How Good is LASIK?

The Myths, Misconceptions, and Reality

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Disclosure: Eric Donnenfeld, M.D.

- I am a consultant for:
  - Acufocus
  - Allergan
  - Alcon
  - AMO
  - Aquesys
  - Avedro
  - Bausch & Lomb
  - Beaver-visitec
  - Blephex
  - CRST
  - Elenza
  - EyePoint Pharma
  - Foresight
  - Glaukos
  - Icon Biosciences
  - Kala
  - Katena
  - Lacripen
  - Lensgen
  - Mati Pharmaceuticals
  - MDBackline
  - Merck
  - Mimetogen
  - Mynosis
  - Novabay
  - Novaliq
  - Ocuhub
  - Ocular Therapeutics
  - Odyssey
  - Omega Ophthalmics
  - Omeros
  - Oyster Point
  - Pogotec
  - PRN
  - RPS
  - Shire
  - Strathspey Crown
  - Surface
  - SUN
  - Tearlab
  - TearScience
  - TLC Laser Centers
  - TrueVision
  - Versant Ventures
  - Visionary Ventures
  - Zeiss
Is LASIK Worth Saving?
The Facts, Fiction and Future

- In spite of LASIK’s long clinical and historical presence, misconceptions regarding the risks and benefits of this procedure persist, eroding both the reputation of the procedure and of those in the field that remain its unwavering supporters.

- The aim of this lecture is to explore the myths and realities of the LASIK procedure using an evidenced-based approach and to evaluate upcoming advancements.
LASIK: Myths and Misconceptions

- Physicians would not have LASIK on their own eyes
- The long term effects of LASIK are not known
- Contact lenses are safer than LASIK
- LASIK significantly increases the risk of a patient having glare and halo
- The safety and efficacy of LASIK has not improved over time
- Dry eye is extremely common following LASIK
The Evolution of LASIK

Technology Advances
- Blend Zones
- Pupil Tracking
- Centroid Shift Compensation
- Cyclotorsion
  - Prolate Ablations
- Wavefront Ablations
- Topographic Ablations
- Improved Microkeratomes
- Femtosecond Laser Flap Formation
- Crosslinking
- Diagnostic Equipment

New Generation Excimer Lasers

Microkeratome
- 1958

Excimer Laser
- 1985

Femtosecond Lasers

Jose Barraquer

Steve Trokel
FDA Approves Summit Laser for PRK

Ms. Kimberley Doney
c/o Ms. Maureen O’Connell
Regulatory, Clinical, and Quality Affairs
Summit Technology, Inc.

4. All promotion and advertising for this device must include the following information on indications, risks and benefits:
   
a. Approval is for the Summit Technology’s application for the SVS Apex laser to correct mild to moderate nearsightedness (-1.5 to -7.0 diopters when concomitant astigmatism is no greater than 1.5 diopters) in a procedure called photorefractive keratectomy (PRK) using an excimer laser that emits light at a wavelength of 193nm.

b. PRK is an elective procedure with the alternatives being eyeglasses, contact lenses or radial keratotomy.

c. Approval of the application is based on clinical trials of more than 1600 eyes together with safety information through 3 years of follow up.

d. The studies using the 6mm treatment zone found that of the 341 eyes at 6 months, 95% were corrected to 20/40 or better without spectacles or contact lenses, and 65% to 20/20 or better without spectacles or contact lenses. In 23 out of 340 eyes (6.8%), the best vision that can be achieved with spectacles declined by more than 1 line from preop; none was worse than 20/40.

e. These clinical trials showed the following transient complications: pain (24-48 hrs), corneal swelling, double vision, feeling something in the eye, shadow images, light sensitivity, tearing and pupil enlargement. These problems lasted up to several weeks.

f. The clinical trials using the 6mm treatment zone showed the following adverse events occurred in at least 1.0% of the patients within 6 months post-treatment: night vision difficulty (1.0%); elevation of intraocular pressure (1.8%); hazy cornea affecting vision (2.3%); overcorrection or became farsighted (5.0%); undercorrection or still nearsighted (5.6%); loss of the best vision that can be achieved with glasses (6.8%); mild halo (9.7%); and, minor glare (10.0%).

g. Long term risks of PRK beyond 3 years have not been studied.
FDA Summit Trial Results:
1.5-7.0 Diopters Myopia

Re-epithelialization: Occurred in 95.4% of eyes within 72 hours; 100% of eyes within 1 week

6 Months:
- Uncorrected visual acuity: 20/20 or better: 66.0%
- Uncorrected visual acuity: 20/40 or better: 95.0%
- Predictability: % of eyes within +/- 0.5 D: 64.8%
- Predictability: % of eyes within +/- 1.0 D: 89.4%
- Success*: 91.8%

1 Year:
- Uncorrected visual acuity: 20/20 or better: 80.5%
- Uncorrected visual acuity: 20/40 or better: 98.8%
- Predictability: % of eyes within +/- 0.5 D: 51.2%
- Predictability: % of eyes within +/- 1.0 D: 86.6%
- Success*: 97.6%

*For this clinical investigation success was defined as an uncorrected visual acuity of 20/40 or better. Any patients who met this criteria but had a loss of best spectacle corrected visual acuity of more than 1 line and a best spectacle corrected visual acuity of 20/25 or worse were considered failures. Also any patients with major visual/ocular complications were considered failures.

