 66 years of age, spherical equivalent refraction up to −12.00 D, cylinder up to 3.50 D, free of ocular surface disease, with no signs of keratoconus (using a standardised protocol including corneal tomography curvature maps and front and back surface elevation), and no previous ophthalmic surgery. The standardised protocol for preoperative keratoconus screening is described in the online supplementary appendix 1 (download available: http://www.londonvisionclinic.com/downloads/BJO2012Appendix1.pdf).

All patients underwent a baseline ophthalmic examination conducted by an optometrist that included a medical and ocular history, measurement of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, slit-lamp examination, dilated fundus examination, corneal topography, keratometry and pachymetry using Orbscan II (Bausch and Lomb Inc., Rochester, New York, USA) and scotopic pupil diameter measurement using the Colvard pupillometer (Oasis Medical, Glendora, California, USA). The standard protocol for refraction has been previously described.[5] On the day of surgery, the surgeon repeated the refraction which was used for treatment (no nomogram adjustments were made) after referring to the optometrist's manifest and cycloplegic refractions.

A standardised LASIK technique was used at all surgical centres (http://bjo.bmj.com). The Hansatome microkeratome (Bausch & Lomb Inc.) was used to create a superior hinged flap with the 160 head. The Technolas 217C planoscan excimer laser with software V.2.9993 was used. The mean optical zone (transition zone 3 mm) was 5.73±0.36 mm (range 5.0–7.0 mm), selected based on scotopic pupil diameter and corneal pachymetry. Flaps were centred on the corneal vertex as closely as possible by manually positioning the microkeratome ring. Ablations were centred on the corneal vertex by moving the aiming beam.

Postoperatively, all patients were seen by the surgeon the day after surgery. Postoperative examinations were then offered at 1, 3 and 6 months with an optometrist and included the same tests as the preoperative examination. Cycloplegic refraction was not routinely performed postoperatively. Accommodation was avoided during the postoperative refractions by 'pushing plus', as described in the standard protocol for refraction.[5] Data from the last postoperative visit are reported here.

DATA COLLECTION AND ANALYSIS

As part of the company quality control procedure, a custom-built database called PIQASO was developed by two of the authors (DZR, WBT) using FileMaker Pro 5 software (FileMaker Inc., Santa Clara, California, USA). The intention of designing the PIQASO database was to be able to analyse, audit and compare efficacy, predictability and safety for all 38 surgeons, and to develop individual nomograms.

Given the staff and time costs required for data entry in a high-volume environment, a sample size analysis was performed to determine the percentage of patients that should be included to achieve a sufficiently low level of error at the 99% confidence level. A sampling rate of 50% was chosen, which would result in a ±0.4% potential error at the 99% confidence level for a population of 90 000 eyes. This level of error was significantly less than that suggested in the 1997 FDA guidelines for assessment of refractive surgery lasers,[6] which states that a sample size of 300–400 subjects is sufficient to assess safety and efficacy, and that follow-up should be no less than 90%. These requirements translate to a ±2.5% potential error at the 99% confidence level. A systematic sampling method was employed and data from every other patient treated within each clinic was entered into the database.

In addition, due to the large population, the follow-up percentage does not need to be as high as the FDA-suggested level of 90% for the error level to be sufficiently low. For example, in a population of 45 000 eyes, if postoperative data were only available for 50% of eyes, the potential error would only be ±0.6% at the 99% confidence level. This degree of error was considered satisfactory for efficacy and predictability where the results are in the region of 70%; that is, if 70% of eyes in the sample population were 20/20, there would be 99% confidence that the percentage was between 69.6% and 70.4% for the whole population. On the other hand, safety relies on the identification of rare events, and a 0.4% error of a statistic in the range of 0.5% becomes a significant error (ie, 0.1–0.9%). For this reason, a parallel sampling system was employed to address the different magnitude of error for safety; all patients

Table 1 LASIK outcomes of all eyes in the present study compared with FDA-controlled trials between 1999 and 2000 for lasers other than the Technolas 217Ca

	FDA criteria[6]	Present report	FDA 1999[9]	FDA 2000[10]	FDA 2000[11]
Eyes (at 3 months)		35 360	903	153	988
Laser		Technolas 217C	S2	LADARVision	EC-5000
Age		38 (21 to 66) yrs	42 (18 to 84) yrs	43 (21 to 65) yrs	43 (19 to 70) yrs
Preoperative sphere		−3.63±1.91D (−0.25 to −12.00 D)	−5.85±2.80D (−0.25 to −14.50 D)	NR (0.00 to −11.00 D)	NR (0.00 to −14.00 D)
Preoperative cylinder		0.78±0.69 D (0.00 to 3.50 D)	NR (0.00 to 4.75 D)	NR (0.00 to 6.00 D)	NR (0.00 to 4.00 D)
Post-SE		−0.21±0.47D (−3.88 to +4.00 D)	NR	NR	NR
Post-SE within ±0.50 D	50%	81%	NR	76%	56%
Post-SE within ±1.00 D	75%	95%	87%	93%	78%
UDVA 20/20 or better		71%	48%	55%	42%
UDVA 20/40 or better	85%	95%	92%	91%	77%
Loss ≥2 lines CDVA	<5%	0.57%	NR	1.20%	0.80%
Loss >2 lines CDVA		0.11%	0.30%	0%	0.66%
Post CDVA worse than 20/25		0.31%	NR	0.30%	NR
Post CDVA worse than 20/40		0.03%	0.40%	0%	0.13%

Data at the 3-month time point are presented to compare the mean follow-up of the present study.
Technolas 217C (Bausch & Lomb), S2 (VISX), LADARVision (Alcon), EC-5000 (NIDEK).
CDVA, corrected distance visual acuity; FDA, Food and Drug Administration; NR, not reported; SE, manifest spherical equivalent refraction; UDVA, uncorrected distance visual acuity.

