

2010 Laser Vision Correction: Using Biostatistics to Revolutionise Refractive Surgery Outcomes

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Introduction

Redefining Laser Vision Correction

Refractive surgeons everywhere can benefit from the lessons learned by Optical Express

As we refine and redefine patient selection, clinical protocols and laser vision correction (LVC) outcomes, surgeons everywhere can gain important information from the tremendous data being generated by Optical Express, now the largest refractive surgery provider in Europe.

Results from more than 30,000 treatments provide us with very credible, detailed information that we can all use. In these pages, you'll read more from statistician Keith Hettinger on the power of – and inherent challenges in – large data sets, and how practices can use their own data to improve outcomes. We'll also hear from Steve Schallhorn MD, about the excellent results in low and moderate myopes – and how those results can be duplicated in clinical practice.

All of us who have been involved with Optical Express believe in evidence-based, continuous quality improvement. At the end of the day, improving patient outcomes is not only good for one practice or company, but good for the entire refractive surgery community. Better results in every practice improve patient confidence, which eventually results in the global growth of refractive surgery.

What is very clear from this supplement is that our standard for excellence in refractive surgery is rapidly moving beyond 20/20. It is now quite reasonable to expect that the majority of patients with low to moderate myopia will achieve better than 20/20 uncorrected vision. We're also seeing better quality of vision than ever before, with fewer complications. And all of this means that it is also reasonable to expect very high rates (upwards of 95 per cent) of patient satisfaction with LASIK.

For anyone who has been involved in refractive surgery from the early days, these are heady numbers. How have we gotten to this point? The good news is that Optical Express has shared the "secret sauce" in its recipe for success – and it's a recipe that clinicians everywhere can duplicate with a little attention to detail.

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My take on the ingredients of this recipe:

Technology matters

Advanced technology has certainly played a major role in Optical Express's clinical outcomes. All of the patients in the published studies have had wavefront-guided treatments with the latest VISX Star S4 excimer laser and aberrometry devices, and most had an IntraLase femtosecond laser-created lamellar flap, as well.

Joseph Colin MD, has contributed an article for this supplement about the importance of keratome selection in improving outcomes. The precision and predictability of femtosecond laser technology, combined with all the advancements in excimer lasers and aberrometry in recent years, have improved quality of vision, speeded visual recovery and eliminated much of the inconsistency in results we saw in years past.

Gather data

Anyone who seriously wants to improve results must know first of all what those results are – regular data collection and analysis are essential. There are many reasonable ways to gather data: one need not have a staff of statisticians and a huge corporate database, as Mr Hettinger points out, but one must be meticulous. Often, the very act of measuring and recording sparks improvement in consistency and results.

Base clinical protocols on data

So much of what we do as surgeons happens because of our training, anecdotal experience or perceptions. Through careful reviews of the literature and its own data analysis, Optical Express discovered that there were better ways to match the wavefront refraction to the manifest refraction in their nomograms, and that some criteria for ruling candidates out were not appropriate. It turns out, for example, that thousands of patients who had been turned down for surgery based on preoperative keratometry were actually perfectly good candidates. In an article in this supplement, Mitchell Brown OD, addresses the role of keratometry and appropriate patient selection for refractive surgery.

Focus on the patient experience

Even during difficult economic times, when many practices have seen declines of 30 per cent or even 70 per cent in refractive surgery procedures, Optical Express has been experiencing growth. And that growth isn't only through acquisitions. Same-clinic growth has consistently been better than 20 per cent, year over year. The lesson for all of us in this growth pattern is that results do matter. Patients who are happy with their visual outcomes and with their experience throughout the entire process refer their friends, family, and colleagues. In his article, John Vukich MD, will discuss the key factors in patient satisfaction, and how satisfaction contributes to growth.

Emphasise excellence

Set the goal of achieving excellence and then hold everyone, from receptionists to technicians to optometrists and surgeons, accountable for achieving it. Optical Express has achieved great standardisation across its many clinics through meticulous attention to detail in clinical protocols. I believe that individual surgeons can do a great deal on their own, both to inspire staff members to improve the patient experience, and to improve their own surgical results, simply by striving to achieve



H Burkhard Dick, MD

excellence. The drive for excellence is an ethos that carries over into everything we do, from selecting waiting room furniture to adjusting surgical nomograms.

Equally important to one's overall results is an effective system for dealing with sub-optimal. Optical Express has a very clearly defined, tiered system for handling complications. While this might not be necessary for an individual practice, it is absolutely critical to be proactive in enhancing visual outcomes, forthright in addressing complications, and to direct extra resources and attention to those patients with less-than-ideal outcomes, rather than ignoring them or hoping the problem will go away.

I commend David Mouldsdale, the CEO of Optical Express, for supporting the public release of so much corporate data. In fact, one of the company's goals is to be an active contributor to the knowledge base of information in refractive surgery. This is no small feat – no other corporate laser provider has shared their data in any comprehensive way.

I hope you'll find that the articles in the supplement, taken together, demonstrate that by combining the advanced technology of the iLASIK platform with an intense focus on patient care, every surgeon can surpass patient expectations and prior results to succeed in refractive surgery in any economic environment.