6.8% of eyes lost 2 or more lines of BCVA
FDA VISX Trial Results:
1.0-6.0 Diopters Myopia

- 58.3% 20/20 or better
- 93.8% 20/40 or better
- 9.8% deviated from intended treatment by >1 D
Complications of Laser In Situ Keratomileusis for the Correction of Myopia

Complications occurred in approximately 5% of cases

Complication rates can be greatly reduced as the surgical team gains experience

- Intraoperative complications, 3.1% to 0.7%
- 4.7% of eyes lost 2 or more lines of BCVA

Table 4. Postoperative Complications*

<table>
<thead>
<tr>
<th>Type</th>
<th>No.</th>
<th>≥2 Line Loss BSCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flap slippage, partial</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Flap slippage, total</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Epithelial ingrowth</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>Keratitis, culture negative</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Flap folds</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>1</td>
</tr>
</tbody>
</table>
LASIK Complications: Etiology, Management, and Prevention

Samir A. Melki, MD, PhD, and Dimitri T. Azar, MD

TABLE 1

Incidence of LASIK Flap Complications from Studies with ≥1000 Eyes

<table>
<thead>
<tr>
<th>Study</th>
<th>Thin flap</th>
<th>Irregular flap</th>
<th>Buttonholed flap</th>
<th>Dislodged flap</th>
<th>BCVA loss ≥2 lines</th>
<th>Incomplete flap</th>
<th>Flap folds</th>
<th>Epithelial ingrowth</th>
<th>DLK</th>
<th>Infectious keratitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gimbel (1998)</td>
<td>0.3%</td>
<td>NR</td>
<td>0.3%</td>
<td>1.2%</td>
<td>1.6%</td>
<td>1.2%</td>
<td>1.5%</td>
<td>NR (1.0%)*</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Lin (1999)</td>
<td>0.49%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>2.0%</td>
<td>0%</td>
<td>0.3%</td>
<td>1.1%</td>
<td>NR (2.2%)*</td>
<td>3.2%</td>
<td>NR</td>
</tr>
<tr>
<td>Stulting (1999)</td>
<td>0.75%</td>
<td>0.09%</td>
<td>0.56%</td>
<td>1.1%</td>
<td>4.7%</td>
<td>0.75%</td>
<td>0.2%</td>
<td>9.1% (1.3%)*</td>
<td>0.2%</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

NR = Not reported; BCVA = ; DLK = Diffuse lamellar keratitis.
*% requiring surgical intervention

- Majority of complications flap related

Outline

I. Anatomic complications
   A. Thin/irregular/buttonholed flap
   B. Incomplete flap
   C. Dislodged flap
   D. Free cap
   E. Flap folds
   F. Epithelial implantation and ingrowth
   G. Interface debris
   H. Epithelial defects
      I. Corneal perforation
      J. Corneal ectasia
II. Refractive complications
   A. Central islands
   B. Decentration
   C. Over- and under-correction
   D. Residual/induced astigmatism
   E. Regression
   F. Halos and glare
   G. Loss of contrast sensitivity
III. Loss of best-spectacle corrected visual acuity (BSCVA)
IV. Dry eyes
V. Infectious keratitis and sterile infiltrates
VI. Diffuse lamellar keratitis
VII. Other complications
VIII. Conclusions
Complications of LASIK higher in patients with over 7 D myopia

Patients being treated with LASIK for up to 25 diopters of myopia
special report

Infectious keratitis after laser in situ keratomileusis: Results of an ASCRS survey

Renée Solomon, MD, Eric D. Donnenfeld, MD, Dimitri T. Azar, MD, Edward J. Holland, MD, F. Rick Palmon, MD, Stephen C. Pflugfelder, MD, Jonathan B. Rubenstein, MD

ASCRS White Paper
Management of infectious keratitis following laser in situ keratomileusis

Eric D. Donnenfeld, MD, Terry Kim, MD, Edward J. Holland, MD, Dimitri T. Azar, MD, F. Rick Palmon, MD, Jonathan B. Rubenstein, MD, Sheraz Daya, MD, Sonia H. Yoo, MD

- Mycobacterium: 48%
- Staph: 33%
- Strep: 3%
- Fungal: 10%
- Nocardia: 3%
- Noccardia: 3%
- Gram Negative: 3%

- Incidence: 1/2,919
Selecting the Right Patient and Treatment

Pupil Size and Quality of Vision after LASIK

Patients with large pupils had more quality of vision symptoms in the early postoperative period, but no correlation was observed 6 months after surgery.

Incidence and Associations of Retreatment After LASIK

Higher initial corrections, astigmatism, and older age are risk factors for LASIK retreatment. Most LASIK flaps can be lifted using the manual technique described up to 3 years after initial surgery.

Infections Following Laser in Situ Keratomileusis: An Integration of the Published Literature

Importance of changing the microkeratome blade between eyes. Gram-positive and mycobacterial infections were most common in this study.

Laser in situ keratomileusis in patients with autoimmune diseases

In this series, they found good outcomes when correcting refractive errors using LASIK in selected patients with controlled rheumatic diseases.

To lift or recut: Changing trends in LASIK enhancement

LASIK enhancement surgery can be performed safely and effectively by lifting the flap but a second flap formation is usually not indicated.

Corneal Epithelial Adhesion Abnormalities Associated with LASIK

Corneal epithelial dysadhesion and defects occurring in the course of LASIK surgery may be associated with an intrinsic compromise of the basement membrane adhesion complex.
There is a significant transient loss of corneal sensation following LASIK.

Corneal sensation improves to preoperative levels at 6 months following surgery.

