LASIK NIGHTMARES

PARAG A. MAJMUDAR, MD
ASSOCIATE PROFESSOR OF OPHTHALMOLOGY
RUSH UNIVERSITY MEDICAL CENTER
CHICAGO CORNEA CONSULTANTS, LTD.
LASIK in the news

- April 2008: FDA hearings on LASIK
- Increased public awareness of complications
- LASIK Quality of Life Collaboration Project – 2009
- Patient-Reported Outcomes with LASIK (PROWL-1 and 2) – initiated in 2012
LASIK Complications

- We should strive to ensure that complications are minimized.
- Careful patient selection is paramount, maintaining the proper equipment and staying current with training is also important.
- As you will see from the following cases, complications can happen to good surgeons.
- (No, they are not all mine.)
45 year old male nurse presented complaining of decreasing visual acuity and mild redness in his left eye a few days after uneventful bilateral LASIK.
Four days later...

Courtesy of Eric Donnenfeld, MD
Initial Treatment

- Elevate flap;
- Scrape stromal bed for culture

- Irrigate antibiotic under the flap
One week later the necrotic flap was removed.

Topical mitomycin C applied to prevent scarring.

Ophthalmic Consultants of Long Island
3 WEEKS LATER: UCVA = 20/40
Infections after Elective Surgery

- Most surgery that we do is “elective”
- We assume some risk when we perform surgery
- The only way to avoid complications is to avoid surgery
- But, infections after *refractive* elective surgery can be more emotionally troubling for patient (and surgeon) as the pre-operative level of vision is usually “perfect”
Post-LVC Infections

- Infection after PRK – may be related to epithelial defect or contact lens use
- Infections following LASIK should be less likely as Bowman’s remains intact
- Nonetheless, the incidence may be up to 1.5% (Chang et al.)

From Agarwal A: *Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes*
Risk Factors

- Endogenous contaminants
- Exogenous contaminants:
  - Instruments
  - Operating room
- Excessive surgical manipulation
- Epithelial injury
- Steroid Use
- Decreased corneal sensation

From Agarwal A: *Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes*
Features Unique to LASIK

- The interface acts as a virtual space within which organisms can become sequestered.
- Interface infections become more difficult to treat as they are protected from the natural ocular surface defenses.
- Also, antimicrobials do not penetrate as effectively into the interface.
- Perforation maybe more likely as the infection can access deeper layers of the stroma more rapidly and the cornea is overall thinner.
The ASCRS Cornea Clinical Committee Survey: Infectious Keratitis Following LASIK Questionnaire.¹

¹ Donnenfeld, Solomon, Azar, Holland. Infectious Keratitis Following LASIK. J Cataract Refract Surg
116 post-LASIK infections were reported by 56 surgeons who had performed an estimated 338,550 procedures for an incidence of 1 infection for every 2919 procedures performed.
2001 ASCRS SURVEY

Rate of Infection: 1 in 2919 cases

- Mycobacteria
- Staphylococcus
- Streptococcus
- Fungal
- Nocardia
- Gram Negative
Incidence

  - 76 presented within 1\textsuperscript{st} week
  - 7 during 2\textsuperscript{nd} week
  - 17 between 2\textsuperscript{nd} and 4\textsuperscript{th} weeks
  - 16 beyond 1 month

From Agarwal A: \textit{Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes}
Results

- Ten cases required penetrating keratoplasty.
- One case required enucleation.
Shift in Incidence

- 2004 ASCRS Survey:
  - Gram positive bacteria: 56%
  - Atypical Mycobacteria: 19%
  - Gram negative bacteria: 14%

From Agarwal A: Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes
Shift in Incidence
ASCRS Survey 2004 - Post-LASIK Infections

Rate of Infection: 1 in 2131 cases
Early Onset: (within 1\textsuperscript{st} two weeks)
- Staph
- Strep

Late Onset: (within 2 weeks to 3 months)
- Fungi
- Nocardia
- Atypical Mycobacteria
Diagnosis Of Post Lasik Infectious Keratitis

- Focal infiltration
- Surrounding brawny edema
- Pain uncommon
- Misdiagnosed often as
  - Diffuse intralamellar keratitis
  - Epithelial ingrowth
- Inflammation suppressed with corticosteroids
Focal Infiltrate In Lasik Flap
Diagnosis Of Post-lasik Infectious Keratitis

- Elevate flap scrape and culture
  - Blood agar
  - Chocolate agar
  - Sabourauds
  - Thioglycolate
  - Lowenstein-Jensen
    - Atypical mycobacterium
  - Nocardia
Laboratory Investigation