RECIPE FOR SUCCESS

1. Use State-of-the-Art Technology
2. Capture and Analyze Data
3. Use Data to Guide Clinical Protocols
4. Prioritize Your Patient's Experience
5. Emphasize Excellence Throughout Your Practice

Prof Dick is the German medical director of Optical Express, a member of the Optical Express International Medical Advisory Board (IMAB) and professor of ophthalmology, chairman and head of the University Eye Clinic in Bochum, Germany.

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Updating the LVC Patient Selection Criteria

An evidence-based patient selection process provides surgeons with additional confidence in laser vision correction (LVC) treatment recommendations and helps patients get the best treatment to meet their needs

For nearly the past 20 years, surgeons have been making recommendations to patients about LVC based largely upon inclusion and exclusion (selection) criteria that were used in the original excimer laser studies. Many of these guidelines are quite conservative. Because very little was known about LVC in humans at the time, it made sense to exclude all patients that did not have a completely normal medical and ocular history. While some of these guidelines are based on sound scientific principles, many have never been closely and scientifically scrutinised for validity.

As eye care providers, we strive to be perfect in our clinical care and our recommendations to patients. In terms of patient selection for LVC, 'perfection' means that we are able to consistently recommend surgery to every patient that can safely have surgery, and we direct all others toward alternative treatment options. By employing a systematic, evidence-based approach to LVC selection criteria, eye care professionals can have greater confidence in the scientific foundation supporting their treatment recommendations.

Reviewing and updating the criteria

Optical Express, the largest corporate refractive surgery provider in Europe, developed its evidence-based patient selection guidelines as a method of scientific validation of the criteria that have been followed as the 'community standard' for the last 20 years. The ongoing evaluation of patient selection criteria for LVC is part of a larger process of continuous quality improvement and clinical due diligence. The criterion review process has an evidence-based foundation with five main components:

World-wide literature review

A careful review of international peer-review literature is conducted for a specific treatment or condition. For example, on the topic of treating patients with autoimmune conditions, all applicable literature would be meticulously reviewed and a consensus of all available study data would be formed.

Organisational guidance

The review process also takes into consideration organisational guidance from relevant organisations and groups, such as The American Academy of Ophthalmology (AAO), The European Society of Cataract and Refractive Surgeons (ESCRS), The American Society of Cataract and Refractive Surgery (ASCRS), and other organisational bodies that provide guidance on treating patients. While the scientific foundation of these guidelines may not always be entirely clear, it is nonetheless important to carefully consider these recommendations as part of a comprehensive review.

Database review

An early adopter of electronic medical records, Optical Express has one of the largest ophthalmic clinical data sets in the

world, with data on more than 200,000 surgical patients and 500,000 optical patients. These large sample sizes facilitate analysis with a high degree of statistical power for even low-incidence conditions and sub-analysis of multiple clinical and demographic variables. Scientific interrogation of this data represents one of the cornerstones of the patient selection review process.

Consultation with IMAB

Optical Express' International Medical Advisory Board (IMAB) meets every year. Headed by Steven C Schallhorn MD, former director of refractive surgery for the United States Navy, the IMAB reviews and monitors clinical outcomes, provides insight into new and emerging technology, and shares its collective experience with Optical Express clinicians at educational forums. At this annual meeting the world literature, organisational guidance, and the results of Optical Express data analyses are presented to, and reviewed by the medical advisors. Following open discussion, there is a vote – a unanimous vote is required to change a patient selection guideline. Therefore, under this system there is consideration of the scientific research on the topic and the collective wisdom and clinical experience of these world leaders in ophthalmology.

Optical Express International Medical Advisory Board (IMAB)	
•	Steven C. Schallhorn, MD, IMAB Chairman
•	Jan Venter, MD, IMAB Clinical Director
•	Mitchell C. Brown, OD, IMAB Deputy Medical Director
•	Stephen C. Coleman, MD
•	Joseph Colin, MD
•	Steven J. Dell, MD
•	Colman R. Kraff, MD
•	Marguerite B. McDonald, MD
•	Stephen Slade, MD
•	John A. Vukich, MD

Final validation of changes

Following any change to the guidelines that expand treatment parameters, and with a sufficient sample size of patients treated under the new guidelines, another analysis of patient outcomes is completed and compared against a control population. This second analysis represents an additional measure of safety and efficacy validation for all changes to Optical Express' patient selection guidelines.



Mitchell C Brown, OD

Benefits

This systematic process allows Optical Express to be sure it is providing the best care in the safest possible way to patients seeking this life-changing surgery. In some cases this review process may result in the expansion of the guidelines. In other cases, existing guidelines may be changed to a more conservative approach.

The patient selection criteria undergo continuous scrutiny and are modified whenever medical evidence indicates that change is appropriate. With this evidence-based approach, very high standards of safety and efficacy care can be maintained and surgeons can have added confidence in the treatment process.

Mitchell C Brown, OD, is optometry director for Optical Express.