Dry eye signs and symptoms statistically return to normal at 6 months following surgery.
Risk Assessment for Ectasia after Corneal Refractive Surgery

J. Bradley Randleman, MD, 1, 2 Maria Woodward, MD, 1 Michael J. Lynn, MS, 3 R. Doyle Stulting, MD, PhD 1, 2

Table 5. Ectasia Risk Factor Score System

<table>
<thead>
<tr>
<th>Parameter</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topography pattern</td>
<td>FFKC</td>
<td>Inferior steepening/SRA</td>
<td>ABT</td>
<td>Normal/SBT</td>
<td></td>
</tr>
<tr>
<td>RSB thickness (µm)</td>
<td>&lt;240</td>
<td>240–259</td>
<td>260–279</td>
<td>280–299</td>
<td>&gt;300</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>18–21</td>
<td>22–25</td>
<td>26–29</td>
<td>&gt;300</td>
<td></td>
</tr>
<tr>
<td>CT (µm)</td>
<td>&lt;450</td>
<td>451–480</td>
<td>481–510</td>
<td>&gt;510</td>
<td></td>
</tr>
<tr>
<td>MRSE (D)</td>
<td>&gt;-14</td>
<td>&gt;-12 to -14</td>
<td>&gt;-10 to -12</td>
<td>&gt;-8 to -10</td>
<td>-8 or less</td>
</tr>
</tbody>
</table>

ABT = asymmetric bowtie; CT = preoperative corneal thickness; D = diopters; FFKC = forme fruste keratoconus; MRSE = preoperative spherical equivalent manifest refraction; RSB = residual stromal bed; SBT = symmetric bowtie; SRA = skewed radial axis.

Table 6. Ectasia Risk Factor Score Categories

<table>
<thead>
<tr>
<th>Cumulative Risk Scale Score</th>
<th>Risk Category</th>
<th>Recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 or 2</td>
<td>Low risk</td>
<td>Proceed with LASIK or surface ablation</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Moderate risk</td>
<td>Proceed with caution, consider special informed consent; safety of surface ablation has not been established</td>
<td>Consider MRSE stability, degree of astigmatism, between-eye topographic asymmetry, and family history</td>
</tr>
<tr>
<td>4 or more</td>
<td>High risk</td>
<td>Do not perform LASIK; safety of surface ablation has not been established</td>
<td></td>
</tr>
</tbody>
</table>

MRSE = preoperative spherical equivalent manifest refraction.

Table 7. Ectasia Risk Factor Score Comparisons

<table>
<thead>
<tr>
<th>Category</th>
<th>Ectasia (n = 86)</th>
<th>Controls (n = 133)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>6 (7%)</td>
<td>117 (88%)</td>
<td>&lt;1.0×10^-7</td>
</tr>
<tr>
<td>Moderate risk</td>
<td>2 (2.3%)</td>
<td>11 (8.2%)</td>
<td>0.4</td>
</tr>
<tr>
<td>High risk</td>
<td>78 (90.7%)</td>
<td>5 (3.8%)</td>
<td>&lt;1.0×10^-7</td>
</tr>
</tbody>
</table>

Sensitivity = 91%; specificity = 96%.

Figure 12. Bar graph showing comparison of ectasia screening strategies. The screening strategy proposed in this article is significantly better at identifying ectasia cases as high risk than the Orbscan technique proposed by Tabbara and Korb. 80
**FDA Public Hearing**

- 140 complaints to the FDA after over 10 million procedures
- Anti-LASIK activists wished to ban the procedure
- Public testimony included personal stories of depression, suicide or suicidal ideation, and other psychological problems

### When is LASIK not for me?

You are probably NOT a good candidate for refractive surgery if:

- **You are not a risk taker.** Certain complications are unavoidable in a percentage of patients, and there are no long-term data available for current procedures.
- **It will jeopardize your career.** Some jobs prohibit certain refractive procedures. Be sure to check with your employer/professional society/military service before undergoing any procedure.
- **Cost is an issue.** Most medical insurance will not pay for refractive surgery. Although the cost is coming down, it is still significant.
- **You required a change in your contact lens or glasses prescription in the past year.** This is called refractive instability. Patients who are:
  - In their early 20s or younger,
  - Whose hormones are fluctuating due to disease such as diabetes,
  - Who are pregnant or breastfeeding, or
  - Who are taking medications that may cause fluctuations in vision,
  - Who are more likely to have refractive instability and should discuss the possible additional risks with their doctor.
- **You have a disease or are on medications that may affect wound healing.** Certain conditions, such as autoimmune diseases (e.g., lupus, rheumatoid arthritis), immunodeficiency states (e.g., HIV) and diabetes, and some medications (e.g., retinoic acid and steroids) may prevent proper healing after a refractive procedure.
- **You actively participate in contact sports.** You participate in boxing, wrestling, martial arts or other activities in which blows to the face and eyes are a normal occurrence.
- **You are not an adult.** Currently, no lasers are approved for LASIK on persons under the age of 18.
FDA Public Hearing

- I spoke on behalf of LASIK at the hearing, but mostly I listened.

- Overwhelmingly the most common concern I heard was that the patient felt a sense of abandonment by the surgeon.
LASIK World Literature Review

Quality of Life and Patient Satisfaction

Kerry D. Solomon, MD,1 Luis E. Fernández de Castro, MD,1 Helga P. Sandoval, MD, MSCR,1 Joseph M. Biber, MD,1 Brian Groat, MD,1 Kristiana D. Neff, MD,1 Michelle S. Ying, MD, MSPH,1 John W. French, MD,1 Eric D. Donnenfeld, MD,2 Richard L. Lindstrom, MD,3 for the Joint LASIK Study Task Force*
Total Number of Eyes: 32,000
Dry Eye Rates
Pre- & Post-Operative

Preoperative Rate: 32%
Postoperative Rate: 35%
A 10-Year Prospective Audit of LASIK Outcomes for Myopia in 37,932 Eyes at a Single Institution in Asia

Leonard H. Yuen, MD, MPH, Wing Kwong Chan, FRCOphth, FRCS(Ed), Jane Koh, Adv. Dip. Stat. (Sp), Jodhpur S. Mehta, FRCOphth, FRCS(Ed), Donald T. Tan, FRCOphth, FRCS(Ed), for the SingLasik Research Group*

Figure 1. Overall efficacy of myopic LASIK from 1998 to 2007: percentage of eyes achieving uncorrected visual acuity (UCVA) of ≥20/40, ≥20/20, and ≥20/15.