- **Scrapings:**
  - Stains: Gram, GMS, Ziehl-Nielsen, Auramine-rhodamine fluorochrome (AFB)

- **Culture Media:**
  - Thioglycolate broth
  - Blood agar
  - Chocolate agar
  - Lowenstein-Jensen/Middlebrook (atypical myco)
  - Sabouraud’s agar

From Agarwal A: *Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes*
Treatment Of Post Lasik Infectious Keratitis

**SPECIAL CONCERNS:**
- Deep inoculation of organisms
- Flap prevents penetration of antimicrobials
  - Scrape off epithelium
  - Remove flap
  - Irrigate antimicrobials under flap
- Flap prevents egress of inflammatory cells
- Patient often receiving corticosteroids
Treatment of Post-LASK Keratitis

- Early Flap elevation and culturing
- Stains, PCR
- Irrigate stromal bed with:
  - Fortified vancomycin 50 mg/ml for rapid-onset infxn
  - Fortified amikacin 35 mg/ml for delayed-onset
- Fourth generation FQ
  - Loading dose q 5 min x 3
  - Every 30 minutes
- Fortified Cephazolin 50 mg/ml every 30 min

From Agarwal A: Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes
Treatment of Post-LASIK Keratitis

- If MRSA suspected – use F. vancomycin 50 mg/ml
- If atypical mycobacteria suspected:
  - Topical amikacin plus
  - Topical and oral clairithromycin
- Other potential agents: azithromycin
- Oral doxycycline 100 mg BID – anti-collagenolytic
- Stop Steroids!

From Agarwal A: Refractive Surgery Nightmares: Conquering Refractive Surgery Catastrophes
Infection Not Responding To Treatment

- Re-establish diagnosis:
  - Culture and Scrape
  - Biopsy
- Excise flap if visual axis compromised
- Therapeutic Keratoplasty
Late-Onset Infections

- 6 years after LASIK: Shewanella putrefaciens
- 6 years after LASIK: Pseudomonas
- 2 years after LASIK: Fusarium solani

Vieira AC, Pereira T, de Freitas D. Late-Onset Infections After LASIK, *J Refract Surg*, vol. 24, No. 4, April 2008
Beware of Eye Trauma following LASIK

- Nocardia keratitis in a repositioned flap
- Acremonium atrogriseum keratitis after a wood chip injury post-LASIK


Endophthalmitis after LASIK

- Strep pneumoniae
- J Refract Surg 1997, Dublin, Ireland
CONCLUSION

 помпом A high level of suspicion and early diagnosis with cultures and scrapings in combination with aggressive therapeutic treatment can minimize the ocular morbidity of infectious keratitis following LASIK.
Non-infectious LASIK Complications

- In the last section, we discussed infectious complications of LASIK.
- Non-infectious complications may also result in significant visual morbidity.
- Awareness of these complications may allow us to manage them more appropriately and improve outcomes.
SPEAKING OF HACK JOBS...
61 yo WM presented for a second opinion on his LASIK outcome
He underwent LASIK OD only on 4-14-08 for -3.00 -1.00 x 140
The operative notes state that the patient had tight fissures, and during the keratome pass, “no flap was created.”
The surgeon adjusted the diameter of the suction ring and made a second attempt which was successful in creating a nasally hinged flap.
Excimer laser ablation was performed uneventfully.
At the slit lamp, an “epithelial defect” was noted paracentrally, temporal to the pupil.
There was noted to be a stromal defect as well, as the rough surface of the stroma was visible, rather than the smooth appearance of Bowman’s layer.
It became apparent that there WAS a small, free flap created at the time of the first keratome pass.
A therapeutic CTL was placed.
Case Report

- On my exam, the visual acuity sc was 20/200
- BCVA was 20/80 with +5.00 +4.50 x 175
- Slit lamp exam revealed a nasally-hinged flap with a paracentral area of flattening temporally within the flap.
Case Report

Topography:
Course

- Therapeutic Options:
  - Observation – patient is symptomatic
  - Rigid contact lens – probably the best option until the refraction stabilizes
  - Wavefront-guided Excimer ablation
    - May be difficult to capture wavefront
    - Refractive error exceeds custom approvals in the USA
  - Topographically-guided excimer ablation
    - In the long-run this will be the best option, as all of the induced aberrations are corneal, and wavefront captures total optical aberrations
Is Epi-LASIK safer?

- Epi-LASIK uses a “microkeratome” with a blunt “blade” to separate Epithelium and Basement Membrane from Bowman’s Membrane without the use of alcohol.
- Theoretically it should be just as safe and effective as PRK or LASEK.
- However, it is not entirely without complications either...
Stromal Incursion
William Trattler, M.D.