Table 2 Summary of outcomes statistics grouped by preoperative spherical equivalent refraction and compared with the 3-month data from the Bausch & Lomb FDA trials with the Technolas 217A

	Moderate myopia, low cylinder		Moderate myopia, high cylinder		High myopia	
	Present report	FDA 2000[7]	Present report	FDA 2000[7]	Present report	FDA 2002[8]
# Eyes	17 454	110	16 005	276	1901	292
Age	38 (21 to 66) yrs	37 (21 to 66) yrs	40 (21 to 66) yrs	38 (21 to 66) yrs	40 (21 to 62) yrs	38 (19 to 61) yrs
Preoperative sphere	−3.41±1.52D (−0.25 to −7.00 D)	−3.86±1.52D (−1.00 to −7.00 D)	−3.33±1.68D (−0.25 to −7.00 D)	−3.59±1.42D (−1.00 to −7.00 D)	−8.19±0.93D (−7.25 to −12.00 D)	−8.65±1.17D (−7.25 to −12.25 D)
Cylinder	0.27±0.21 D (0.00 to 0.50 D)	0.07±0.14 D (0.00 to 0.75 D)	1.33±0.62 D (0.75 to 3.50 D)	1.07±0.66 D (0.25 to 3.50 D)	0.78±0.63 D (0.00 to 3.25 D)	0.92±0.77 D (0.00 to 3.50 D)
Post-SE	−0.19±0.42D (−3.38 to +2.28 D)	NR	−0.20±0.46D (−3.75 to +3.75 D)	NR	−0.47±0.82D (−3.88 to +4.00 D)	NR
Post-SE within ±0.50 D	84%	83%	81%	82%	57%	60%
Post-SE within ±1.00 D	96%	97%	95%	97%	79%	80%
UDVA 20/20 or better	76%	86%	69%	84%	45%	48%
UDVA 20/40 or better	96%	100%	96%	99%	84%	90%
Loss ≥2 lines CDVA	0.41%	1.9%	0.64%	0.7%	1.37%	3.1%
Loss >2 lines CDVA	0.07%	0.0%	0.13%	0.0%	0.32%	0.3%
Post CDVA worse than 20/25	0.19%	0.0%	0.38%	0.0%	0.92%	2.6%
Post CDVA worse than 20/40	0.017%	0.0%	0.026%	0.0%	0.172%	0.3%

CDVA, corrected distance visual acuity; FDA, Food and Drug Administration; NR, not reported; SE, manifest spherical equivalent refraction; UDVA, uncorrected distance visual acuity.

who lost two or more lines of CDVA who were not previously included were additionally entered for statistical analyses. Therefore, the database included all eyes in which two or more lines of CDVA were lost, but the denominator for calculating the percentage was left as that of the 50% sample, meaning that the safety results reported here represent a worst case scenario.

However, there is also the potential for the results to be influenced by bias; it could be argued that patients who had a bad result might seek a second opinion rather than return for follow-up. On the other hand, it can be argued that patients who had a good result do not return for follow-up because they are happy with the result. To assess the potential impact of a systematic bias, the key statistics (% 20/20, % lost two lines CDVA, within ±0.50D) were recalculated assuming a best and worst case scenario for the results in those eyes lost to follow-up.

Internet connectivity enabled data to be entered simultaneously into the PIQASO database on location at each clinic by local office staff and checked for consistency by a database manager. The database manager checked data daily, and ran a self-check programme with a number of validity flags to ensure the accuracy of data entry (eg, refraction against UDVA).

Pooled analysis of the entire cohort was performed. Additionally, refractive outcome analyses were stratified into the groupings used in the Food and Drug Administration (FDA) clinical trials for the Technolas 217a excimer laser.[7 8] The Waring standard graphs were used for analysis. The attempted versus achieved scatter plot was slightly modified by using different colours to give greater weight to points where multiple eyes had identical data, otherwise, single outliers would carry the same weight visually as the common values. Efficacy results were restricted to only include patients where the target refraction was emmetropia and the preoperative CDVA was 20/20 or better. Stability could not be evaluated due to the relatively short follow-up. Finally, the key statistics for efficacy (% 20/20), predictability (% within ±0.50 D) and safety (loss of ≥2 lines CDVA) were calculated for each surgeon individually and summarised as box plots with surgeons grouped into those who had undergone the training course

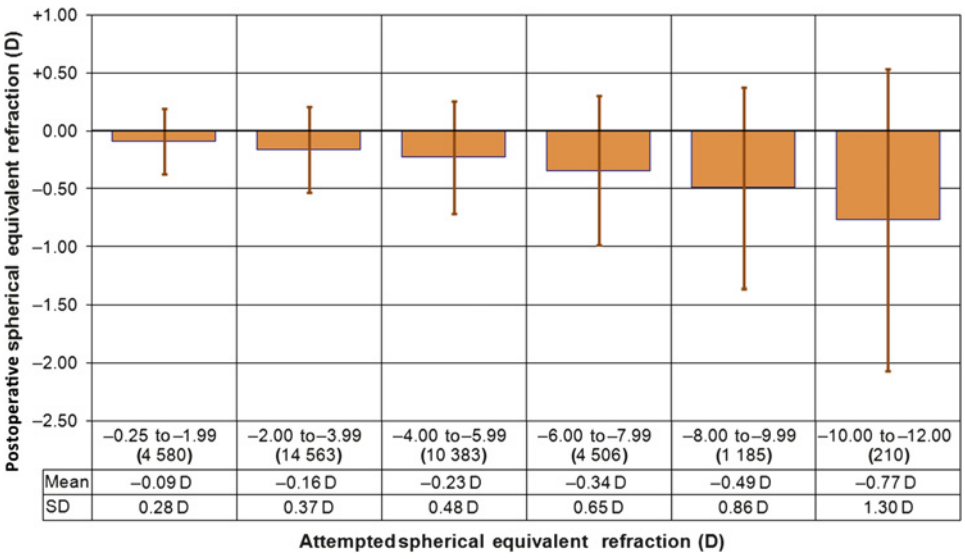


Figure 1 Mean and SD of postoperative spherical equivalent refraction grouped by attempted spherical equivalent refraction.