Capturing Wavefront First

Using the aberrometer refraction as the starting point for the manifest aids efficiency and clinical decision making

Steven C Schallhorn, MD

The manifest refraction is a measure of the sphere, cylinder and axis needed for a patient to achieve the best possible subjective vision. Through trial and error, the patient selects the combination that gives him the best vision from the choices presented by the practitioner at the phoropter or in trial lenses.

A wavefront refraction, by contrast is a completely objective, automated measurement of a patient's sphere, cylinder, and axis errors extracted from the overall ocular aberrations.

In order to obtain an accurate refraction with either method, one must ensure that the patient has a good tear film, is properly fixating, and is not accommodating. For a wavefront exam, the technician must be well trained in observing the Hartmann-Shack image during capture to ensure a good quality wavefront exam. Setting the conditions for good refractions – both wavefront and manifest – is a very important part of the clinic flow when performing custom treatments.

Even when both are done absolutely correctly, the wavefront and manifest refractions can be different from one another. Because the wavefront aberrometer measures all ocular aberrations, there can be a coupling effect between lower- and higher-order aberrations that cannot be duplicated with a phoropter that corrects only for lower-order aberrations. Both refractions can still be correct. So how does one decide where to begin and which refraction to rely on?

Ideally, the wavefront exam should be performed first, and the wavefront refraction then used as a starting point for the manifest refraction. Practices that do not have an aberrometer on site or that have always done preoperative exams in a different order may not be accustomed to doing this, but it is worth considering, both for clinical value and practice efficiency.

For accuracy, the wavefront should be captured early during the preoperative evaluation before dilating or other drops have been instilled. And it is highly beneficial to have both the wavefront exam and the manifest refraction in hand when examining a patient who is a candidate for custom laser vision correction. Looking at both measurements gives the surgeon a better appreciation of the wavefront and the best way to make physician adjustments. This approach can therefore help drive better outcomes.



Taking a patient's wavefront measurement

Performing the wavefront first is also useful in terms of patient flow and productivity. With modern aberrometers, wavefront refractions are highly accurate and can reduce the time spent performing the manifest refraction significantly. Starting out closer to your goal can also limit the need for repeated exams.

In a non-keratoconic, virgin eye, the cylinder value and axis are extraordinarily accurate. Although I can conceive of situations where one might need to adjust the wavefront cylinder, I don't think I have ever done so. When the manifest cylinder doesn't match the wavefront, it has always been my experience that the patient sees better when presented with the aberrometry-derived cylinder correction.

For both accuracy and efficiency, it is very helpful to perform the wavefront refraction first and use it to guide the rest of your surgical planning.

Steven C Schallhorn, MD, is medical director and chair of the International Medical Advisory Board for Optical Express.

Improving Outcomes through Keratome Selection

The predictability of flap depth and speed of visual rehabilitation are better with a femtosecond laser flap

Many surgeons ask whether LASIK with a femtosecond laser flap is truly better – or if it is just marketing hype. A very large study demonstrates that there is a difference between the two flap-making methods in terms of outcomes and the speed of visual recovery, at least in the short-term. The reality is that femtosecond laser flaps make a very good procedure even better. And I believe the gap between the two flap-making methods will keep growing as femtosecond laser technology continues to evolve.

A retrospective analysis was performed on 2,000 eyes treated in 2008 for low myopia and astigmatism¹. Investigators analysed consecutive treatments that met their definition of low myopia (≤ 3.00 DS with ≤ -0.75 DC), comparing 1,000 eyes with the IntraLase FS 60 femtosecond laser (Abbott Medical Optics) flaps to 1,000 eyes with flaps created with the Evo3 One Use-Plus mechanical microkeratome (Moria). All eyes were subsequently treated with the Star S4 excimer laser (AMO) and advanced CustomVue ablation. Postoperative examiners were unaware of the method of flap creation.

The two groups were well matched, with no clinically relevant differences between groups. In the femtosecond laser group, flap depth was programmed to be between 100-120 microns, and the median flap depth was 110 microns. A 130-micron head was used with the mechanical microkeratome.

Visual acuity results

The speed of visual rehabilitation was much faster in the femtosecond laser group. At every time point through three months, more eyes in the femtosecond laser group achieved 20/20 or better uncorrected visual acuity (Figure 1), with statistical significance reached at one day and one week. In addition to the faster visual recovery, the femtosecond eyes also achieved significantly better three-month UCVA, with 78 per cent at 20/16 or better, compared to 70 per cent of the eyes in the mechanical microkeratome group. Refractive predictability was similar in both groups at all follow-up examinations.

Best spectacle-corrected acuity was very good in both groups. However, in the early postoperative period (one week), only 0.9 per cent of eyes in the femtosecond laser group lost two or more lines of BSCVA, compared to 2.8 per cent in the mechanical microkeratome group. By three months, loss of BSCVA was similarly low in both groups (Figure 2).