Courtesy of William Trattler, MD
Don’t make a bad situation worse...

- Replace the epithelial and stromal tissue carefully
- DO NOT ablate the cornea!
- This should be obvious but...
59 yo male underwent Epi-LASIK for +1.00 D OD – uncomplicated

The left eye (+1.25 D, targeted for monovision+3.25 D) resulted in a stromal incursion 3 x 5 mm

The surgeon should have stopped here...
Epi-LASIK complication

• But he didn’t…
• The ablation was performed, with the thought process that since the hyperopic ablation would be peripheral, it would not interfere with the stromal divot
• However, the epithelial flap was discarded and the stromal divot was NOT replaced
• 3 months post-op:
  • +0.50 + 2.50 x 40, shaky 20/20 (not crisp)
Stromal Incursions: Key Points

Avoidance: no Epi-LASIK for:
- EBMD/RES
- Prior LASIK, RK, PKP
- Anterior Stromal Scars

Management:
- Recognize the incursion
- Replace the stromal and epithelial tissue
- BCL
- Later: Transepithelial PRK (with MMC)
ANOTHER STRANGE OCCURRENCE....
Another Nightmare

❖ A 43 yo WM presents for refractive surgery
❖ Uneventful LASIK is performed OU
❖ On POD#1, the patient complains of blurred vision in BOTH eyes
❖ Visual acuity is 20/100 OU, and subjectively very hazy
Differential?

- PISK (pressure-induced stromal keratitis)?
  - Increased IOP may cause transudation of fluid into the flap interface – may mimic DLK
  - IOP should be checked at peripheral flap
  - IOP in both eyes was normal
  - Probably too soon for this entity

- Infection?
  - Always a concern
  - No true infiltrate, “dry” appearance
  - Could be atypical, but usually less rapid onset
Differential?

- DLK?
  - Immune-mediated response
  - Classically appears at day 3 or 4
  - May be seen earlier
  - Staged classification
Differential?

- CTK? Central Toxic Keratopathy
  - Entity described by Maloney et al.
  - Characterized by a focal white lesion
  - Well-demarcated (i.e. does not involve entire diameter of flap)
  - No inflammatory cells (like in DLK)
  - The opacity in DLK occurs late (Stage IV) and is usually confined to the interface
  - In CTK, the opacity may be either above or below the interface, and may be full thickness
  - Volume loss results in central thinning and hyperopic shift
CTK

- **Etiology?**
  - May be due to laser photoactivation of povidione-iodine

- **Treatment:**
  - Irrigation has no effect
  - Steroids are not indicated as there is no inflammation
  - Observation is the preferred treatment
    - The opacity may clear but hyperopia and striae may remain
Course

- This patient underwent flap lift, culture and irrigation
- Cultures were negative and the irrigation as expected had no effect on the opacity
- At 1 week, I saw the patient for consultation
- Clinically his vision was 20/40 OU with the following slit lamp appearance:
Slit Lamp Exam at 1 week
3 month exam

OD: UCVA = 20/30
-0.50 +1.50 x 005 = 20/15\(^{-2}\)

OS: UCVA = 20/30
pl +1.25 x 145 = 20/20\(^{-2}\)
AAAAAGHGHGHGH!
THIS WILL
MAKE YOUR HEAD SPIN....
Oh my God!

- A 34-year-old male -6.00 D OD and -6.25 D sphere OS.
- Central corneal pachymetry measured 534 µm OU.

- Planned -6.00 D ablation for both eyes Visx Star S4 laser (Advanced Medical Optics, Inc., Santa Ana, CA) conventional bilateral LASIK.

- The ablation began on the patient's right eye after the uncomplicated creation of 75-µm-thick flap. Approximately 60% of the way through the ablation, the surgeon realized that the process was taking longer than expected. In addition, he noted that the fluorescence pattern of the ablation was in the peripheral cornea. The procedure was stopped.
Oh my God!

The surgeon saw that +6.00 D had been inadvertently programmed for both eyes instead of -6.00 D. He aborted the original procedure after 568 of 968 pulses had been delivered to the peripheral cornea of the patient's right eye.

What would you do NOW?
Oh my God!

The surgeon replaced the flap and reprogrammed the laser for the correct parameters for the patient's right eye. Then, he lifted the flap and proceeded to perform an ablation of -6.00 D. The left eye's flap and ablation were completed uneventfully.