Figure 3. Overall safety of myopic LASIK: percentage of eyes with loss of 1 line or 2 lines of best spectacle-corrected visual acuity.

Ten year trend of continuous improvement in visual acuity and safety
# Femtosecond Lasers for LASIK Flap Creation

**A Report by the American Academy of Ophthalmology**

Ayad A. Farjo, MD,¹ Alan Sugar, MD, MS,² Steven C. Schallhorn, MD,³ Parag A. Majmudar, MD,⁴ David J. Tanzer, MD,⁵ William B. Trattler, MD,⁶ John B. Cason, MD,⁷ Kendall E. Donaldson, MD, MS⁸ George D. Kymionis, MD, PhD⁹

<table>
<thead>
<tr>
<th>Laser Device Name</th>
<th>Company</th>
<th>Date Approved</th>
<th>K Number</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMTO LDV (formerly Du Vinci Femtosecond Surgical Laser)</td>
<td>Ziemer Ophthalmic Systems AG* (Port, Switzerland)</td>
<td>March 10, 2006</td>
<td>K053511</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>iFS Laser System</td>
<td>Advanced Medical Optics, Inc.* (Santa Ana, CA)</td>
<td>April 25, 2008</td>
<td>K073404</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>Intralase Fusion Laser, Intralase FS Laser, Intralase FS Laser, Models 1,2,3</td>
<td>Intralase Corp.*</td>
<td>August 16, 2006</td>
<td>K060372</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>Intralase FS Laser, Keratome</td>
<td>Intralase Corp.*</td>
<td>September 29, 2003</td>
<td>K031960</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>Technolas Femtosecond Workstation Custom Flap (formerly Fem Tec Laser Micromatrix)</td>
<td>Technolas Perfect Vision GmbH* (Munich, Germany)</td>
<td>February 18, 2004</td>
<td>K033354</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>VisuMax Laser Keratome</td>
<td>Carl Zeiss Meditec AG</td>
<td>July 8, 2010</td>
<td>K100253</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
<tr>
<td>WaveLight FS200 Laser System</td>
<td>Alcon Laboratories, Inc. (Fort Worth, TX)</td>
<td>October 21, 2010</td>
<td>K101006</td>
<td>Creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
</tr>
</tbody>
</table>
Long-term follow-up after laser vision correction in physicians: Quality of life and patient satisfaction

Theodore A. Pasquali, MD, David Smadja, MD, Michael J. Savetsky, MD, Glauco H. Reggiani Mello, MD, PhD, Fadiah Alkhawaldeh, Ronald R. Krueger, MD, MSE

- **132 physicians**
- **Satisfaction 95.3%**
- **Improved quality of vision compared to glasses 84.8%**

### Table 2. Patient responses to question 10: “How bothered have you been by each of the following items?” (n = 128).

<table>
<thead>
<tr>
<th>Response</th>
<th>No Trouble At All</th>
<th>A Little Trouble</th>
<th>Moderate Trouble</th>
<th>Severe Trouble</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your eyes feeling irritated</td>
<td>64 (50)</td>
<td>52 (41)</td>
<td>10 (8)</td>
<td>2 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Eyes being sensitive to light</td>
<td>90 (70)</td>
<td>29 (23)</td>
<td>5 (4)</td>
<td>3 (2)</td>
<td>1</td>
</tr>
<tr>
<td>Pain in your eyes</td>
<td>118 (92)</td>
<td>8 (6)</td>
<td>0</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Changes in your vision during the day</td>
<td>99 (77)</td>
<td>26 (20)</td>
<td>0</td>
<td>2 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Glare (reflections off shiny surfaces, snow)</td>
<td>72 (56)</td>
<td>47 (37)</td>
<td>8 (6)</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Seeing a halo around lights</td>
<td>75 (58)</td>
<td>38 (30)</td>
<td>14 (11)</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Seeing in dim light</td>
<td>83 (65)</td>
<td>30 (23)</td>
<td>14 (11)</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Judging distance when going up or down steps</td>
<td>121 (95)</td>
<td>6 (5)</td>
<td>0</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Your depth perception</td>
<td>113 (88)</td>
<td>14 (11)</td>
<td>0</td>
<td>0</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>
Prevalence of laser vision correction in ophthalmologists who perform refractive surgery

Guy M. Kezirian, MD, MBA, Gregory D. Parkhurst, MD, Jason P. Brinton, MD, Richard A. Norden, MD

Table 1. Reasons reported for the 54 (33.5%) of the 161 ophthalmologists who indicated they have refractive errors but were “ineligible for corneal laser refractive surgery.”

<table>
<thead>
<tr>
<th>Reason</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive error exceeded FDA approval</td>
<td>13</td>
<td>24.1</td>
</tr>
<tr>
<td>Dry eyes</td>
<td>13</td>
<td>24.1</td>
</tr>
<tr>
<td>Keratoconus or keratoconus suspect</td>
<td>5</td>
<td>9.3</td>
</tr>
<tr>
<td>Medical/ophthalmic contraindication</td>
<td>4</td>
<td>7.4</td>
</tr>
<tr>
<td>Prior procedure before lasers were approved</td>
<td>4</td>
<td>7.4</td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td>2</td>
<td>3.7</td>
</tr>
<tr>
<td>Had a lens-based procedure</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Prior corneal surgery</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Not specified</td>
<td>11</td>
<td>20.4</td>
</tr>
</tbody>
</table>

FDA = Food and Drug Administration

Table 2. Reasons reported log the 49/116 (42%) surgeons in the LVC candidate cohort who were candidates for LVC but reported they had not had a procedure.