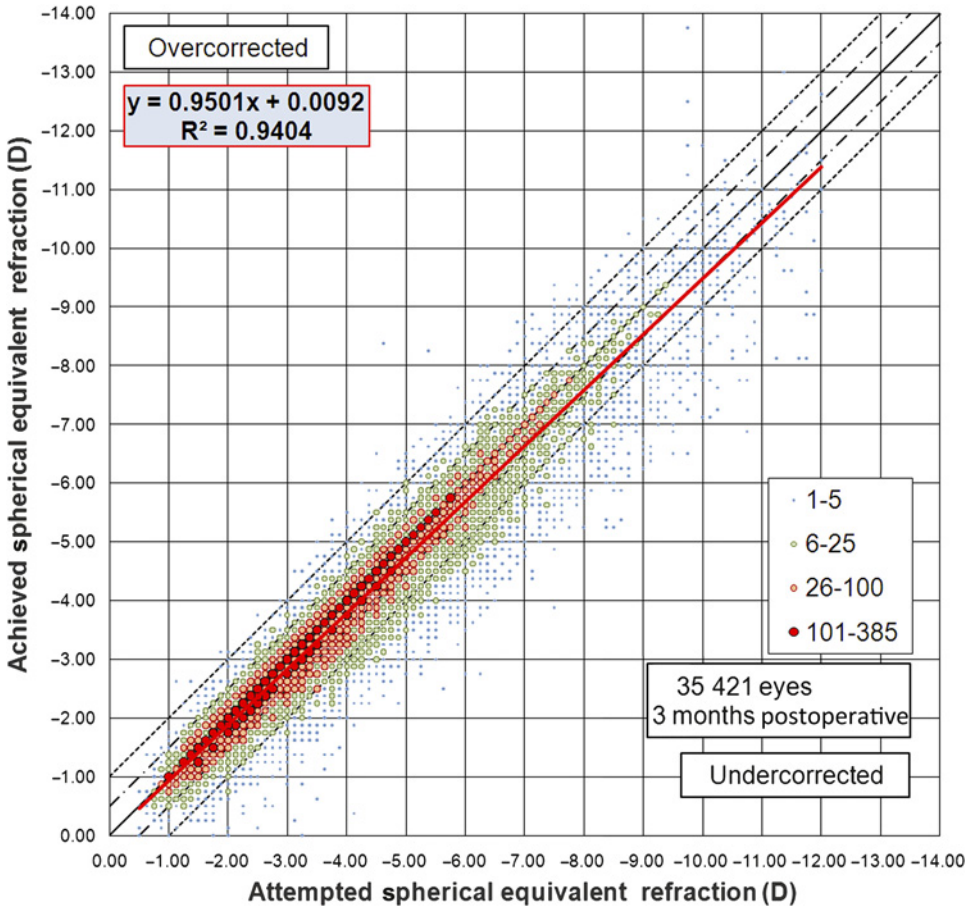
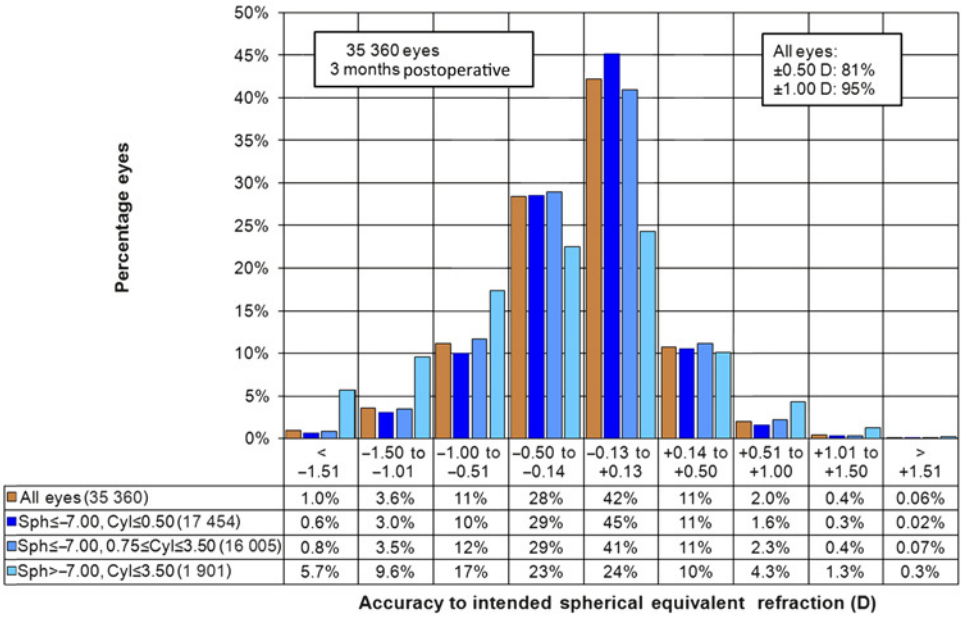


Figure 2 Attempted versus achieved manifest spherical equivalent refraction of 35 360 eyes that underwent LASIK at 11 surgical centres. The thick black dotted lines represent ±0.50 D intervals. The thin black dotted lines represent ±1.00 D intervals. The linear regression line is plotted in dark red. The linear regression equation and coefficient of determination (R^2) are displayed. Different colours have been used to give greater weight to points where multiple eyes had identical data. The blue data points represent between 1 and 5 eyes, green data points represent between 6 and 25 eyes, orange data points represent between 26 and 100 eyes and red data points represent between 101 and 385 eyes.

and those who had not. Microsoft Excel 2007 (Microsoft Corporation, Seattle, Washington, USA) was used for statistical analysis.