There are several possible explanations for why femtosecond laser flaps might achieve better vision, faster. Flap thickness, flap planarity, edge profile, the smoothness of the stromal bed, the lack of inflammation and debris in the interface and differences in damage to the ocular surface may all play a role. In any case, we know that patients prefer speedy visual recovery - that is why they choose LASIK in the first place.

Even if the microkeratome eyes eventually catch up to the femtosecond laser results, in both uncorrected and best-corrected acuity, the slight lag in recovery is meaningful for an elective procedure in active adults with high expectations.

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Predictability of flap depth

In a smaller study in my own clinic in Bordeaux, France, we compared results with the IntraLase FS 60 laser (programmed for a flap depth of 120 microns) and the Moria M2 microkeratome (130 head). A retrospective analysis of 106 eyes of 53 patients undergoing bilateral myopic LASIK who had complete pre-op and one-month postoperative data was conducted². Flap and residual stromal bed thickness were measured intraoperatively by an observer.

Flaps in the femtosecond laser group were significantly more predictable. The mean flap thickness in this group, where the expected flap was 120 microns, was 117.50 ± 1.02 microns, with a range of 98-130 microns. In the microkeratome flap group, with an expected flap thickness of 130 microns, the mean flap thickness was $162.11 \mu\text{m} \pm 3.41$, with a range of 111-180 microns.

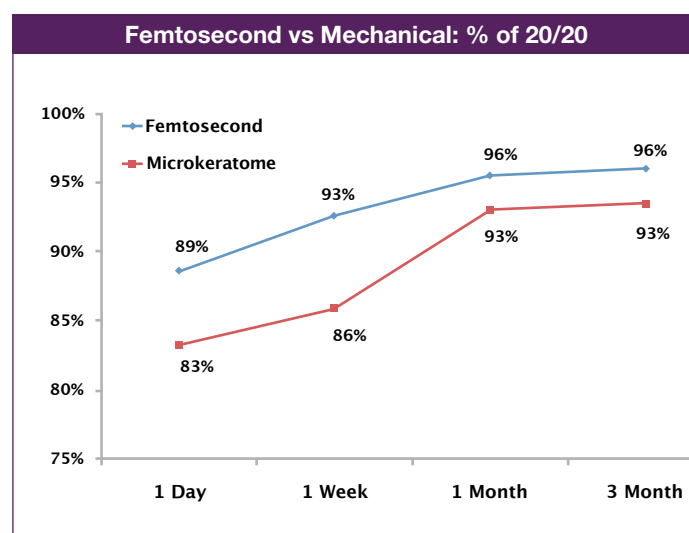


Figure 1: The femtosecond laser group achieved higher rates of 20/20 UCVA at every time point



Joseph Colin, MD

Ectasia is one of the most serious potential complications of LASIK. While we do not fully understand all the factors that contribute to ectasia, we know that insufficient residual posterior stroma puts the eye at much greater risk. To mistakenly cut a 180-micron flap – a full 50 microns thicker than intended – in an eye with limited stromal reserves could be disastrous.

There were, however, no differences between the two groups in our study in terms of the biomechanical properties of the cornea (cornea hysteresis or corneal resistance factor) or the change in higher-order aberrations (SA and coma).

Margin of safety

In another analysis of more than 32,000 eyes treated at Optical Express, which included both mechanical microkeratome and femtosecond laser flaps, there were three times as many intraoperative complications in the microkeratome group than in the femtosecond group. All but one of the femtosecond intraoperative complications allowed the surgeon to complete the procedure on the same day, whereas all the microkeratome complications caused delays. Postoperatively, there were seven flap displacements with the microkeratome, and only one with the femtosecond laser³. There was also less chance of epithelial ingrowth with the femtosecond laser.

Complications are possible with either flap-making method, particularly during a surgeon's learning curve. However, a femtosecond laser complication is much less likely to lead to an aborted or delayed procedure. For the surgeon, there is great comfort in knowing that in the rare case of a flap complication, you can just wait for the plasma bubbles to dissipate and repeat the procedure in a few hours or days later. With a steel blade, once the cornea is cut, it is cut forever.

This extra margin of safety – both in the predictability of the flap thickness and in the ability to deal with rare complications more easily – is the main reason that I now recommend a femtosecond laser flap for every patient. Both methods are good, but there is no longer any question in my mind that laser is better.

“All-laser” LASIK is also very appealing to patients. Despite significantly higher cost, about 75 per cent of Optical Express patients opt for a femtosecond laser flap.

I am now using the next-generation IntraLase laser, the iFS laser, which offers additional advantages, including flap and sidecut customisation, faster speed and a very intuitive user interface. In most eyes, I make the same type of flap that I would with the FS 60 laser because the “normal” flap typically offers the widest stromal exposure. But I do opt for an oval flap in astigmatic eyes and a more sharply-angled sidecut in highly myopic eyes with thin corneas.