<table>
<thead>
<tr>
<th>Reason</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concern or fear of complications</td>
<td>2</td>
<td>5.0</td>
</tr>
<tr>
<td>Waiting for alternate technology</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td>Prefer to wear glasses and/or contacts</td>
<td>37</td>
<td>92.5</td>
</tr>
</tbody>
</table>

WHAT WAS KNOWN

- The prevalence of refractive errors amendable to LVC is approximately 42% in the general U.S. population, and approximately 13.1% of the eligible U.S. population has had LVC. Satisfaction rates average 95.4% worldwide, ranging from 87.2% to 100%.

WHAT THIS PAPER ADDS

- Refractive surgeons were approximately 4 times more likely to have LVC than the general population. Between 90.2% and 98.6% recommended LVC to their immediate family members. The incidence of ametropia among ophthalmologists performing refractive surgery was significantly higher than in the general population. The prevalence of myopia was 53.4% and of refractive errors overall was 69.4%.
LASIK Quality of Life Collaboration Project

PIs: Malvina Eydelman (FDA)
Frederick Ferris (NE)
Study Director: C. Pat Wilkinson (FDA)

PROWL-1
PIs:
Elizabeth Hofmeister (DoD)
Malvina Eydelman

PROWL-2
PIs:
Malvina Eydelman
Frederick Ferris
3 Month Uncorrected Visual Acuity Outcomes

<table>
<thead>
<tr>
<th></th>
<th>PROWL-1 N=225</th>
<th>PROWL-2 N=270</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCVA 20/20 or better</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OD</td>
<td>97%</td>
<td>91%</td>
</tr>
<tr>
<td>OS</td>
<td>98%</td>
<td>92%</td>
</tr>
<tr>
<td>OU</td>
<td>99%</td>
<td>96%</td>
</tr>
</tbody>
</table>

- No enhancements performed
# 3 Month Acuity and Refractive Safety Outcomes

<table>
<thead>
<tr>
<th></th>
<th>PROWL-1 N=450 (eyes)</th>
<th>PROWL-2 N=540 (eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of 2 lines or more BCVA</td>
<td>1 (0.2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>BCVA worse than 20/40</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Increase of greater than 2D of cylinder compared to baseline</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>BCVA worse than 20/25 if 20/20 or better pre-op</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

- **0.1% of eyes lost 2 lines of BCVA from pre-op to 3 Months**
Prevalence of Symptoms: Pre-Operative vs. Month 3

- **Ghosting**: 29 (Preoperative), 7 (Month 3)
- **Glare**: 33 (Preoperative), 23 (Month 3)
- **Halos**: 41 (Preoperative), 41 (Month 3)
- **Starburst**: 56 (Preoperative), 56 (Month 3)

The prevalence of visual symptoms did not increase postoperatively.
Subjects Developing New Dry Eye Symptoms (OSDI Categories) at 3 Months

- Mild: 25% (3 Month: 23, 3 Month: 23)
- Moderate: 10% (3 Month: 3, 3 Month: 2)
- Severe: 5% (3 Month: 1, 3 Month: 3)

Up to 30% of subjects developed new dry eye symptoms.
Overall Satisfaction With Present Vision

96% and 98.7% of subjects were satisfied with their vision at Month 3.

PROWL 1
- Preoperative
- Month 3

PROWL 2
- Preoperative
- Month 3

- Completely satisfied
- Very satisfied
- Somewhat satisfied
Prevalence of Visual Symptoms at 3 Months Dissatisfied vs. Satisfied (Present Vision)

- The majority of dissatisfied subjects reported visual symptoms.
Modern laser in situ keratomileusis outcomes

Helga P. Sandoval, MD, MSCR, Eric D. Donnenfeld, MD, Thomas Kohnen, MD, PhD, FEBBO, Richard L. Lindstrom, MD, Richard Potvin, OD, David M. Tremblay, MD, Kerry D. Solomon, MD

Laser in situ keratomileusis (LASIK) articles published between 2008 and 2015 that contain clinical outcomes data were reviewed and graded for quality, impression, and potential bias. All 37 relevant articles (representing 67,853 eyes) provided a positive or neutral impression of LASIK. Industry bias was not evident. The aggregate loss of 2 or more lines of corrected distance visual acuity was 0.61% (359/58,653). The overall percentage of eyes with uncorrected distance visual acuity better than 20/40 was 99.5% (59,503/59,833). The spherical equivalent refraction was within ±1.0 diopter (D) of the target refraction in 98.6% (59,476/60,329) of eyes, with 90.9% (59,954/66,974) within ±0.5 D. In studies reporting patient satisfaction, 1.2% (1,292/87,206) of patients were dissatisfied with LASIK. Aggregate outcomes appear better than those reported in topography. Results in numerous studies have shown good efficacy, safety, stability, and predictability in treating both myopia and hyperopia with or without astigmatism.