RESULTS

Between July 1998 and January 2001, a total of 69 701 eyes were entered into the PIQASO database after undergoing LASIK. Of these, 15 480 were excluded as they had been treated using the VISX S2 (Abbott Laboratories Inc., Abbott Park, Illinois, USA) excimer laser. Further exclusions included 3070 hyperopic eyes, 1126 eyes with mixed astigmatism, 2383 photorefractive keratectomy treatments, and 934 eyes that did not meet the other inclusion criteria (age, spherical equivalent refraction, CDVA). A total of 46 708 eyes of 24 138 patients met the inclusion criteria. Given the 50% sampling rate, approximately 140 000 eyes were



	< −1.51	−1.50 to −1.01	−1.00 to −0.51	−0.50 to −0.14	−0.13 to +0.13	+0.14 to +0.50	+0.51 to +1.00	+1.01 to +1.50	> +1.51
All eyes (35 360)	1.0%	3.6%	11%	28%	42%	11%	2.0%	0.4%	0.06%
Sph≤−7.00, Cyl≤0.50 (17 454)	0.6%	3.0%	10%	29%	45%	11%	1.6%	0.3%	0.02%
Sph≤−7.00, 0.75≤Cyl≤3.50 (16 005)	0.8%	3.5%	12%	29%	41%	11%	2.3%	0.4%	0.07%
Sph>−7.00, Cyl≤3.50 (1 901)	5.7%	9.6%	17%	23%	24%	10%	4.3%	1.3%	0.3%

Figure 3 Histogram of postoperative spherical equivalent refraction for all 35 360 eyes (orange bar) and stratified by sphere and cylinder (blue bars). The number of eyes for each group is denoted in brackets.

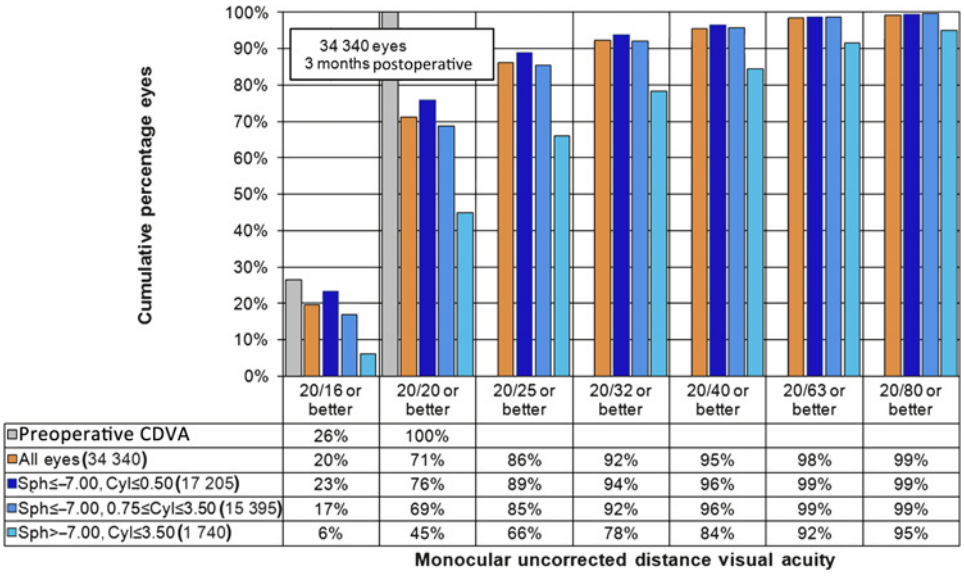


Figure 4 Postoperative uncorrected distance visual acuity compared with preoperative corrected distance visual acuity (CDVA) (grey bar) for all 34 340 eyes (orange bar) and stratified by sphere (Sph) and cylinder (Cyl) (blue bars). The number of eyes is denoted in brackets.

treated in total during this period across all clinics. Postoperative data for 35 360 eyes (76%) of 18 195 patients were available at 1 month or later. Mean follow-up period was 2.9±1.5 months (range 1–8 months); the last follow-up was 1 month for 27%, 3 months for 58%, and 6 months for 15% of eyes. In the population, 979 (3%) eyes were treated in 1998, 5549 (16%) in 1999 and 28 832 (81%) in 2000. There were 9583 (53%) women and 8612 (47%) men.

The mean preoperative spherical equivalent refraction for the entire cohort was −4.02±1.93 D (range −0.50 to −12.00 D). Table 1 includes the mean preoperative sphere and cylinder for the entire cohort, while table 2 includes this data for the three refractive groups. Preoperatively, CDVA was 20/25 or better in 100%, 20/20 or better in 97% and 20/16 or better in 26% of eyes.

Table 1 includes the key statistics for predictability, efficacy and safety for the entire cohort, and table 2 includes this data for the three refractive groups. Figure 1 presents a bar chart of the postoperative spherical equivalent refraction grouped by refraction. Waring graphs are presented in figure 2 (attempted versus achieved spherical equivalent refraction), figure 3 (predictability), figure 4 (efficacy), figure 5 (safety) and figure 6 (refractive astigmatism), showing data for the entire cohort and the three refractive groups.

Figure 7 shows box plots for efficacy (% 20/20), predictability (% within ±0.50 D) and safety (loss of ≥2 lines CDVA) for each surgeon individually, summarised as box plots with surgeons grouped into those who had undergone the training course and those who had not.

The result that 81% of eyes were within ±0.50 D could potentially range between 74% (if 50% of eyes lost to follow-up were within ±0.50 D) and 83% (if 90% of eyes lost to follow-up were within ±0.50 D).

The result that 71% of eyes achieved 20/20 or better could potentially range between 66% (if 50% of eyes lost to follow-up achieved 20/20 or better) and 76% (if 90% of eyes lost to follow-up achieved 20/20 or better).