I used my microkeratome only to make LASIK flaps. Femtosecond lasers have already proven useful for creating

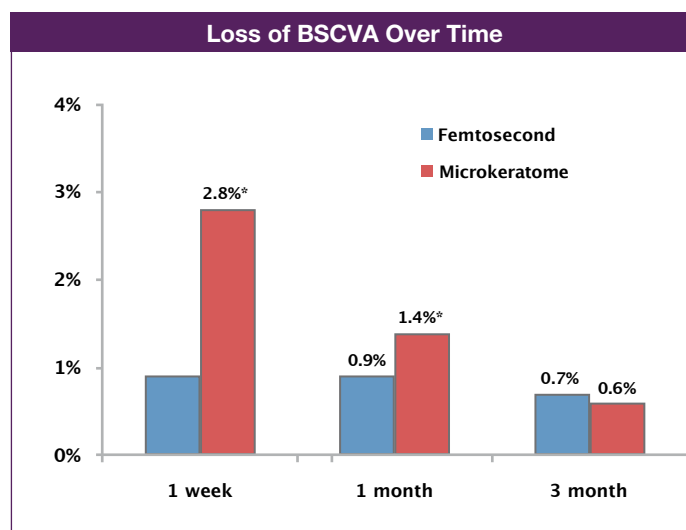


Figure 2: Eyes in the mechanical microkeratome group were three times as likely to lose two or more lines of BSCVA during the immediate postoperative period, although this effect did not persist at three months

corneal ring segment pockets and for lamellar keratoplasty dissection, and may soon have other applications as the technology evolves. The femtosecond laser, not the microkeratome, is the platform on which future LASIK flap and corneal innovations will be based.

Joseph Colin, MD, is chairman of the Department of Ophthalmology at Bordeaux University Medical School. He is also a member of the Optical Express International Medical Advisory Board.

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Outcomes in Typical LASIK Patients

Steven C Schallhorn, MD



The new benchmark for low to moderate myopes is achieving better than 20/20 postoperative UCVA

Recent data indicate that we can expect to achieve better than 20/20 vision in the majority of low to moderate myopic LASIK treatments. Dr Jan Venter and I recently reported on one-month outcomes in 32,569 eyes of 17,713 patients who were treated at Optical Express centres in 2008¹.

This was a retrospective review of all eyes in the Optical Express central database with a preoperative manifest spherical equivalent (MSA) of ≤ 6.00 D, preoperative cylinder of ≤ 6.00 D, a refractive target of emmetropia and no prior refractive procedures. Of the 42,143 eyes that met our criteria, one-month results were available for 77 per cent. Patients who did not attend the one-month follow-up visit tended to be slightly younger, more likely male, and more likely to have had a microkeratome flap. The impact on results from the eyes lost to follow-up is unknown.

To our knowledge, this is the largest study to report on the safety and efficacy of LASIK. It demonstrates the value of data in analysing and improving treatments for our patients (see article opposite).

The LASIK treatments in this study were performed by 30 different surgeons at 41 centres, using standardised protocols. All treatments were performed with the STAR S4 IR excimer laser system (AMO) using a wavefront-guided ablation profile (Advanced CustomVue, AMO). Flaps were created with either the AMO IntraLase FS-60 laser (75.7 per cent) or the Moria Evo3 One Use-Plus microkeratome (24.3 per cent), depending on patient preference. The programmed flap depth in the femtosecond eyes was 100-120 μm . For the microkeratome eyes, a 130- μm head was used.

The majority of eyes (71.6 per cent) achieved UCVA of 20/16 or better at one month, with 91.8 per cent seeing 20/20 or better (Figure 1). The average increase in UCVA was 10 lines (Figure 2). Among the patients who underwent bilateral LASIK, 88.8 per cent achieved 20/16 or better uncorrected binocular vision and 98.1 per cent were 20/20 or better.

The postoperative MSE was within 0.50 D of target for 93.7 per cent of eyes and within 1.00 D for 99.3 per cent of eyes. Mean defocus equivalent at one month was 0.27 ± 0.31 D. Mean manifest cylinder was -0.17 ± 0.26 D.

The safety index (mean post-op BSCVA/mean pre-op BSCVA) was 1.02. The rate of complications (occurring at any point during the post-op period, not just the first month) was very low, at 0.64 per cent. The most common complications, as have been reported in other LVC studies, were dry eye, mild diffuse lamellar keratitis and night vision symptoms. Flap complications were more common in eyes treated with a microkeratome flap, including seven of eight traumatic flap dislocations. A few rare and potentially sight-threatening complications were reported, including six cases of microbial keratitis (all successfully treated) and one case of ectasia occurring three months after surgery. Despite these complications, no eye had postoperative BSCVA worse than 20/40. These results demonstrate that LASIK has attained a high level of safety.

What we have learned from the Optical Express experience is that it is possible to take the already very good results that most surgeons achieve with LASIK, and make those results even better, through incremental improvements in patient selection, surgical technique and patient care.