An analysis of early outcomes data from 1994 to 2004 documented the complications associated with LASIK. Most were related to the use of early microkeratomes, excimer laser ablation profiles, and surgeon experience. An FDA panel meeting was held in 2008 in response to 140 dissatisfied LASIK patients to reevaluate the procedure. As a result of the panel, a comprehensive literature review of patient satisfaction was conducted in 2008. Results showed high patient satisfaction; approximately 95% of patients were satisfied with their visual outcome after myopic and hyperopic LASIK.
Three-Year Longitudinal Survey Comparing Visual Satisfaction with LASIK and Contact Lenses

Marianne O. Price, PhD,1 David A. Price, BS,1 Frank A. Bucci, Jr., MD,2 Daniel S. Darrie, MD,1
William I. Bond, MD,1 Francis W. Price, Jr., MD3

Purpose: To assess patient satisfaction and perceived outcomes with different methods of refractive error correction through annual surveys administered over a 3-year period.

Design: Prospective, longitudinal, parallel-group, multicenter survey.

Participants: A total of 1800 subjects, aged 18 to 60 years, who had LASIK or continued using contact lenses.

Methods: Twenty sites across the United States enrolled subjects who completed a study-specific baseline survey during a contact lens examination or while being evaluated as a candidate for LASIK. Links to follow-up surveys were emailed annually for 3 years. Between-group differences were assessed by analysis of variance.

1800 Patients studied over 3 years
Significantly greater satisfaction with LASIK
Better night driving with LASIK
Less infections and ulcers with LASIK
Risk of infection with LASIK and soft contact lenses similar
Risk of infection much less with LASIK than extended wear contact lenses

and approximately 8 million people in the U.S. have

Accepted: May 19, 2009.

From a private practice (McGee), Pittsburgh, Pennsylvania, and
Casey Eye Institute (Mathers), Oregon Health & Science University,
Portland, Oregon, USA.

Neither author has a financial or proprietary interest in any material
or method mentioned.

Supported in part by an unrestricted grant to Casey Eye Institute
from Research to Prevent Blindness, New York, New York, USA.

Corresponding author: William D. Mathers, MD, Casey Eye Insti-
tute, 3375 Southwest Tenochtitlan Boulevard, Portland, Oregon
97239-4197, USA. E-mail: mathersw@ohsu.edu.
Risk of Infection with daily wear contact lenses 5.5 times greater than LASIK at 5 years

Risk of Infection with extended wear contact lenses 40 times greater than LASIK at 5 years

multifactorial and includes associations with lens type, wear schedule, and hygiene. Although contact lens wear has long established as a major cause of microbial keratitis, microbial keratitis has more recently been described as a potential complication after refractive surgery.¹

The burden of microbial keratitis, and specifically microbial keratitis associated with contact lens wear, has more recently come forth.² With approximately 38 million contact lens wearers in the United States, there were an estimated 1 million clinical visits secondary to microbial keratitis and contact lens–related ICD-9 codes in the year 2010. This correlated with an economic burden of or irregular astigmatism. Contact lenses have traditionally been considered safer than refractive surgery as a means of correcting refractive error; however, recent analyses and dialog have questioned this assumption.³ When assessed independently, comparisons between the rates of contact lens–related microbial keratitis and microbial keratitis after laser in situ keratomileusis (LASIK) can be inferred; however, the risk for microbial keratitis from contact lens use cannot be directly compared with the risk for post-LASIK microbial keratitis. Large-scale randomized studies comparing these 2 entities would be impossible given the relative rarity of each condition and the statistical power needed to obtain a significant
Surgical Complications LASIK
Post Surgical Complications LASIK
LVC Problem ➔ LVC Solution

Ablation decentration ➔

- Pupil tracking
- Centroid shift compensation
- Cyclotorsion compensation
- Z tracking
LVC Problem → LVC Solution

PRK corneal haze → Mitomycin C

Mitomycin-C for post-PRK corneal haze

Tal Raviv, MD, Parag A Majmudar, MD, Richard F Dennis, Randy J Epstein, MD
LVC Problem → LVC Solution

Flap complications →

- Femtosecond laser
- Better microkeratomes
LVC Problem \( \rightarrow \) LVC Solution

Glare and halo \( \rightarrow \)

- Blend Zones
- Customized Ablations
- Optimized Ablations
Ectasia

Better diagnostic equipment/patient selection

Crosslinking
Topography Based Ablations

- Placido topographer
- Calculates height data
- Locates pupil centroid
- Locates corneal apex

Treatment Notebook

- Treatment Zernikes
- HOA
- Height Profile

Combines Z2 from MR with Z3 and higher from topography to create shot file
Subtracts best asphere and calculates high-order Zernikes
Calculates mean height profile from 4–8 images
Topography-Guided Ablation Steepens Flat and Flattens the Steep Areas

Hyperopic Treatment

Myopic Treatment
Refractive & Corneal details

<table>
<thead>
<tr>
<th>Refraction</th>
<th>+0.00 D +0.00 D @ 0 º / 12.0 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pupil/Medication</td>
<td>6.5 mm / keines</td>
</tr>
<tr>
<td>Pachometry Superior</td>
<td>476 µm</td>
</tr>
<tr>
<td>Pachometry Temporal</td>
<td>476 µm</td>
</tr>
<tr>
<td>Pachometry Central</td>
<td>476 µm</td>
</tr>
<tr>
<td>Pachometry Nasal</td>
<td>476 µm</td>
</tr>
<tr>
<td>Pachometry Inferior</td>
<td>476 µm</td>
</tr>
<tr>
<td>K1 / Q1</td>
<td>44.06 D @ 131 º / ---</td>
</tr>
<tr>
<td>K2 / Q2</td>
<td>45.92 D @ 41 º / ---</td>
</tr>
</tbody>
</table>