The result that 0.57% lost two or more lines CDVA could potentially range between 0.45% (if 0.01% of eyes lost to

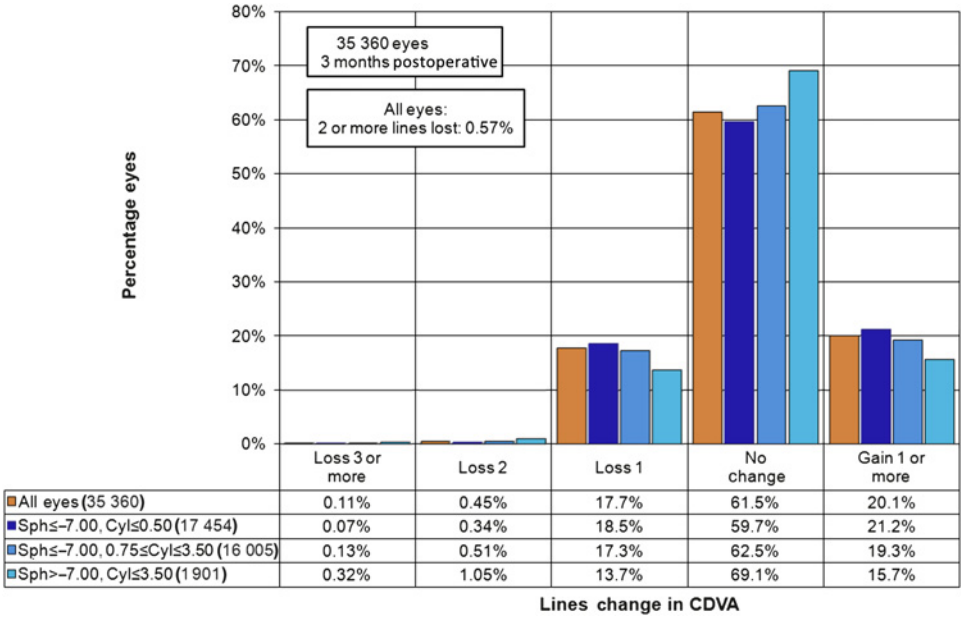


Figure 5 Change in corrected distance visual acuity (CDVA) for all 35 360 eyes (orange bar) and stratified by sphere (Sph) and cylinder (Cyl) (blue bars). The number of eyes is denoted in brackets.

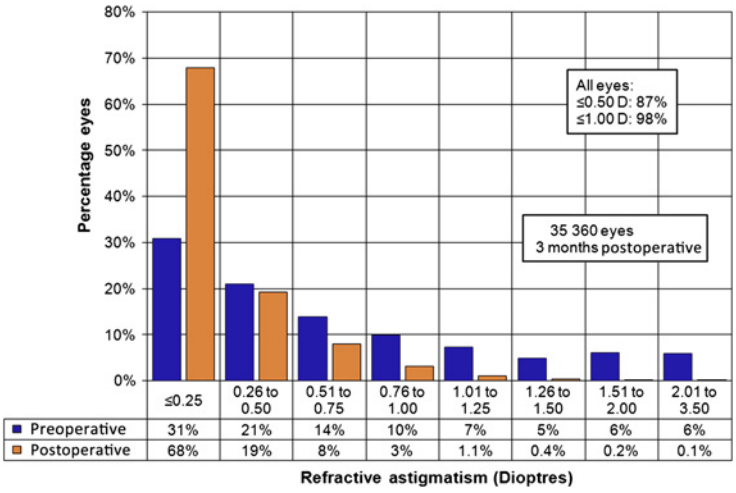


Figure 6 Histogram of preoperative (blue bars) and postoperative (orange bars) refractive astigmatism for 35 360 eyes.

follow-up lost two or more lines CDVA) and 2.86% (if 10% of eyes lost to follow-up lost two or more lines CDVA).

DISCUSSION

The results of this population represented the first report of a corporate high-volume, multi-surgeon LASIK population when presented at the the American Society of Cataract and Refractive Surgery in 2001.[12] These results exceeded the FDA criteria[6] and were comparable with the highly controlled, relatively low-volume studies such as FDA premarket approval of excimer laser platforms in the same period.[7–11] Table 2 presents a summary of the key outcome measures for the present study alongside the FDA studies.

The present study is an important addition to the peer-reviewed literature as, currently, there are only two other articles that report the outcomes of a multicentre high-volume refractive surgery corporate practice.[2 3] Even though the results of the present study are of short term (similarly, both other studies[2 3] report 1–2-month outcomes), they are equally valid in terms of real data and create an important benchmark reference for other corporate organisations and for the general population interested in refractive surgery.

The results among surgeons (who had undergone the training course) were reasonably comparable with an 8% IQR for both efficacy and predictability (figure 7). However, there were a few outliers with a total range of 34% for efficacy and 19% for predictability. The analysis comparing surgeons also highlighted the significant benefit achieved by the training course and standard protocols, as the results were considerably worse for those surgeons who declined to attend the training course.

Comparison with the outcomes of the Technolas 217a FDA trial (table 2) demonstrate that predictability was almost identical for each refractive group; however, efficacy was slightly lower in the present study. Possible reasons for this are that there was more ocular surface/dry-eye optimisation in the FDA trials, or there may have been a higher incidence of microfolds or epithelial ingrowth in the present study. In addition, there was a tendency for under-correction in the present study, meaning that there might have been more eyes with −0.50 D compared with the FDA trials where there may have been more eyes with +0.50 D. The safety was very similar to the FDA trials.