On the first postoperative day,
- UCVAs of 20/count fingers in his right eye and 20/25 OS
- The refraction in his right eye was -4.50 +1.50 X 35 = 20/20
- At 1 week, the patient's refraction was -3.50 +1.00 X 78 = 20/15 in his right eye
Data Entry Errors in LASIK

Can take many forms:

- Transcription errors
  - Converting from Plus cylinder to Minus Cylinder
- Errors of Omission or Commission
  - Leaving off the last “zero”
    - -8.00 +4.00 x 100 entered as -8.00 +4.00 x 10
    - You’ve nearly doubled their astigmatism
- Wrong sign: -6 D ablation entered as +6
Data Entry Errors in LASIK

- Prevention is key!
  - Time Out
  - Triple Check
  - Watch cylinder transposition
- If there is such a mistake...
  - Do NOT hide it from the patient
  - Patients may accept human error, but never dishonesty
  - Be reassuring and let the patient know you will help them in any way possible
  - They will still sue you, though.
THIS WILL FLOOR YOU...
Intraoperative Pachymetry

Since 2000, I have been using intraoperative pachymetry on every LASIK.

Earlier microkeratomes were notorious for cutting extra-thick flaps.

Problems like the one we just saw, or more commonly, post-LASIK ectasia, can be avoided.

With the advent of modern microkeratomes and femtosecond lasers, and more uniform and reproducible flap thicknesses, intraoperative pachymetry may not be mandatory.
Yet another LASIK nightmare

- 53 yo WF underwent Restor cataract surgery
- Post-operatively, her refractive error was +2.00 +1.75 x 85, and her uncorrected visual acuity was not satisfactory for distance or near
- LASIK was attempted for the residual refractive error
- The patient had a steep cornea (46D) but since this was a hyperopic treatment, a large-diameter suction ring was used 9.5)
During creation of the flap, there was some patient movement, and a buttonhole flap resulted.
Case Report

Options?

- Observation/Contact lens
- Recut the flap
- PRK with MMC

  - Normally a good idea, but since this is a hyperopic treatment, the ablation will not be central

- Piggyback IOL with myopic endpoint and later PRK?

  - Patient refused this intervention the first time
Course

- The patient did not want a second intraocular procedure
- PTK/PRK with MMC was performed at 1 month post-buttonhole
- Initially, PTK was performed to remove the central buttonholed flap
- Then, at the same sitting, a hyperopic PRK was performed, increasing the total spherical power to compensate for the shift induced by the PTK
The VISX laser was programmed for 1000 PTK pulses at 6.0 mm (not all were used)

Fluorescence patterns and masking agents were used and the patient taken to slit lamp multiple times
Course

- PRK programmed for the initial refractive correction PLUS approximately 2 additional diopters of hyperopia (could have added more but with MMC use, there was some cut-back)
- MMC used (0.02% for 2 minutes)
Course

Post-operatively the patient did fairly well from an anatomic standpoint (i.e. no corneal scarring secondary to the buttonhole or the PRK)

However, the refractive error actually worsened to +3.00

Currently the patient is using an RGP contact lens and is not “happy” but is not “unhappy” either

Future consideration is a piggyback IOL in the sulcus (coming full circle!)
Lessons

- Do not use a 9.5 ring on a steep cornea
- Sometimes an intraocular approach works best for fixing intraocular surgery
- Consider PRK in high-risk cases
- Femtosecond technology may be able to avoid some complications, but is not completely without risks either
“Zombie” (1979)
MAKES YOU WANT TO USE A FEMTOSECOND LASER....
Femtosecond Lasers

Led by Intralase, femtosecond lasers have carved out quite a niche.

Not only are the flap dimensions and shape completely customizable, the risk of buttonhole flaps is minimized greatly.

When gas break through occurs, (this is equivalent to a mechanical keratome passing out through the epithelium) as long as the flap is not lifted, the gas bubbles will dissipate and the flap may be recut as early as hours later (as opposed to weeks).
Femtosecond Issues

 Aside from issues such as DLK and Epithelial ingrowth, which may occur with ANY type of keratome, and

 Aside from Transient Light Sensitivity (TLS) and Rainbow glare which is ONLY seen in femtosecond flaps,

 The major distinction lies in the incidence of flap complications with the femtosecond lasers
Femtosecond Issues

- A recent study evaluated the incidence of flap complications with the femtosecond laser in 3009 eyes.
- 1 eye had DLK resulting in loss of BCVA.
- Flap tear.
- Free Cap.
- Bubble Escape.
- Flap Folds.
- No buttonhole, short flap, or flap striae.