Treatment details

| Measured     | -0.84 D -2.88 D @ 159 º / 12 mm |
| Target       | --- D --- D / --- / ---   |
| Correction   | +0.00 D +0.00 D @ 0 º / 12 mm |
| Target Q     | ---                         |
| Optical zone | 6.50 mm                    |
| Transition zone | 1.25 mm                  |
| Ablation zone | 9.00 mm                    |
| Nmogram      | S101                       |
| Planned flap | 110 µm                     |
| Cornea thickness | 476 µm                  |
| Residual stroma | 285 µm                   |

Treatment related information

| Cyclorotation (static) | --- º |
| Pachometry records     |       |
| Central X/Y            | 370 µm / 350 µm |
| Total duration          | 19 s   |
| Breaks                  | 0 (0 s) |

Ablation profile

Memo

ALCON Laboratories, Inc.
6201 S. Freeway
Fort Worth, TX 76134, USA

Technical Service Hotline
Phone: +1 949-753-1393
Internet: www.alcon.com

Printed at 01.04.2016 by user LASIK
Wavelight® WPS
Visual and keratometric outcomes of keratoconus patients after sequential corneal crosslinking and topography-guided surface ablation: Early United States experience

Alanna Nattis, DO, Eric D. Donnenfeld, MD, Eric Rosenberg, DO, MSE, Henry D. Perry, MD

Purpose: To evaluate a sequential treatment algorithm for visual and keratometric improvement in keratoconus patients after treatment with sequential treatment of corneal crosslinking with a custom topographic-guided surface ablation. The BCVA and keratometric outcomes were analyzed for significance and a correlation with visual and astigmatic outcomes.

62 eyes follow for a minimum of 6 months following topographic PRK

Mean improvement of spectacle BCVA from 20/60 to 20/30
LVC Problem ➔ LVC Solution

Dry eye ➔

- Pre-op tear film testing and treatment
- Thinner flaps
- Smaller flaps
- Topical cyclosporine


Better Dry Eye Diagnosis and Management

- Point of service objective dry eye diagnostics.
- Better treatments for dry eye disease.
The Future: Dry Eye Pipeline

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Company</th>
<th>MOA</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclokat</td>
<td>Santen</td>
<td>Immunosuppressive</td>
<td>EMA approval 3/15</td>
</tr>
<tr>
<td>Mim-D3</td>
<td>Mimetogen</td>
<td>Cyclokat (Ikervis)</td>
<td>Phase 3</td>
</tr>
<tr>
<td>SI-614</td>
<td>Seikagaku</td>
<td>Modified HA</td>
<td>Phase 3</td>
</tr>
<tr>
<td>KPI-121</td>
<td>Kala</td>
<td>Immunosuppressive</td>
<td>Phase 3</td>
</tr>
<tr>
<td>SKQ1</td>
<td>Mitotech</td>
<td>Mitochondria-targeted antioxidant</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Dexamethasone punctal plug</td>
<td>Ocular Therapeutix</td>
<td>Slow-release dexamethasone</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Cross-linked HA</td>
<td>Jade</td>
<td>Modified HA</td>
<td>Phase 2</td>
</tr>
<tr>
<td>CycloASol</td>
<td>Novaliq</td>
<td>Immunosuppressive</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Cis-UCA</td>
<td>Herantis</td>
<td>Anti-inflammatory, protective effect to UVB stress</td>
<td>Phase 2</td>
</tr>
<tr>
<td>EBI-005</td>
<td>Eleven</td>
<td>II-1 antagonist</td>
<td>Phase 3</td>
</tr>
<tr>
<td>RGN-259</td>
<td>ReGenTree</td>
<td>Thymosin beta-4</td>
<td>Phase 3</td>
</tr>
</tbody>
</table>
LASIK Myth #1: Physicians Would Not Have LASIK on Their Own Eyes

LASIK Fact:
- Physicians have among the highest prevalence of having undergone LASIK of any occupation.
LASIK Myth #2:
The Long Term Effects of LASIK are Not Known

◆ LASIK Fact:

- LASIK has over a 20 year track record
- Long term studies have shown refractive stability and safety
LASIK Myth #3: Contact Lenses are Safer Than LASIK

LASIK Fact:

- Daily wear contact lenses are likely less safe than LASIK when worn for 30 years
- Extended wear contact lenses are definitely less safe than LASIK when worn for 30 years
LASIK Myth #4: LASIK Increases the Risk of Glare and Halo Compared to Glasses

LASIK Fact:

- Modern LASIK improves glare and halo for the majority of patients
- There are a minority of patients who will develop glare and halo that did not have symptoms preoperatively

Tanzer LASIK in Pilots JCRS 2013
Price LASIK vs Contact Lens
LASIK Myth #5:
The Safety and Efficacy of LASIK Has Not Improved Over Time

◆ LASIK Fact:

- LASIK is the safest procedure with the greatest patient satisfaction of any surgery performed in the world today

- The safety and efficacy have both improved markedly over the last 20 years and will continue to improve with new and improved technology advances
LASIK Myth #6:
Dry Eye is Extremely Common After LASIK

◆ LASIK Fact:

- Dry eye is extremely common after LASIK for the first 3 months
- Dry eye after LASIK usually resolves after 6 months
LASIK Myth # 7

LASIK Patients are Bad Premium IOL Candidates

New Generation Laser Systems

Technology Advances in IOL Therapy
Low Add Multifocal IOLs are Better Tolerated by Patients

Percent of patients who would elect to have the same IOL again:

- TECNIS® Multifocal +4.0 D: 87%
- TECNIS® Multifocal +3.25 D: 94%
- TECNIS® Multifocal +2.75 D: 97%
Low Add Multifocal IOLs are Better Tolerated by Patients

Would you have the same implant again?