At that time, LASIK was a relatively new technique and just starting to gain popularity over photorefractive keratectomy, as found by surveys,[13] and numerous studies comparing LASIK and photorefractive keratectomy.[14] Hence, there was little consensus on LASIK surgical technique,[15] and the major issues were how to avoid and manage flap complications,[16] microfolds,[17] epithelial ingrowth[18] and other complications. There was also very strong

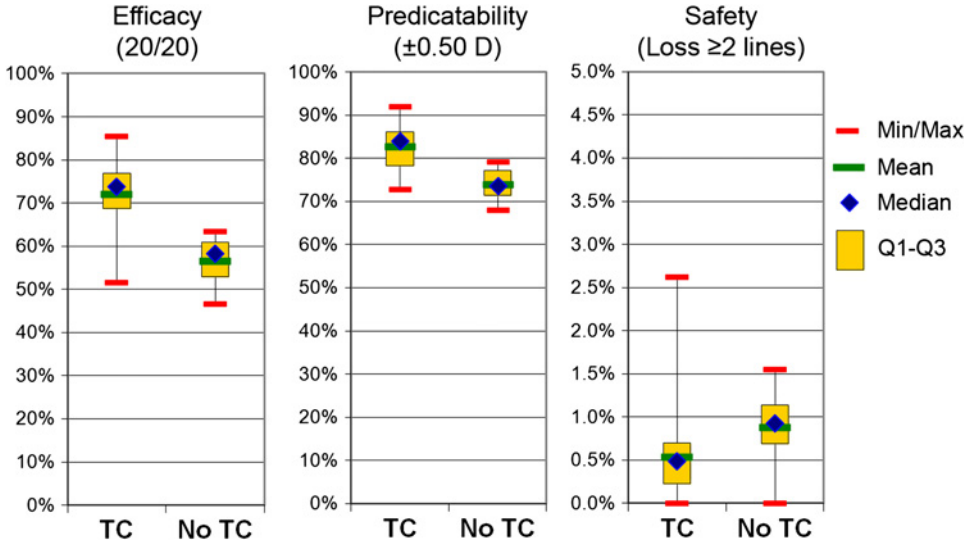


Figure 7 Box plots showing the key statistics for efficacy (% 20/20), predictability (% within ±0.50 D) and safety (loss of ≥2 lines corrected distance visual acuity) for each surgeon individually, with surgeons grouped into those who had undergone the training course (TC, n=31) and those who had not (No TC, n=7).

opposition within the ophthalmic community towards corporate LASIK.[19] However, the high-volume corporate environment provided the opportunity to optimise quality control and assurance.

Today, corporate high-volume LASIK chains face the challenge of competing with the results of specialist clinics. For example, an accurate nomogram can significantly improve predictability of results and, hence, reduce enhancement rates.[20] However, the development of a nomogram requires a high follow-up percentage, something that is generally not prioritised in the corporate setting.

The follow-up percentage of 76% might at first glance be viewed as a limitation of the study; however, the potential error is just ±0.3% (with 99% confidence) when the sample size is taken into account. Therefore, the total error is only ±0.7%, once combined with the ±0.4% error due to the 50% sampling rate. This is better than the error level of an FDA clinical trial, where 90% follow-up in a population of 300 eyes[6] would introduce an error of ±4.3% (with 99% confidence).

Another limitation of the study was that the rates of complications could not be evaluated as these data were not available in PIQASO. A chart review to collect data was not possible with the resources currently available to us.

In summary, the present study demonstrates that standardised protocols for surgical technique enabled a high-volume multi-surgeon LASIK corporation to achieve short-term results comparable with those achieved in highly controlled, relatively low-volume FDA clinical trials with equivalent equipment in the period 1998–2001. It would be of interest to compare the outcomes of current corporate practices with those of individual private practices in this day and age.

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Contributors Conception and design: DZR, WBT, RC, EC, HFFS, TJA and MG. Acquisition of data: DZR, WBT, RC, EC and HFFS. Analysis and interpretation of data: DZR, WBT, TJA and MG. Drafting the article: TJA and MG. Revising it critically for important intellectual content: DZR, WBT, RC, EC, HFFS, TJA and MG. Final approval of the version to be published: DZR, WBT, RC, EC, HFFS, TJA and MG.

Competing interests None.

Patient consent This was a retrospective review of LASIK outcomes.

Ethics approval This was a retrospective review of LASIK outcomes.

Provenance and peer review Not commissioned; externally peer reviewed.

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Appendix 1: Standardized Protocol for Preoperative Keratoconus Screening

The Standardized Protocol for Keratoconus Preoperative Screening consisted of five elements used to rule out possible cases of sub-clinical keratoconus and keratoconus.

1) Orbscan II corneal topography acquisition and interpretation protocol

All surgical centers used standardized acquisition and interpretation protocols for corneal topography. The measurements were repeated to obtain the best possible exam free of lid and other measurement artifacts with the target of achieving a diameter of at least 9 mm. The quad display including the anterior elevation best-fit sphere (BFS), posterior elevation BFS, total optical power and pachymetry maps was used for evaluation with standardized scales and settings. The following interpretation criteria were considered suspicious for keratoconus;

I. A significant "red" bulge on the posterior elevation BFS
II. A posterior elevation BFS apex that was significantly displaced from the corneal vertex
III. A minimum corneal thickness below 490 microns on the pachymetry map
IV. Coincidence of the thinnest point of the cornea and an eccentric apex of the posterior elevation BFS
V. An eccentric red apex on the anterior elevation BFS coincident in location with the apex of the posterior elevation BFS
VI. The more eccentric the front corneal apex, the greater the index of suspicion.
VII. Inferior steepening on the keratometric map as described previously[67, 68]

2) *Patient age*

A patient younger than 35 years old with some or all of the topographic features described in 1 above would further increase the index of suspicion.

3) *Simulated keratometry*

Simulated corneal keratometry greater than 46 D and/or corneal astigmatism greater than 2 D would further increase the index of suspicion.

4) *Corrected distance visual acuity*

Loss of CDVA, quantified as a preoperative CDVA of 20/25 or worse, would further increase suspicion of keratoconus.