Femtosecond “Complication”

During a routine Intralase procedure, the patient had a violent blepharospasm and suction was lost 60% into the procedure. 30 min later, the cornea was clear but the patient elected not to have treatment that day. Uneventful PRK was performed. This case would have been disastrous with a microkeratome.
Case Presentation

- 21 yo Caucasian Male
- Underwent uncomplicated LASIK
- Flap OS was lifted 3 weeks later (reason unknown – possibly DLK?)
- Vision reportedly improved OS for 1 week, then declined
Case Presentation

On presentation

- Acuity sc OD = 20/20
- Acuity sc OS = 20/CF

Refraction

- OD: +0.50 +0.25 x 095 = 20/20
- OS: -11.50 +3.50 x 180 = 20/200
Current Medications (OS)

- Pred Forte BID
- Azopt BID
- Combigan BID
Slit lamp exam:
- Clear LASIK flap OD
- Edematous cornea OS
Chicago Cornea Consultants, Ltd.
1585 N. Barrington Rd.    Hoffman Estates IL 60199    847-882-5900

OD

Patient: Tedics, Anthony
Physician: Majmudar, Parag A.
Operator: rosser, vicl

Exem Date: 02/25/2013
DOB (age): 03/22/1981 (23)
Gender: M
Ethnicity: 
Algorithm Version: A6, 2, 2, 73

Pachymetry

Pachymetry:

Report Date: Wednesday January 07 20:10:29 2015

Software Version #6, 2, 2, 73

Defining the OCT Revolution
Defining the OCT Revolution
IOP – OS – centrally with tonopen = 12,
OS – peripherally with tonopen = 8

Specular Microscopy:
- Normal OD
- Decreased cell count OS (poor image quality)
Course

- Added Muro 128 ung QID
- Stopped Topical Steroids
- Observation – did not lift flap
- Reassurance (?)
1 month later

- Acuity sc OD = 20/20
- Acuity sc OS = 20/100
- Refraction
  - OS: -1.00 = 20/100
- IOP
  - OS = 10
1 month later
3 mos later
6 mos later

561 µm
1 year later
1 year later

- Acuity sc OD = 20/20
- Acuity sc OS = 20/40

**Refraction**
- OD: +0.25 +0.25 x 095 = 20/20
- OS: +0.50 +0.50 x 045 = 20/30
Diagnosis??

- Was this DLK?
- Was this PISK?
  - IOP was always normal (although patient presented on IOP-lowering medication)
- Was this CTK?
  - Atypical presentation
  - Usually should have flap compaction, scar, thinning, hyperopia
Future?

- Patient inquired about further treatment
- Interface scar limits surface laser options
- I discouraged flap amputation or lamellar transplant...
As long as there is a flap...

- There will be flap complications regardless of the flap cutting device used.
- There will also be interface complications such as DLK, CTK, epithelial ingrowth, and striae.
- Careful pre-operative selection is critical as is meticulous technique for prevention of complications.
- Knowledge of the above complications and their proper management will help to ensure good visual outcomes in the face of these occurrences.
ANOTHER TYPE OF NIGHTMARE....
UNEXPLAINED PAIN AFTER LASIK

(Pointer)
25 yo male 6 mos s/p hyperopic LASIK
(Pointer)
UCVA: 20/20 OD and 20/40 OS (amblyopia)
(Pointer)
Slit lamp and topography look perfect
(Pointer)
But he complains of Pain, Burning in the right eye starting from day 1.
(Pointer)
Nothing has helped including topical anesthetics
UNEXPLAINED PAIN AFTER LASIK

- New syndrome? "keratohyperalgesia" or "keratoneuralgia"
- I recommended oral lyrica/gabapentin, amytryptiline, and autologous serum drops
- Scleral contact lens?
- Flap lift and refloat? (possible aberrant nerve regeneration)
UNEXPLAINED PAIN AFTER LASIK

- The problem is that this young man is becoming depressed.
- The few other patients I have seen with this over the past 18 years also had some "psychiatric" issue.
- Not sure which came first, the psych symptoms or the pain.
- Reminds me of the way fibromyalgia patients were treated back in the day (as if they were crazy).
This is truly a nightmare for patient and surgeon alike.

Main objective is to identify patients at risk BEFORE surgery – often difficult – but patients with psychiatric issues should be carefully evaluated.

Once surgery has been performed, in addition to above interventions, professional counselling is extremely important.
“A Nightmare on Elm Street” (1984)
DON'T BE AFRAID....
Conclusions

- Both infectious and non-infectious complications may result in significant visual morbidity.
- Prevention of complications is paramount, but
- Awareness of these complications may allow us to manage them more appropriately and improve visual outcomes and create happy patients (and happier surgeons!)
Thank You For Your Attention!
pamajmudar@chicagocornea.com