Percent of Subjects

- IQ ReSTOR® IOL +3.0 D [N=138]
- IQ ReSTOR® IOL +4.0 D [N=131]

Source: AcrySof® IQ ReSTOR® IOL Package Insert
## Clinical Effectiveness Criteria for EDOF IOLs

<table>
<thead>
<tr>
<th>Metric</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of focus (monocular)</td>
<td>≥0.5 D greater than the monofocal control at 0.2 logMAR</td>
</tr>
<tr>
<td>DCIVA (monocular)</td>
<td>Superior to the monofocal control</td>
</tr>
<tr>
<td>DCIVA (monocular)</td>
<td>Achieve 0.2 logMAR or better in 50% of eyes</td>
</tr>
<tr>
<td>BCDVA (monocular)</td>
<td>Non-inferior to the monofocal control</td>
</tr>
</tbody>
</table>

BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity

1. MacRae S et al. Ophthalmology 2017;124:139
Symfony Extended Depth of Focus IOL

- Diffractive echelette design feature introduces a novel pattern of light diffraction that elongates the focus of the eye resulting in an extended range of vision\(^1\)
AcrySof IQ Vivity: Surface Transition Elements Alter the Wavefront

- Surface Transition Element #1 alters the wavefront, stretching it
- Surface Transition Elements #2 shifts the wavefront to ensure all the available light is usable
**Vivity Defocus Curve**

All-implanted analysis set; first eye; at 6 month post-op

Mean Monocular Defocus Curve with 95% Confidence Limits

**Met EDOF Effectiveness Criteria:**

*Vivity™ IOL demonstrated a monocular defocus range greater than 0.50 D compared to the monofocal control IOL at 0.20 logMAR at 6 Months*
Effectiveness Objective: Co-Primary

All-implanted analysis set; at 6 month post-op

Spectacle Independence

18% more vs AcrySof® IQ Monofocal IOL (95% CI 9.65, 27.37)

A greater proportion of AcrySof® IQ Vivity™ Extended Vision IOL implanted patients reported spectacle independence vs monofocal IOL implanted patients

Responded “Never” to Q1 of the IOLSAT Questionnaire: “Overall, in the past 7 days, how often did you need to wear eyeglasses to see?”

n represents number of patients with concordant data (consistent responses to the leading and sub-questions)

LCL, lower confidence limit
Binocular Uncorrected Visual Acuity

All-implanted analysis set; at 6 month post-op

UCDVA  
20/20

UCIVA (66)  
>20/25

UCNVA (40)  
20/32

Mean and Standard Deviation were reported.  
Snellen VA was converted from logMAR VA. A Snellen notation of 20/20 or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
No significant differences were observed between the two groups, except for blurred vision where significantly more patients with the AcrySof® IQ Vivity Extended Vision IOL reported “no blurred vision.”
What is the same?

• Refractive technology (no rings).
• Visually indistinguishable from the TECNIS® IOL (ZCB00)
• Same base geometry as all other TECNIS® lenses
• Same material (chromatic dispersion), spherical aberration and A-constant

What is different?

• Designed to improve intermediate vision while providing distance vision comparable to the aspheric monofocal, TECNIS® 1-Piece IOL (ZCB00)
• Progressive in power: The power changes continuously from the center to the periphery of the lens, creating a unique anterior surface power profile
• Power profile is created with a higher order asphericity
Monocular First Eye Defocus Curve at 6 months
ICB00 and ZCB00
All Subjects, Safety Population

TECNIS 1 piece IOL (ZCB00)  TECNIS Eyhance IOL (ICB00)
Monocular distance vision with TECNIS Eyhance® IOL is comparable (non-inferior within 1 line) to that of TECNIS® 1-Piece IOL¹

Contrast Sensitivity

TECNIS Eyhance® IOL provides distance contrast sensitivity at the level of an aspheric monofocal IOL \(^1\)

---

Enhanced monocular intermediate vision with TECNIS Eyhance® IOL vs TECNIS® 1-Piece IOL

- TECNIS Eyhance® IOL provides statistically significant improvement in monocular intermediate vision at 66 cm¹

The Future: Better Technology

- Advanced wavefront technology
  - 1200 data points
  - 5 times more resolution than current technology

- Advanced wavefront ablations
  - 93.4% UCVA 20/20
  - 79.0% UCVA 20/16
  - 14.0% gained 1 or more lines of BCVA
  - 98.5% patient satisfaction
The Future: Better Technology

- **Topographic laser ablations**
  - 92.7% UCVA 20/20
  - 68.8% UCVA 20/16
  - 31.6% UCVA 20/12.5
  - 29.6% gained 1 or more lines of BCVA

- **Ability to treat irregular corneas including keratoconus**
The Future: Better Technology

- **SMILE**
  - Femtosecond small incision lenticule removal
  - Potentially less dry eye
SMILE FDA Trial
Predictability of MRSE at 6 Months

93.7 % within ± 0.5 D
99.1 % within ± 1.0 D
Is LASIK Worth Saving? Yes!

- LASIK IS THE SAFEST, most successful and most studied elective procedure in the world.
- LASIK has the highest patient satisfaction rate of any elective procedure.
- LASIK results have continually improved as technology and surgical techniques advance and preoperative diagnostic screening and patient selection become more refined.
Moving Forward

- Our goal is continued improvement of patient satisfaction and 100% of patients seeing the same or better following LASIK than prior to surgery.

- We need to embrace patients who are dissatisfied with their vision following LASIK and never allow them to feel abandoned.

- We need to provide a better informed consent to our patients particularly those with psychiatric disease.

- We need to continue to invest resources into improving the safety and efficacy of laser vision correction.
In Conclusion

- The golden age of laser vision correction is today and tomorrow looks even brighter.
- We should be proud of what we have accomplished.
- We should never be satisfied.
Thank You