5) *Clinical Signs*

Clinical evidence of keratoconus was also considered such as instability of refraction, and Fleischer rings or Vogt’s striae on slit lamp examination.

Appendix 2: Standard Surgical Treatment Protocol

Prior to starting the surgery, calibrate the laser based on the manufacturer's recommendation.

1) Ensure standard room atmospheric conditions are present (18–24°C, and less than 50 % relative humidity). Ensure that there is no fan or air-conditioner blowing toward the patient's head/treatment area.
2) Confirm that the correct patient is lying under the laser (name and date of birth).
3) Cross-check the refraction entered into the laser software with respect to the medical record.
4) Verify the optical zone size according to pupil size.
5) Verify residual stromal thickness of at least 250 microns.
6) Centration of patient; Ensure proper head alignment and positioning, body straight and centred on laser bed, legs uncrossed. Patient position should be attained with no muscular effort (e.g. do not ask patient to raise or lower their chin into a position requiring continuous muscular effort).
7) Tell the patient to look at the fixation light while you join the two lateral beams (adjusting the z-axis position).
8) Move the patient in the x-y axis to centre the joint beams within the center of the entrance pupil.
9) Keep the x-y-axis positioning centered throughout the entire procedure – you will use this position to ensure that the cornea is vertically below the laser (x-y position).
10) Instil local anaesthetic drop into the eye about to be treated, explaining that it may sting for a moment. (It is a good idea to continuously talk to the patient delineating each step as you are about to proceed – this helps keep the patient from becoming startled.)
11) Tape the other eye shut. (The time taken to do this gives time for the anesthetic in the eye to be treated to take effect and stop stinging.)
12) Dry the lashes of tears produced by the instillation of the anesthetic (otherwise drapes or tape will not stick properly to the lid margins and eyelashes).
13) Drape or tape the lashes. Check if there are any lashes in the way, or any tape in the way.
14) Avoid abrading the cornea with drape or tape.
15) Use standard solid blade speculum (Asico AE-1045) to obviate the need for taping of the lashes (while reducing the chances of expressing meibomian contents into the field from the lid margins).

16) Insert the lid speculum. Open it very gradually – startling the patient at this point can make things much more difficult for the rest of the procedure.
17) Ensure adequate exposure – you need equal exposure of sclera surrounding the limbus above and below. High brow patients should have their neck extended to ensure this symmetrical exposure.
18) Mark the surface of the cornea with 6mm ring marker pressed into ink pad (gentian blue) asymmetrically including the central 4-mm zone of the cornea (in case of central flap irregularities/buttonhole).
19) While marking, indent the surface of the cornea heavily so that in the event of a flap slip overnight, you can still see the epithelial marks the next morning with fluorescein stain.
20) In preparation for applying the suction ring, if unequal scleral exposure exists, here you may ask patient to alter head position to ensure perfect and equal scleral exposure all around the limbus. (e.g. Have the patient lift their chin up or down or turn his/her head toward the nose to move eye temporally within the palpebral fissure). Tell the patient that this will be necessary only for about 1 minute and that they must hold as still as they can.
21) Place the suction ring on the eye: Centration is key. Center the ring in relation to the visual axis, rather than the pupil or the limbus. This is especially important in patients with large angle-kappa.
22) Double-check the exact centration of the ring.
23) Look to make sure that the gear track of the suction ring unit is not about to trap lower lid skin between the overhanging portion of the gear track and the speculum blade. Have your assistant hold any excess skin overhanging the speculum (usually lower lid skin) to optimally expose the field.
24) Create conjunctival/scleral indentation by pressing the ring down for 5 seconds: Use your thumb and ring finger to press down on the arms of the speculum and create retropulsion of the eye from the orbit while applying counter pressure downward on the eye with the index finger on the pivoting-post of the ring.
25) Start suction. Tell the patient “as the pressure increases in the eye, the lights will go dim”.
26) Keep downward force on the speculum which also ensures tightening of the conjunctiva to produce adequate suction of the sclera into the ring.
27) Verify that suction level is satisfactory (on the console of microkeratome).

28) Ask the patient: “Are the lights dim? Are they out?”. (The answer should be affirmative – but if only dim, pay extra attention to the next step)
29) Ensure that the cornea is not too wet before applying the Barraquer tonometer to test pressure. You may additionally use the tip of your finger on the cornea to verify adequate firmness of the globe if in any doubt.
30) Wet the cornea with more anaesthetic (*not* Balanced Salt Solution as this can lead to salt deposits in the microkeratome head) and wet the keratome track and/or post with a lubricant to ease the engagement of the microkeratomes head on the ring.
31) Perform a short “buzzing test” telling the patient that this is the sound that they will shortly hear.
32) Engage the head of the microkeratome on the post of the ring.
33) Check again if the lower lid is in the way. You may choose to tilt the post of the ring slightly away from the proximal lid at the beginning of the pass to avoid ‘catching’ anything during the passage.
34) Use your ring finger of your ‘temporal’ hand to push any excess lower lid skin out of the way (your thumb, index and middle finger are holding the microkeratome head)
35) So the patient does not startle, warn the patient not to move or squeeze as the buzzing sound starts.
36) Make sure no tension or pulling on the power cord to the motor and suction tubing (your assistant may hold these to ensure no tension).
37) Press the forward foot-pedal for the microkeratome. Remind the patient to not squeeze. Keep talking to the patient, reassuring that there are only a few more seconds to go.
38) Watch the pass with particular attention to the patient’s lids and speculum.
39) Look at the “end position” of the microkeratome head. Have a particular land-mark on the ring memorized if this is not already present to verify a full pass has taken place. With the Hansatome, this is 4 teeth from the suction post.
40) Press the backward foot-pedal to reverse.
41) Deactivate the suction.
42) Wait a brief moment while depressing the ring on the eye before removing the ring from the eye to allow suction to decline – this avoids generating a sudden “sucking sound” that can startle the patient.