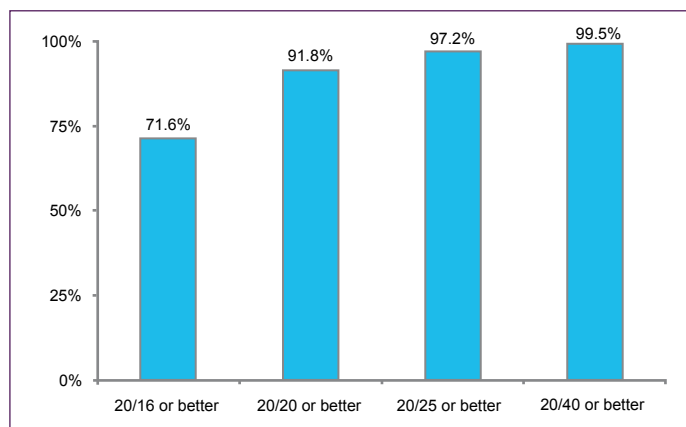


Figure 1: The majority of low to moderate myopic eyes achieved 20/16 or better UCVA following wavefront-guided LASIK

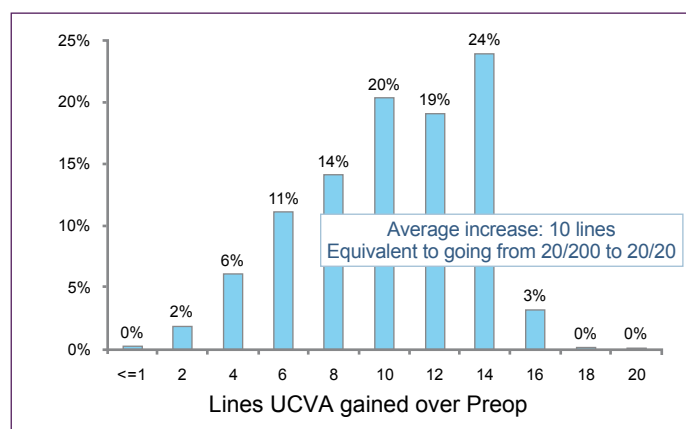


Figure 2: UCVA at one month improved an average of 10 lines compared to pre-op

But achieving better outcomes isn't free. It requires a commitment to excellence and an investment in advanced technology, such as wavefront-guided surgery, femtosecond lasers and outcomes tracking software. Surgeons and staff also need to invest the time to standardise preoperative testing, push for the most accurate postoperative refractions by testing beyond 20/20, and effectively gather the data needed to understand trends and personalise nomograms. Those who make such a commitment will see the payoff in improved visual results and higher rates of patient satisfaction.

Reference:

- Schallhorn SC, Venter JA. One-month outcomes of wavefront-guided LASIK for low to moderate myopia with the VISX STAR S4 laser in 32,569 eyes. *J Refract Surg* 2009;25 (Suppl):S634-41.

Using Biostatistics to Improve Outcomes



Keith A Hettinger, MS, MBA

With increasing prevalence of electronic medical records and unprecedented data storage capabilities, the role of biostatistics in a clinic setting presents a great opportunity. Using these data resources along with valid statistical analyses, clinicians are well positioned to improve patient outcomes.

Typically, the statistician's challenge is in drawing valid conclusions from limited amounts of data. In the Biostatistics Department at Optical Express, however, a different set of challenges present themselves. With a medical records database consisting of more than 5.5 million patients, our sample size allows for extremely robust estimation. But as statistical significance becomes more readily observable with such large samples it is imperative that clinical significance be carefully considered. It is also necessary to take caution when drawing inference from statistical methodologies derived from small sample theory.

Another challenge we have is the number of surgeons and staff members who routinely enter patient data into our system. While we continuously emphasise the importance of precision and consistency, it is imperative that the data be frequently and thoroughly reviewed for accuracy. Features like range validations, range restrictions, and comment boxes to verify unexpected values are among the methods we use to enhance quality as the data is being entered. Following data entry, we work to identify outliers and follow up with clinics that have unusual data trends. We also employ the assistance of third-party vendors in an effort to objectively measure the accuracy of our data. Last year, to ensure there were no errors in our data, an independent audit was conducted by Registrat, Inc., (Lexington, KY), a third-party clinical research organisation that specialises in data management. All of these measures give me great confidence in the accuracy of the Optical Express data that has been reported.

Our primary objective in the analyses of this data is to enhance patient outcomes. There are essentially three ways that data can be used to improve clinical outcomes.

1. Continual outcome monitoring. In order to avoid purely anecdotal conclusions, often prone to be influenced by recent cases or unhappy patients, it is necessary to review larger samples of patient outcomes in an ongoing manner. This approach not only helps to differentiate between anecdotal and data-driven observations, but also lends itself well to identifying variations in outcome trends.

At Optical Express we continually work with our surgeons to provide periodic outcomes reports. These reports serve as a valuable means by which the surgeon can individually review the outcomes of all their patients over time.

2. Statistical analyses can be used to drive technology choices and technique improvements. For instance: in a recent analysis we were able to conclude that patients achieved faster visual recovery and better postoperative UCVA with the IntraLase femtosecond laser compared

to a mechanical microkeratome¹. We also discovered that when a physician adjustment was used to alter the treatment sphere, it was more effective to make the treatment sphere equivalent to the manifest sphere than to make it within 0.5 D of manifest (as long as both the wavefront refraction and the manifest refraction were of high quality). These types of analysis-based findings help make treatment and technology decisions that improve patient outcomes.

3. Before/after comparisons are critical to verify the effects of a change. In the above case, the change in how physician adjustments were made to the treatment sphere yielded a three per cent increase in the percentage of patients achieving an UCVA of 20/20. Tracking and analysing performance following a recommended change ensures the accountability of the findings.

Of course, most medical practices don't have the luxury of a Biostatistics Department or access to the huge number of records discussed here. This does not mean that efforts should not be made to analyse clinical data. A few fundamental guidelines to maximise the utility of data in a clinic setting are outlined below.

- If possible, use an **electronic medical records (EMR)** system. When patient data are entered electronically, accuracy is improved and compiling data for research questions becomes considerably more efficient.
- Use commercially available software packages for **outcomes tracking and analysis**, or even a simple spreadsheet, to analyse your results.
- Preemptively consider what questions you want to ask and be sure to **capture the data** that will reasonably answer those questions – without overwhelming yourself and your staff with the burden of too much information.
- **Concentrate on descriptive statistics.** While sophisticated statistical methodologies are important, standard description measurements (such as postoperative, refraction, uncorrected visual acuity and change in best corrected vision) are crucial to accurately interpreting the data. Often these statistics prove to be the most meaningful.
- **Track changes over time.** Point-in-time analyses provide insight into the overall performance of the clinic. However, measurements of change over time will present valuable information regarding the variation, and potential causes, from this baseline.

Mr Hettinger is director of biostatistics at Optical Express.

Reference:

1. Tanna M, Schallhorn SC, Hettinger KA. Femtosecond laser versus mechanical microkeratome: a retrospective comparison of visual outcomes at 3 months. *J Refract Surg* 2009;25(Suppl):S668-71.

The Increasing Importance of the Patient Satisfaction Metric

Analysing the patient experience from start to finish reveals more realistic and holistic outcomes evaluations

Laser vision correction (LVC) patients reported a positive patient experience and high level of postoperative satisfaction, according to a recent large-scale study of more than 13,000 patients. This study assessed the level of patient satisfaction after LVC performed by Optical Express, a large corporate provider of refractive surgery. An interactive computer survey was used to query patients about their satisfaction with the services, experience and results of their LVC procedure. Studies such as this one provide practices with insights into the patients' perceptions of their entire experience.

Satisfaction metric

Patient satisfaction is an increasingly important metric for LVC surgeons and their centres. Most succinctly, the results can help a practice be more successful. Measuring and analysing satisfaction reveals how we can do a better job taking care of our patients. After all, an exceptional patient experience drives word-of-mouth referrals. In addition, patients are increasingly using the Internet as a source of information. Websites are expanding which have patient testimonials of both positive or negative experiences. With a clinic focussed on measuring and improving patient satisfaction, these Internet sites could essentially serve as a referral source.

Satisfaction factors

In addition to the visual outcome, many other factors influence patient satisfaction, including the friendliness of the staff, and how, or even if, patient anxiety is addressed before and during the procedure. Patient satisfaction can also be affected by the laser centre's physical appearance and the waiting time prior to examinations or treatment.

Vital patient experience information can be attained by asking simple questions, yet this is not performed in many practices. And even if it is, the results are often not thoughtfully or thoroughly analysed. A patient satisfaction survey helps surgeons gather feedback, modulate their approach and perhaps make course corrections based on responses. This is done so that patients' perceptions of their outcomes from the time they start the LVC process to the time they are finished are positive. This type of survey is advantageous, but it does take work. It requires the collected effort of all in the practice to administer, record data, interpret and make appropriate clinical/personnel adjustments as needed.

The Study

In 2008, Optical Express introduced an electronic patient satisfaction questionnaire to gauge the quality of care provided at its centres, how well patient expectations were being met, and the overall level of patient satisfaction. All LVC patients are asked to complete the questionnaire, which is accessible at private computer stations at Optical Express clinics, immediately after their one-day, one-week, one-month and three-month post-op follow-up appointments.

For this study, the population included all LASIK and laser epithelial keratomileusis (LASEK) patients. The ablations were performed using a STAR S4 IR excimer laser system (Abbott Medical Optics [AMO], Santa Ana, Calif). For LASIK patients, corneal flaps were created with either the IntraLase FS-60 (AMO) or the Moria Evo3 One Use-Plus microkeratome (Moria SA, Antony, France). For LASEK procedures, the epithelium was removed with an alcohol solution.

Questionnaire data were analysed from the responses of 13,655 consecutive patients who completed their one-month postoperative examination. Mean patient age was 39.4 years, 45 per cent male, and 55 per cent female. Myopic and hyperopic corrections (mean manifest spherical equivalent: -2.27 ± 2.66 D) were performed using LASIK (91 per cent) and LASEK (nine per cent).