43) Remove the keratome head and ring together for simplicity, trying to avoid causing a displacement of the flap on the stromal bed or the entry of fluid into the interface. This is best done by tilting everything downward in case the inferior flap edge becomes caught in the flap recess within the head.

44) You may want to slightly loosen speculum at this point (if very tight).

45) Ask the patient to look at the fixation light – this will allow you to know that their vision has recovered from the black-out caused by the suction ring.

46) Reposition head to the "natural" effortless position, so the patient is comfortable and relaxed again. Reassure them that "the hardest part is now done and the rest is easy".

47) Recheck patient x-y position and ensure that the fixation beam reflection from the cornea is at the corneal vertex while the patient is looking at the fixation light. This ensures that the cornea is vertically below and therefore perpendicular to the laser beam avoiding parallax errors.

48) Bend *both* infrared light illumination sources toward the eye to be treated.

49) Increase the microscope field to whole cornea field.

50) Activate the eye-tracker.

51) Move the Purkinge image of the aiming beam so that it coincides with the Purkinge image of the fixation beam while the patient is coaxially fixating. You will see a flash-back when the aiming beam is being reflected from the vertex of the coaxially fixated eye.

52) Reduce the microscope magnification to whole field.

53) Verify the patient's head and body position (is there tilting or torsion that could affect the axis of astigmatism?).

54) With the toothless McPherson's forceps holding a wet rectangular sterile sponge (3 x 6 mm), place the sponge horizontally and lengthways approximately 1-mm superior to the hinge. This may need to rest on the upper blade of the speculum.

55) With the same McPherson's forceps use the lower blade to enter at the inferotemporal edge of the flap, pass the forceps across the bed under the flap approximately 1/3rd of the distance from the inferior border of the flap, and then lift the flap slowly without bending the flap so that it is opened as if a stiff door bending only at the hinge.

56) Place the epithelial side onto the wet sterile sponge so that the epithelial surface remains moist (as well as Bowmans') during the ablation so that when repositioning the flap there is minimal drying of the flap and hence avoiding Bowmans' cracks.

57) Increase the magnification to whole cornea field.

58) Perform a "drying sweep" of the stromal bed and hinge (use sponges that do not release particles eg Versatool). This should be standardized and performed on every single eye in the same way to ensure homogeneous hydration and lack of excess hydration of the stromal surface before ablation.

59) Telling the patient to "continue looking into the center of the big red light", warn the patient of the "buzzing" of the laser about to start.

60) With one hand, hold the patient's head to stabilize this and ensure that the x-y positioning remains centered on the corneal vertex.

61) Ensure that the level of hydration of the bed is constant and homogeneous during the ablation – continue monitoring the stromal surface during the ablation – careful that sometimes fluid is drawn up by capillary action into the hinge area.

62) Try to keep the timing of the time between flap-lift, drying sweep and start of ablation as consistent as you can from case to case.

63) Begin the ablation.

64) During ablation continuously talk to the patient while the assistant is counting down out loud the time remaining for the ablation.

65) Use one hand to hold the head during ablation

66) Use the other hand to hold a sponge over the hinge of the flap to ensure that no ablation takes place on the underside of the flap.

67) Continue to ensure that the position of the x-y axis lateral position is centered on the position of the corneal vertex (not visible with the flap up) with the patient fixating on the fixation light throughout the ablation.

68) On completion of the ablation, with the 27G cannula on a 5-mm syringe of BSS place a drop of fluid at the inside of the hinge and then slowly return the flap by stroking the epithelial side as atraumatically as possible – no bending, stretching or pulling - so that the flap closes again like a door on a hinge.

69) Irrigate under the flap with a single-hole 27G anterior chamber type cannula. The 5-ml syringe ensures the appropriate force and irrigation jet of BSS to ensure a high fluid pressure/velocity for a short time to help ‘blow’ debris from the interface while minimally increasing the stromal bed or flap hydration (Bernoulli's principle). This will ensure a good “fit” for the flap with minimal gutter. Irrigation should usually consist of 1-2-ml over 2-3 seconds.

70) Before all the irrigation fluid has left the interface, using a very wet spear-tip sponge, very gently brush-align the flap. Alignment should be primarily based on the corneal markings. (Gutter spacing may have changed due to asymmetric swelling of the flap during hydration).

71) Look under high-power magnification for debris.

72) You may wish to gently dry the gutter to help verify that the distension of the flap is complete throughout.

73) Instil the antibiotic and steroid drops.

74) Ask patient to continue to look at the fixation light, while you start preparing for the procedure on the second eye

75) Print the treatment report for this eye

76) Load the treatment parameters for the second eye

77) Perform microkeratomes running-checks after resetting it for the second eye.

78) The time taken to perform steps 71)-73) will ensure at least a 60 second interval to ensure proper flap adhesion (longer if you required additional irrigation).

79) Remove speculum slowly while carefully holding lids, and reminding patient to continue to look straight at the fixation light and not to squeeze.

80) Remove tape/drape carefully.

81) Re-examine flap position with blinking

82) Tape the eye shut if you are going to proceed to the other eye at the same sitting.

83) Go to step number 7) to perform LASIK in the fellow eye.

84) On completion of second eye:

85) Remove tape shutting the first eye.

86) Take patient to the slit-lamp in the operating room to check flap position and interface debris. Minor flap edge re-positioning can be carried out at the slit-lamp using a sterile spear-tip sponge if

necessary. Debris can be irrigated out using the 27G/BSS if required, followed by sterile spear-tip sponge brushing for repositioning.

87) Have the patient go to the recovery room and remain there for 20 minutes with their eyes closed.

88) Re-iterate post-operative instructions and medications, including the use of the eye-shields at night.

89) Allow patient to return home with their accompanying person, instructing them to keep their eyes closed as much as possible until the 1 day post-operative visit the next morning.