Results

A very high level of satisfaction was observed both for the visual results obtained (95.0 per cent) and for the quality of postoperative care provided (98.6 per cent). Ninety-four per cent indicated that the surgery improved their life, and most said they would recommend both the LVC procedure and the corporate provider to friends and family. Most patients also gave positive feedback about the specific aspects of their care. For example, 98.6 per cent of patients reported being satisfied with their postoperative care, and most patients said they did not have to wait long before the start of their postoperative appointment. In addition, 95.0 per cent reported being satisfied with their visual results after surgery. Ninety-four per cent of patients indicated that their visual results met or exceeded their preoperative expectations. Eighty-three per cent of patients indicated that their vision was better after surgery than it had been with spectacles or contact lenses (Figure 1).

A good deal of patient satisfaction data isn't driven by visual outcome. Frequently, it is driven by perception of the process. This study is not an outcome measure of quality of vision; it is an outcome measure of the process.

The patient experience is an important aspect of the overall success of a refractive surgery practice. This study shows that, as we know intuitively based on anecdotal feedback, LVC is a very satisfying procedure and patients are happy with their quality of care, visual results and overall experience. These



John A Vukich, MD

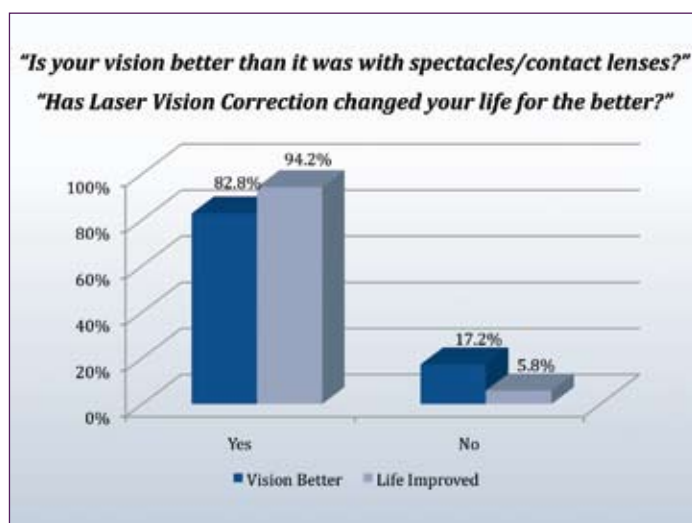


Figure 1: Overall 83 per cent of patients responded that their vision after surgery was better than it had been with spectacles or contact lenses. 94 per cent of patients said the procedure changed their life for the better

findings concur with a recent worldwide systematic review of more than 200 cases, conducted by the Joint LASIK Study Task Force¹. The task force's meta-analysis found that an average 95.4 per cent of 2,198 patients were satisfied with their outcome after LASIK surgery, the highest of any reported elective procedure.

Pearls for practices

Overall, patients are very pleased with the outcome of LVC and it has a positive impact on their lives, as demonstrated by this study of over 13,000 patients. This reinforces what is being done well but also points to where we can do a little bit better. For example, 97 per cent of patients rated their overall experience with Optical Express as "good" or "excellent". This allows us to focus on those few patients where we could do better. Was it an inadequate patient experience, such as the lack of a warm greeting or a lengthy wait before surgery? If we know what the problems are, it is easy to find solutions.

As is now evident, patient satisfaction is not solely determined by visual outcome. More important, it is the perception of the experience. The outcome measure of this study was not the quantity or quality of vision; rather, it was an assessment of the process from the patient perspective. This requires a different level of understanding. While it is time-honored and easy to measure acuity, an interactive survey reveals the entire start-to-finish process in the opinion of those who count most: our patients. It details the things that made them feel good about the care they received and the way they were treated. This is how we should determine success.

Sample Post-Operative Questionnaire

1. How satisfied are you with the post-operative care that we have provided for you since your treatment? (Very satisfied; Satisfied; Neither satisfied or dissatisfied; Dissatisfied; Very dissatisfied)
2. Overall how would you rate your experience so far? (Excellent; Good; Average; Poor; Very Poor)
3. How long did you wait in the clinic before your post-operative appointment commenced? (Less than 10 minutes; 10-20 minutes; More than 20 minutes)
4. How is your vision now compared with your expectations pre-treatment? (Better; Same; Worse)
5. How satisfied are you with your vision today? (Very satisfied; Satisfied; Neither satisfied or dissatisfied; Dissatisfied; Very dissatisfied)
6. Is your vision better than it was with spectacles/contact lenses? (Yes/No)
7. Has Laser Vision Correction changed your life for the better? (Yes/No)
8. Would you recommend Laser Vision Correction to your friends and family? (Yes/No)
9. Would you recommend our center to your friends and family? (Yes/No)

Figure 2: Sample Post-Operative Patient Satisfaction Questionnaire

Practices can easily implement an interactive survey as demonstrated by the Optical Express questionnaire (Figure 2). Careful and thoughtful analysis of results can be used to implement changes to improve patient satisfaction. This will greatly benefit everyone.

John A Vukich MD, is surgical director of the Davis Duehr Dean Center for Refractive Surgery in Madison, Wisconsin. He is a member of the Optical Express International Medical Advisory Board (IMAB) and a consultant for Abbott Medical Optics Inc.

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